

As confidentially submitted to the Securities and Exchange Commission on September 13, 2024.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BETA BIONICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)

47-5386878
(I.R.S. Employer
Identification Number)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting the unaudited interim financial statements of Beta Bionics, Inc. as of and for the six months ended June 30, 2023 and 2024. While this financial information is otherwise required by Regulation S-X, we reasonably believe that it will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated , 2025

PROSPECTUS

Shares
Beta Bionics
Common Stock

This is the initial public offering of shares of common stock of Beta Bionic, Inc. We are selling shares of our common stock.

Prior to this offering, there has been no public market for our common stock. We currently expect the public offering price for our common stock to be between \$ and \$ per share. We intend to apply to list our common stock on the under the symbol “ .” We believe that upon the completion of this offering, we will meet the standards for listing on the , and the closing of this offering is contingent upon such listing.

We are an “emerging growth company” and a “smaller reporting company” under the federal securities laws and are subject to reduced public company disclosure standards. See the section titled “Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company.”

Investing in the common stock involves risks that are described in the section titled “[Risk Factors](#)” beginning on page 16 of this prospectus.

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See the section titled “Underwriting” for additional information regarding compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares of our common stock at the initial public offering price, less the underwriting discounts and commissions.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on or about , 2025.

BofA Securities
Piper Sandler
Stifel
Lake Street

Leerink Partners

The date of this prospectus is , 2025.

New Treatment Paradigm For People with Diabetes

iLet Bionic Pancreas (iLet): first FDA-cleared pump that utilizes adaptive closed-loop algorithms that are initialized only with a user's body weight and requires no additional insulin dosing parameters

Beta Bionics

iLet: Determines and Delivers 100% of All Insulin Doses



Adaptive algorithms learn each person's unique and ever-changing insulin requirements to simplify and improve diabetes management

Beta Bionics

Unique Algorithms Require Minimal Human Intervention

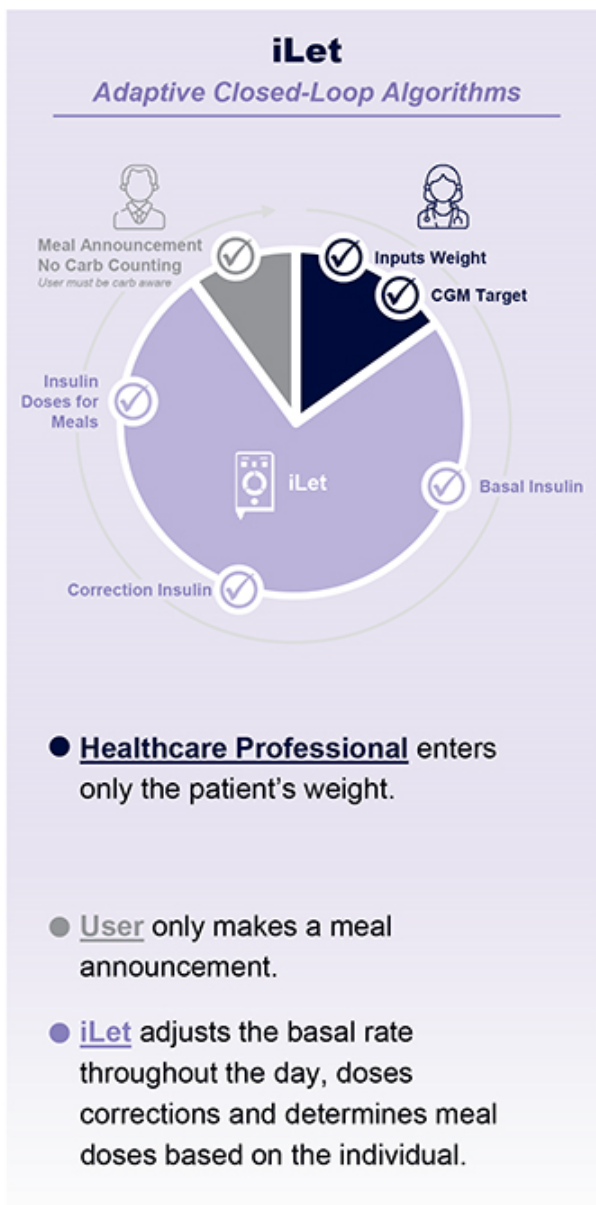
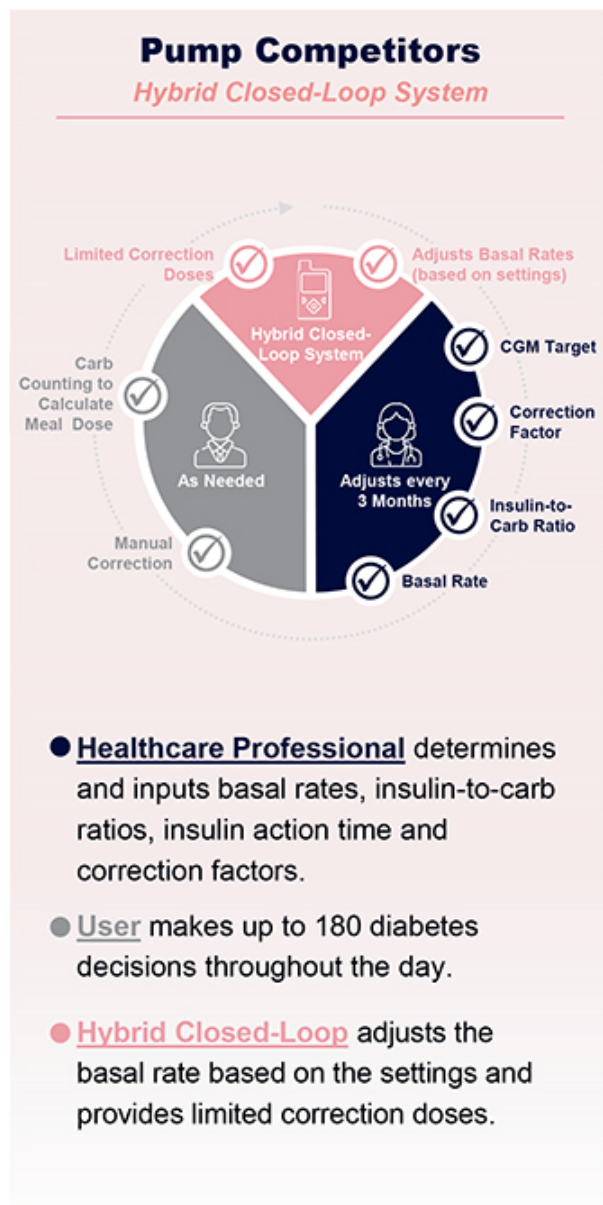


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Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights selected information included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Special Note Regarding Forward-Looking Statements,” and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context otherwise requires, all references in this prospectus to “Beta Bionics,” “Registrant,” “we,” “us,” “our” and “the company” refer to Beta Bionics, Inc.

Overview

We are a commercial-stage medical device company engaged in the design, development and commercialization of innovative solutions to improve the health and quality of life of insulin-requiring people with diabetes (PWD) by utilizing advanced adaptive closed-loop algorithms to simplify and improve the treatment of their disease. Diabetes is a serious, chronic and often lifelong condition with no known cure that is characterized by extended periods of elevated levels of glucose in the bloodstream, or hyperglycemia, resulting from the body’s inability to either produce or effectively utilize the hormone insulin. To treat their diabetes, PWD must undergo a rigorous regimen of daily insulin substitution, as elevated levels of glucose in the blood over time can lead to serious and often life-threatening cardiovascular, metabolic and nervous system complications. Despite decades of innovation that have advanced the quality of care available, a significant unmet need remains as the vast majority of PWD still cannot manage their diabetes effectively. Our product, the iLet Bionic Pancreas (iLet), is the first insulin delivery device cleared by the U.S. Food and Drug Administration (FDA) to utilize adaptive closed-loop algorithms to autonomously determine every insulin dose without requiring a user to count carbohydrate intake. We believe this marks a significant advancement over other insulin delivery technologies by offering a differentiated combination of improved glycemic control and a vastly simplified experience for users and caregivers.

The iLet was specifically designed to provide improvements in glycemic control relative to currently available treatment options, such as insulin pumps, including partially automated insulin delivery (AID) systems (also known as hybrid closed-loop systems), and multiple daily injections (MDI), while also reducing the complexity and burden of achieving these improved results for PWD. It is enabled by adaptive closed-loop algorithms that continuously learn each person’s unique and ever-changing insulin requirements and then autonomously delivers the correct insulin doses every five minutes throughout the day and night. Only the user’s body weight is required for device initialization and the autonomous determination of all insulin doses, unlike insulin pumps and hybrid closed-loop systems, which require a complex host of parameters to configure. We believe that the iLet represents one of the first significant advances in insulin delivery technology since the commercial availability of hybrid closed-loop systems began in 2017, and that its convenient product features, coupled with improved glycemic control, will appeal to broad segments of PWD who are seeking a simple path to improved disease management.

Our initial commercialization efforts for the iLet are focused on the type 1 diabetes (T1D) market. T1D is an autoimmune disorder that often develops during childhood or adolescence, but can occur at any age, and arises from a person’s immune system attacking and destroying the insulin-producing beta cells in the pancreas. There are approximately 1.8 million people with T1D currently in the United States, all of whom require daily insulin replacement to manage their disease. The average hemoglobin A1C (HbA1c), a measure of average blood-glucose (BG) levels over an extended period of time, among adults in the United States with T1D is 8.2%, and currently only about 20% of adults with T1D meet or exceed the American Diabetes Association (ADA) goal for HbA1c. The remaining 80%, therefore, are at elevated risk of developing an array of potentially life-threatening complications that arise as a result of chronic exposure to hyperglycemia. We believe that one of the

principal causes of these suboptimal outcomes is that the complexity of the user experience with most currently available insulin pumps and hybrid closed-loop systems has kept the majority of PWD from adopting them despite the improved disease management they can offer. These systems require PWD to set and to periodically adjust several insulin pump parameters, to quantify daily carbohydrate intake and to frequently calculate proper doses of insulin for their pump to deliver. We believe this complexity, and the constant engagement that is required in order to enjoy the full therapeutic benefits that these systems can offer, limits their uptake to a subset of PWD and to subspecialty healthcare providers (HCPs). Currently, approximately one-third of people with T1D in the United States utilize insulin pumps or hybrid closed-loop systems, while the majority receive their daily insulin via MDI therapy, which is less complex, but often less effective, and associated with higher HbA1c levels. Our initial commercial results suggest that the iLet's value proposition is resonating strongly within the MDI population, as approximately % of the iLet's adoption as of September 30, 2024 has come from PWD who were previously utilizing MDI.

Operating Results Since Commercial Launch

We believe our financial and operating results and clinical and real-world data to date validate our opportunity, strategy and execution. In the five full quarters since launching the iLet in May 2023, our quarterly revenue has grown over %—from \$3.1 million for the quarter ended September 30, 2023 to \$ million for the quarter ended September 30, 2024—while our operating expenses have grown only % during the same time period—from \$10.0 million to \$ million, respectively.

Our revenue for the nine months ended September 30, 2024 was \$ million, more than that of our annual revenue of \$12.0 million for the year ended December 31, 2023. Our revenue for the nine months ended September 30, 2023 was \$3.6 million. Our net losses were \$25.3 million for the nine months ended September 30, 2023 and \$ million for the nine months ended September 30, 2024.

Clinical and Real-World Data Demonstrate the Safety, Effectiveness and Simplicity of the iLet

The safety, effectiveness and simplicity of the iLet were evaluated in the investigator-initiated iLet Bionic Pancreas Pivotal Trial (BPPT) of 440 people with T1D between the ages of six and 83 with starting HbA1c levels between 5.3% and 14.9%, which we believe is the largest and most diverse population ever studied in a pivotal clinical trial of an AID system. The trial met its primary endpoint, finding that, collectively, the participants who randomized to iLet therapy experienced an average reduction in HbA1c from a baseline of 7.9% to 7.3% over 13 weeks, while participants who randomized to standard of care (defined as their existing treatment regimen plus a DexCom, Inc. (DexCom) G6 continuous glucose monitor (CGM) if not already using one), which included some representation of all other available treatment options, saw no change from a baseline of 7.7% over the same period. Additionally, participant cohorts within important subgroups among the overall T1D population, including adults, children, those with starting HbA1c levels greater than 7%, those on MDI, and those on insulin pump therapy without automation, who used the iLet also demonstrated statistically significant and clinically relevant improvements in glycemic control versus the standard of care.

In addition, the improved glycemic control seen in the results of the BPPT has been supported by additional, “real-world” iLet data. Of the 5,190 iLet users who uploaded CGM readings to the Beta Bionics cloud over the first year after our commercial launch (May 19, 2023 to May 18, 2024), 3,300 had at least three-weeks' worth of iLet data and a pre-iLet baseline HbA1c value available. Data from these 3,300 users showed an overall improvement, from an average HbA1c of 8.5% to an average glucose management indicator (GMI)—a CGM surrogate for HbA1c—of 7.3%, which demonstrates a clinically meaningful improvement across this much larger patient population.

The simplicity of achieving the improved glycemic control offered by the iLet has been established by aggregated device-interaction data, as measured by how often users swiped to unlock their iLets, from 324

participants in the BPPT as well as from 3,295 of the 3,300 iLet users in the commercial setting who had device-interaction data available. These data were analyzed using linear regression to assess if correlations existed between user interaction with the iLet and improvements in glycemic control. Correlations were quantified using the R^2 correlation coefficient, which is an indicator of how strongly correlated two metrics are, with a value of “1” representing perfect correlation and “0” representing no correlation. In both the BPPT and the commercial settings, the R^2 correlation coefficients between the average improvements in GMI on iLet therapy and the average daily number of swipes to unlock the screen averaged less than 0.01, indicating that the improvements in glycemic control achieved by the iLet were virtually independent of the frequency of user interaction. These results stand in contrast to those of multiple other large T1D population trials, each with thousands or tens-of-thousands of participants, in which it has been observed that a higher frequency of active glucose monitoring was strongly associated with a lower HbA1c level, and a higher frequency of user-initiated corrective dosages from a sensor-augmented insulin pen or a hybrid closed-loop system correlated strongly with improvements in the amount of time PWD experienced BG levels within the range associated with effective control, or time in range (TIR).

Commercial Opportunity and Strategy

The commercial opportunity for the iLet in T1D is substantial. The T1D total addressable market for insulin pumps in the United States is estimated to be approximately \$6 billion and is forecasted to grow at approximately 2% per year (in line with overall population growth). There are two distinct subpopulations whose needs could be addressed by a product of iLet’s profile:

Existing Pump Users: Approximately One-Third of the Total T1D Population, \$2 Billion Total Addressable Market

The value of the existing pump market in the United States was estimated to be approximately \$2 billion in 2023, with a projected compound annual growth rate (CAGR) of 11% through 2027. The market is concentrated primarily among three leading competitors—Medtronic plc (Medtronic), Tandem Diabetes Care, Inc. (Tandem), and Insulet Corporation (Insulet), who collectively hold approximately 96% market share.

Potential New Pump Adopters: Approximately Two-Thirds of the Total T1D Population, \$4 Billion Total Addressable Market

Approximately two-thirds of people with T1D in the United States do not currently utilize a pump for insulin treatments and instead receive MDI from either a syringe or an insulin pen. PWD who use MDI encounter similar challenges as those who use hybrid closed-loop systems, including the need to count carbohydrates and calculate correction boluses. Furthermore, insulin pens lack the discretion and convenience of pumps. This U.S. patient population, though declining at an approximate 9% CAGR, would be valued at \$4 billion if fully converted to pumps.

In the past, people with T1D have shown willingness to quickly adopt new technologies when the value proposition was far superior to previously available options. We believe the iLet represents such a breakthrough, and its superiority could catalyze an adoption cycle similar to the one observed with CGMs in recent years. In the CGM product space, the innovation of removing manual calibration materially accelerated adoption by improving both user experience and outcomes. Similar to insulin pumps, CGMs struggled for decades to gain a majority share. The first real-time CGM received FDA approval in 2005, but it was not until 2018, with the release of the DexCom G6—the first CGM that did not require fingerstick calibrations—that the CGM value proposition became compelling to a majority of people with T1D. Since then, CGMs have been adopted by an estimated 70% of people with T1D in the United States. We see similar potential for the iLet to dramatically expand the reach of insulin delivery technologies in the marketplace.

To maximize the commercial value of the iLet opportunity, we have assembled a team across our organization with broad experience in the successful commercialization of innovative technologies in the field of diabetes disease management. We are promoting sales of the iLet through an internal sales organization, where our initial direct sales efforts are focused on high volume endocrinology practices and then, over time, the larger, but more diffuse, multispecialty practices in primary care. These primary care physicians (PCP) treat an estimated one-half of the T1D population in the United States, but do so among a much more diversified patient base than endocrinologists. We believe that the iLet's core value proposition of marrying effective glycemic control with the simplicity of use that is brought about by adaptive closed-loop algorithm insulin-dose determination may resonate particularly well among PCP who do not have the subspecialty level of expertise, the resources or the clinical bandwidth that is needed to initiate insulin-pump or hybrid closed-loop therapy or for the continual demand those systems place on clinical practices in follow-on care.

Product Development Pipeline and Future Initiatives

Patch Pump

We are developing an insulin pump that is designed to adhere directly to the skin and administer insulin without the need for tubing, commonly known in the diabetes industry as a "patch pump." Our patch pump features a two-component design: a durable part that contains the electronics and motor, and a disposable part that includes the insulin reservoir, adhesive, insertion device and cannula. This design is intended to enable efficient manufacturing and provide a convenient pump-change experience. Our patch pump is intended to unlock a new pool of PWD who are looking to receive the many benefits of the iLet, but who prefer the patch pump form factor.

Bihormonal iLet

We are also developing a first-of-its-kind bihormonal configuration of the iLet, which combines automated delivery of insulin and glucagon, the BG-raising hormone that protects against low blood sugar, or hypoglycemia, with adaptive closed-loop algorithms where all doses of both hormones are autonomously determined. We believe this bihormonal capability would offer a meaningful additional benefit to PWD, as it would allow the active raising of glycemic levels when they fall too low in addition to the iLet's existing capability of actively lowering glycemic levels when they elevate too high. Currently, there are no commercially available automated devices to raise BG when it is too low, and many people living with T1D live with an ever-present fear of hypoglycemia.

Hypoglycemia, if untreated, can lead to a range of acute medical complications, including tissue and organ damage, seizures and coma, and death. Hypoglycemic episodes are responsible for over half of all emergency room visits by PWD each year, despite their relatively low frequency. Approximately one-third of people living with T1D can also be classified as "hypo unaware," a condition that prevents them from sensing a pending hypoglycemic event and puts them at increased risk for suffering a severe hypoglycemic episode without warning. Due to these primary risks and other secondary risks, such as losing consciousness while driving an automobile, many people living with T1D also live with perpetual fear of a severe hypoglycemic episode. These fears can reduce quality of life, as they may lead to a restriction of otherwise necessary and beneficial activities like exercise in order to avoid the risk of a catastrophic hypoglycemic episode.

In six pre-pivotal outpatient clinical trials conducted from 2012 to 2017, we observed participants utilizing our bihormonal configuration to achieve reduced hypoglycemia and increased TIR relative to both standard-of-care treatment and our insulin-only bionic pancreas configuration. We expect to initiate pivotal clinical trials and seek FDA device clearance for our bihormonal configuration and, if successful, seek FDA marketing authorization for this configuration, as well as FDA approval for a pump-compatible formulation of

glucagon for chronic usage. Glucagon is currently only approved in an acute formulation for rescue from acute hypoglycemia, so approval of a new drug application will be required in addition to FDA clearance for the bihormonal configuration of the iLet as a device.

To realize the full commercial potential of this opportunity, we have entered into an exclusive collaboration and license agreement with Xeris Pharmaceuticals, Inc. (Xeris) to develop and commercialize a pump-compatible glucagon formulation utilizing Xeris' XeriSol technology for use in our proprietary bihormonal pump and pump systems.

Type 2 Diabetes

We intend to pursue expanded use of the iLet to treat people with insulin-dependent T2D, as we believe the size and composition of this population make it a compelling opportunity. While there are certain differences in how T2D is treated relative to T1D, these differences primarily relate to the amount and rate of insulin delivered. Among the T2D population, approximately 1.8 million require intensive insulin therapy, but fewer than 10% have adopted pump technology to date. We believe these PWD, who span socioeconomic and educational levels, and their health care providers, 90% of whom are PCP, may find the iLet's combination of simplicity and efficacy particularly appealing, if the iLet is authorized for marketing for this use.

Overview of the Diabetes Market

Diabetes is a complex, multisystemic disease characterized by sustained and prolonged elevated BG levels, or hyperglycemia, that results from the body's inability to either produce the hormone insulin, which is responsible for the proper metabolization of glucose, or properly utilize it. In the absence of insulin, ketones rise in the blood, which becomes acidotic. In the extreme, insulin insufficiency leads to catabolism (in which the body begins to waste fat and muscle), diabetic ketoacidosis (DKA) and, ultimately, death. PWD also face the daily risk of low blood sugar, or hypoglycemia, which can result from multiple factors, including receiving excess exogenous insulin in the course of disease management. Hypoglycemia, which can strike without warning, starves the brain of needed glucose, and can result in cognitive impairment, loss of consciousness, seizures and death.

As diabetes has no known cure, its treatment paradigm entails an arduous daily regimen of disease management and insulin substitution whereby PWD must maintain constant vigilance regarding both their BG levels and the amount of insulin they receive. The long disease course, daily management requirements and potentially catastrophic consequences of mismanagement each represent a significant burden to PWD, their caregivers and society at large.

There are two principal types of diabetes within the overall population:

- Type 1 diabetes (T1D): an autoimmune disorder that often develops during childhood or adolescence, but can occur at any age, and arises from a person's immune system attacking and destroying the insulin-producing beta cells in the pancreas. There are approximately 1.8 million people with T1D currently in the United States, all of whom require daily insulin replacement to manage their disease.
- Type 2 diabetes (T2D): a metabolic disorder that typically develops in adulthood, whereby the body becomes resistant to insulin, and, consequently, increased insulin production is needed to regulate BG levels. As T2D progresses, the body's beta cells cannot maintain the increased insulin levels needed to regulate BG. In many cases, daily insulin replacement becomes required despite the availability of other classes of medications. There are approximately 36 million people with T2D in the United States, of whom an estimated 1.8 million require intensive insulin therapy.

The dynamic evolution of care in the field of diabetes over the past several decades has been characterized by continuous cycles of innovation that have produced several generations of increasingly sophisticated and complex devices to help maintain BG levels within the normal range or achieve goal, as established by the ADA. The capabilities of devices range from offering convenience features to allowing transformative improvements in efficacy. We believe that, while these new technologies managed to remove or reduce some “twentieth-century burdens” of disease management (e.g., logbooks, fingerstick measurements, not knowing BG levels for large stretches of the day and night), they also added new “twenty-first-century burdens” (e.g., bombardment with overwhelming amounts of data, constant alerts and alarms, and 24/7 information overload). The psychological, emotional and cognitive burden imposed by the continuous need for user engagement to manage the disease is substantial, unsustainable by most and unachievable by many. We believe that the iLet marks a significant breakthrough in the achievement of this ultimate goal, as it has been shown to enable clinically relevant improvements in glycemic outcomes across broad populations of PWD, while dramatically reducing necessary user engagement.

Our Solution: The iLet Bionic Pancreas

The iLet was specifically designed to provide clinically relevant improvements in glycemic control relative to insulin pumps and MDI therapy without the complexity and management burden of current insulin pumps and hybrid closed-loop systems. It is enabled by adaptive closed-loop algorithms that learn each person’s unique and ever-changing insulin requirements and then autonomously delivers the correct insulin doses every five minutes throughout the day and night. Only the user’s body weight is required for initialization, unlike insulin pumps and hybrid closed-loop systems, which require a complex host of parameters to configure. The iLet autonomously determines all insulin doses. We believe this convenient product profile, coupled with improved glycemic control, will appeal to broad segments of PWD who are seeking a simple path to improved disease management. Below is a picture of the iLet. The pumping platform consists of the pump itself and related single-use products, including cartridges for storing and delivering insulin and infusion sets that connect the insulin pump to a user’s body.



Our Strengths

We believe the success and continued growth of our company will be driven by the following strengths:

- **Highly Differentiated Technology Powered by Algorithmically Autonomous Insulin Dosing.** We believe that the combined innovative features of the iLet that are driven by our unique algorithms and improved compatibility represent a meaningful breakthrough over other insulin delivery therapies to treat PWD, and may lead to improved disease management, quality of life and penetration of the large and growing population of PWD.
- **Robust Compendium of Clinical and Real-World Data.** We have developed a significant body of clinical data that demonstrates the safety, effectiveness and simplicity of the iLet. In addition, the improved glycemic control seen in the results of our pivotal trial has been supported by additional, “real-world” data generated from CGM readings over the first year after our commercial launch.
- **Significant New Product Pipeline.** We have invested heavily in our research and development activities to expand the potential therapeutic applications of the iLet based on our scalable technology platform. We are currently developing a smaller, semi-disposable patch pump that is intended to unlock a new pool of PWD who are looking to receive the many benefits of the iLet, as well as a first-in-kind bihormonal iLet that is designed to automatically deliver both insulin and glucagon. We are also developing a glucagon drug product for use in the bihormonal configuration.
- **Extensive Intellectual Property Portfolio.** Our technology is supported by an extensive intellectual property portfolio, which includes patents, know-how, trade secrets and licenses from the Trustees of Boston University (BU) and Xeris.
- **Highly Efficient Business Model.** We have developed a multi-channel coverage and reimbursement strategy that provides maximum flexibility to patients, where we work with payors to establish coverage and reimbursement under both traditional durable medical equipment (DME) and pharmacy benefit plans (PBP). As an alternative to DME, the PBP channel provides a lower upfront cost to the patient and potentially greater economic value to us over the life of the iLet. In addition, we have designed the various hardware, software and electronics platforms of the iLet to maximize scalability, reliability, serviceability and manufacturability from initial development, including multi-sourcing components to support production efficiencies.
- **Experienced Management Team.** Our senior management team has extensive experience, including lived experience, in the diabetes and medical technology industry, with specific experience in commercialization, product development, clinical research, regulatory approval and coverage and reimbursement of innovative medical technology products at well-regarded diabetes companies such as Medtronic, Tandem, Companion Medical, Inc. and DexCom.

Our Strategy

Our mission is to grow our business by successfully commercializing our innovative solutions for safe, simple and effective autonomous glycemic control and to reach as many people living with insulin-requiring diabetes as we can. Our goal is to establish the iLet as the standard of care for insulin delivery. The key elements of our growth strategy are:

- **Continue our commercialization efforts by utilizing our sales force to educate PWD and HCPs on the compelling potential benefits of the iLet and to drive awareness.** To fully realize the

commercial opportunity presented by the iLet, we have developed an integrated commercial strategy to drive adoption across the T1D population and establish and maintain customer loyalty through customer service and educational programs. We are promoting sales of the iLet through an internal sales organization, where the initial direct sales efforts have been focused on high-volume endocrinology practices. Over time, we plan to expand our commercial focus to the larger, but broader, market of PCP in multispecialty practices.

- ***Build our commercial and customer support infrastructure to maximize access to the iLet and maximize customer retention.*** *We have an integrated customer-support strategy designed to efficiently fulfill orders, educate both new users and their caregivers during device initialization and follow-on care and respond promptly to inquiries throughout the life of the product.*
- ***Leverage our in-house manufacturing capabilities to optimize production efficiency and maintain quality.*** We manufacture the iLet and the ready-to-fill insulin cartridges at our facilities located in Irvine, California. By assembling and testing the iLet in-house, we believe that we can maintain better quality control and compliance with our own internal specifications and with applicable regulatory standards.
- ***Obtain third-party coverage and reimbursement from payors under both DME and PBP.*** We are pursuing a multi-channel DME and PBP coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device, provide PWD with advantageous coverage and reimbursement terms and provide us with potential access to higher revenue streams. We believe that utilizing this strategy will make the iLet more accessible for PWD and the HCPs who prescribe and initiate the device.
- ***Increase our addressable market by developing a patch pump and bihormonal iLet, as well as seeking expansion into the treatment of T2D.*** We are leveraging our algorithms to develop two additional products in our pipeline: the patch pump for PWD who prefer that form factor, and the bihormonal iLet. In addition, we intend to pursue expanded use of the iLet to treat people with insulin-dependent T2D, as we believe the size and composition of this population make it a compelling opportunity.

Risks Associated with Our Business

Our business is subject to a number of risks that you should carefully consider before making a decision to invest in our common stock. These risks are more fully described in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- We have a limited commercial history and limited experience marketing and selling our products. We only recently launched our commercial product, which may make it difficult to evaluate the prospects for our future viability and predict our future performance.
- Our quarterly and annual financial condition, operating results and cash flows may fluctuate in the future, which could cause the market price of our stock to decline substantially.
- We currently rely on sales of our iLet and related single-use products to generate all of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.
- Even if we consummate this offering, we may need to raise additional funds in the future, and these funds may not be available on acceptable terms, if at all.

- The failure of our iLet and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.
- We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration and which may allow them to develop additional products for the treatment of diabetes that compete with our iLet.
- We currently have a limited marketing and sales organization and have limited experience as a commercial-stage company marketing devices. If we are unable to successfully expand our marketing and sales capabilities or enter into additional agreements with third parties to market and sell devices, we may not be able to generate product revenue, and our business may be adversely affected.
- Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.
- We are highly dependent on the success of our iLet for the treatment of T1D, which is cleared by the FDA for commercial sale in the United States for the treatment of T1D, and we do not have any other commercial products. If we are unable to obtain and maintain regulatory clearance or approval for planned modifications to the iLet or for new indications, or for any future development-stage products, or if we are unsuccessful in our efforts to continue to commercialize our cleared version of the iLet, our business will be materially harmed.
- The regulatory authorization process of the FDA, or any comparable foreign regulatory authorities, is lengthy, time-consuming and inherently unpredictable. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain marketing authorization or clearance for any of our product candidates. Modifications to our currently commercialized version of the iLet may require new marketing authorizations or clearance.
- Use of our commercial or development-stage products may cause adverse events or undesirable side effects or present other safety concerns which may cause us to suspend or discontinue clinical trials, delay or prevent marketing authorization, limit the commercial profile of labeling for any product that has received marketing authorization, or result in significant negative consequences following marketing authorization.
- We are developing our iLet in combination with other therapies and devices, which requires additional development time and exposes us to additional risks.
- We are substantially dependent on various third parties for the development and potential commercialization of our iLet and product candidates. Certain of our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the development of the investigational devices or other development-stage candidates, such as glucagon, we develop. If our collaborations are terminated or are not successful, our ability to successfully develop and commercialize our iLet and product candidates may be adversely affected.
- We have limited experience manufacturing our products and, if we are unable to manufacture our products in high-quality commercial quantities successfully and consistently to meet demand, our growth will be limited.

- We obtain some of the components and subassemblies included in our iLet from single source suppliers, and the partial or complete loss of one or more of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.
- Our iLet is complex in design and may contain defects that are not detected until use, which could increase our costs, including warranty costs, and reduce our revenue. If our iLet does not perform as expected or the reliability of the technology on which our products is based is questioned, our operating results, reputation and business will suffer.
- We rely and will continue to rely on third parties to conduct clinical trials of our iLet, which means we do not have full control over the conduct of such trials.
- Our iLet is currently cleared only for the treatment of T1D in adults and children six years of age or older. If our iLet is authorized for marketing or cleared in a bihormonal configuration for the treatment of T1D or for any other indications, such marketing authorization or clearance will be limited by the FDA to the specific indication for which granted. We are prohibited from marketing the iLet for other indications, such as T2D.
- If we are unable to obtain or protect intellectual property rights related to the iLet, we may not be able to compete effectively in our market.
- If we fail to comply with our obligations in our current and future intellectual property licenses with third parties, we could lose rights, which may be important to our business.

Corporate Information

We were originally incorporated under the laws of the Commonwealth of Massachusetts in October 2015. In August 2024, we reincorporated under the laws of the State of Delaware. Our principal executive offices are located at 11 Hughes, Irvine, California 92618, and our telephone number is (949) 427-7785. Our website is www.betabionics.com. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (JOBS Act), enacted in April 2012. An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act);
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.235 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and, as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates. However, we may elect to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. We may take advantage of these exemptions up until the time that we are no longer an emerging growth company.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended (Exchange Act). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

The Offering

Common stock offered by us	shares.
Underwriters' option to purchase additional shares of common stock	We have granted the underwriters an option exercisable for a period of 30 days after the date of this prospectus to purchase up to an additional shares of our common stock from us at the initial public offering price, less the underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares of common stock in full).
Use of proceeds	We estimate that the net proceeds to us from the sale of our common stock in this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise their option to purchase additional shares in full), based on the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, to . See the section titled "Use of Proceeds" for additional information.
Risk factors	See the section titled "Risk Factors" for additional information and a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed symbol	" "
The number of shares of our common stock to be outstanding after this offering set forth above is based on (i) the conversion of shares of our Class A common stock, shares of our Class B common stock and shares of our Class C common stock outstanding as of September 30, 2024, all of which are to automatically convert into shares of a single class of common stock and (ii) the automatic conversion of all outstanding shares of our preferred stock into shares of common stock, each immediately prior to the completion of this offering, and excludes: - shares of our Class B common stock issuable upon the exercise of options to purchase shares of our Class B common stock issued under our Amended and Restated 2016 Stock Incentive Plan (2016 Plan) and outstanding as of September 30, 2024, with a weighted-average exercise price of \$ per share; - shares of our Class B common stock issuable upon exercise of stock options granted under our 2016 Plan subsequent to September 30, 2024 and before , 2025, with a weighted-average exercise price of \$ per share;	

- shares of our common stock reserved for future issuance under our 2025 Equity Incentive Plan (2025 Plan), which will become effective upon the execution and delivery of the underwriting agreement for this offering (which shares include new shares plus the number of shares (not to exceed shares) (i) that remain available for the issuance of awards under the 2016 Plan at the time the 2025 Plan becomes effective, and (ii) any shares underlying outstanding stock awards granted under the 2016 Plan that, on or after the 2025 Plan becomes effective, terminate or expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled “Executive and Director Compensation—Equity Incentive Plans”), as well as any automatic increases in the number of our common stock reserved for future issuance under the 2025 Plan; and
- shares of our common stock reserved for future issuance under our 2025 Employee Stock Purchase Plan (ESPP), as well as any annual automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP, which will become effective upon the execution and delivery of the underwriting agreement for this offering.

Unless otherwise indicated, the information in this prospectus reflects and assumes the following:

- the conversion, in accordance with our existing certificate of incorporation, of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock into an aggregate of shares of our common stock in connection with the closing of this offering;
- the conversion, in accordance with our existing certificate of incorporation, of all outstanding shares of our convertible preferred stock into an aggregate of shares of our common stock in connection with the closing of this offering;
- the issuance of shares of our common stock upon the automatic net exercise of warrants to purchase shares of our Class B common stock outstanding as of September 30, 2024, which exercise will occur immediately prior to the closing of this offering at an exercise price of \$0.01 per share (based upon an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus);
- the issuance of shares of our common stock upon the automatic net exercise of warrants to purchase shares of our Series C convertible preferred stock outstanding as of September 30, 2024 (including shares of our common stock upon the automatic net exercise of warrants to purchase shares of our Series C convertible preferred stock issued in February 2022), which exercise will occur immediately prior to the closing of this offering at an exercise price of \$0.01 per share (based upon an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus);
- no exercise of the outstanding options described above;
- no exercise of the underwriters’ option to purchase up to an additional shares of our common stock from us;
- the filing and effectiveness of our amended and restated certificate of incorporation in Delaware and the adoption of our amended and restated bylaws immediately prior to the closing of this offering; and
- a 1-for- reverse stock split of our common stock and convertible preferred stock to be effected prior to the closing of this offering.

Summary Financial Data

The following tables summarize our financial data as of and for the periods indicated. We have derived the summary statements of operations and comprehensive loss data for the years ended December 31, 2022 and 2023, and the summary balance sheet data as of December 31, 2023, from our audited financial statements included elsewhere in this prospectus. Our historical results presented below are not necessarily indicative of the results to be expected for any future period. The following summary financial data should be read in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2022	2023
	(in thousands, except share and per share data)	
Statements of Operations and Comprehensive Loss Data:		
Revenue:		
Net sales	\$ —	\$ 11,995
Collaboration revenue	179	—
Total revenue	179	11,995
Cost of sales ⁽¹⁾	—	5,687
Gross profit	179	6,308
Operating expenses:		
Research and development ⁽¹⁾	31,428	17,943
Sales and marketing ⁽¹⁾	8,827	11,990
General and administrative ⁽¹⁾	25,768	12,225
Total operating expenses	66,023	42,158
Loss from operations	(65,844)	(35,850)
Other income (expense), net:		
Interest income	196	1,777
Interest and other expense	(14)	(68)
Change in fair value of warrant liabilities	911	(9,958)
Total other income (expense), net	1,093	(8,249)
Net loss	\$ (64,751)	\$ (44,099)
Other comprehensive income (loss):		
Unrealized gain on short-term investments	—	137
Comprehensive loss	\$ (64,751)	\$ (43,962)
Net loss per share attributable to common stockholders, basic and diluted ⁽²⁾	\$ (6.58)	\$ (4.22)
Weighted-average common stock outstanding, basic and diluted ⁽²⁾	9,845,122	10,448,817
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽³⁾		\$
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) ⁽³⁾		

(1) Includes stock-based compensation expense as follows:

	Year Ended December 31,	
	2022	2023
	(in thousands)	
Cost of sales	\$ —	\$ 239
Research and development	1,554	1,781
Sales and marketing	384	610
General and administrative	4,162	3,028
Total stock-based compensation expense	\$6,100	\$5,658

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- (2) See Note 16 to our audited financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.
- (3) Pro forma net loss per share, basic and diluted, attributable to common stockholders, is calculated giving effect to (i) the conversion of the Class A common stock, Class B common stock and Class C common stock and (ii) the conversion of the convertible preferred stock. Pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received in this offering. Unaudited pro forma net loss per share attributable to common stockholders for the year ended December 31, 2023 was calculated using the weighted-average number of shares of common stock outstanding, including the pro forma effect of (i) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock and (ii) the conversion of all outstanding shares of our convertible preferred stock, as if such conversions had occurred at the beginning of the period.

	As of December 31, 2023		
	Actual	Pro Forma ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾⁽³⁾
(in thousands)			
Balance Sheet Data:			
Cash, cash equivalents and short-term investments	\$ 96,745	\$	\$
Working capital ⁽⁴⁾	93,016		
Total assets	110,040		
Convertible preferred stock	261,713		
Total stockholders' equity (deficit)	(203,105)		

- (1) Gives effect to (i) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock into an aggregate of _____ shares of our common stock, (ii) the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of _____ shares of our common stock and the related reclassification of the convertible preferred stock to permanent equity in connection with the closing of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering.
- (2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) our sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) Pro forma as adjusted balance sheet data is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' (deficit) equity by approximately \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each one million share increase (decrease) in the number of shares offered by us would increase (decrease) each of our pro forma as adjusted cash, cash equivalents and short-term investments, working capital, total assets and total stockholders' (deficit) equity by approximately \$ _____ million, assuming that the assumed initial offering price to the public remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.
- (4) We define working capital as current assets less current liabilities. See our financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all of the other information contained in this prospectus, including our consolidated financial statements and related notes, before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business, financial condition, results of operations and prospects. If any of the following risks materialize, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Limited Commercial History, Financial Position and Need for Additional Capital

We have a limited commercial history and limited experience marketing and selling our products. We only recently launched our commercial product, which may make it difficult to evaluate the prospects for our future viability and predict our future performance.

We are a commercial-stage medical device company with limited commercial history and may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We launched our first commercial product, the iLet, in May 2023 and therefore do not have a long history operating as a commercial company. Our limited commercial history and limited number of cleared products makes it difficult to evaluate our current business and predict our future performance. These factors also make it difficult for us to forecast our future financial performance and growth. Although we have experienced revenue growth in prior periods, any assessment of our future revenue, profitability or prediction about our future success or viability is subject to significant uncertainty. We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by growing companies in emerging and rapidly changing industries, including scaling up our infrastructure and headcount. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations, and our business, financial condition and results of operations could be materially and adversely affected.

We have incurred significant operating losses since inception and cannot assure you that we will be able to achieve or sustain profitability.

Since our inception, we have incurred annual net losses. For the years ended December 31, 2022 and 2023, our net losses were \$64.8 million and \$44.1 million, respectively. For the nine months ended September 30, 2023 and 2024, our net losses were \$25.3 million and \$ million, respectively. As of September 30, 2024, we had an accumulated deficit of \$ million. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing and business operations, the clinical and regulatory initiatives to maintain and obtain marketing clearance, and the research and development of our current products and product candidates.

To achieve consistent profitability, we need to, among other things, increase sales of our product and the gross profit associated with those sales, increase our sales force and commercialization efforts, maintain an appropriate customer service team, provide ongoing training and support infrastructure, fund research and development activities, create additional efficiencies in our manufacturing processes while adding to our capacity, maintain and obtain regulatory clearance or certification or clearance or other marketing authorization required to commercialize our product candidates in the United States, and obtain reimbursement coverage from payors. We expect our expenses will continue to increase as we pursue these objectives and make investments in our business. Additional increases in our expenses without commensurate increases in sales could significantly increase our operating losses.

Accordingly, we expect to continue to incur operating losses for the foreseeable future, and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline.

Our quarterly and annual financial condition, operating results and cash flows may fluctuate in the future, which could cause the market price of our stock to decline substantially.

As we continue to build our business, we expect our quarterly and annual financial condition, operating results and cash flows to fluctuate significantly due to a variety of factors including, but not limited to:

- the timing of the launch of new products and product features by us and our competitors;
- market acceptance of our products and competing products by PWD, their caregivers and HCPs;
- the timing of regulatory clearance or certification of our products and the products of our competitors;
- the actual efficiencies gained in our manufacturing processes;
- the implementation and impact of third-party payor reimbursement and our multi-channel coverage and reimbursement strategy, including the mix of products sold via the DME and PBP channels;
- expenditures that we may incur to acquire, develop or commercialize additional products;
- sales and marketing efforts and expenses;
- warranty expenses;
- pricing pressures;
- the purchasing patterns of our customers, including as a result of seasonality, which may be impacted by the timing and use of deductibles and out-of-pocket expense maximums;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective;
- changes in the productivity of our sales force,
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry; and
- general economic, political, industry and market conditions.

These fluctuations may make financial planning and forecasting uncertain. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. As a result, comparing our operating results on a period-to-period basis may be difficult to understand and may not be meaningful. You should not rely on our past results as indicative of our future performance.

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We are pursuing a multi-channel DME and PBP coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device and provide PWD with advantageous coverage and reimbursement terms. We are working with payors to expand coverage and reimbursement under both DME and PBP channels. The DME and PBP channels for the iLet and its single-use products entail different payment outlays and therefore differentially impact PWD and our financial results. For a more detailed description of the strategy, see the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” To the extent that our mix of distribution channels fluctuates, our financial results may vary from period to period. Our ability to generate more revenue in the PBP channel over the patient’s lifespan will be dependent upon the continued use of our products by PWD.

The variability and unpredictability caused by factors such as those described above could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or results of operations fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We currently rely on sales of our iLet and related single-use products to generate all of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.

We currently generate all of our revenue from the sale of our iLet and related single-use products. Physician awareness of, and experience with, our iLet and related single-use products is currently limited. As a result, our product has limited product and brand recognition within the medical industry for the treatment of T1D. The novelty of our product, together with our limited commercialization experience, makes it difficult to evaluate our current business and predict our future prospects. Sales of our iLet and related single-use products may be negatively impacted by many factors, including:

- market acceptance of the insulin delivery devices and related products manufactured and sold by our key competitors;
- any safety or effectiveness concerns that arise regarding our products;
- the potential that breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin delivery devices obsolete or less desirable;
- adverse regulatory or legal actions relating to our products, or similar products or technologies of our competitors;
- the implementation of our multi-channel coverage and reimbursement strategy and any issues faced with such strategy, including the retention of PWD via the PBP channel;
- changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third-party payors;
- competitive pricing and attrition rates of consumers who cease using our products;
- our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;
- problems arising from the expansion of our manufacturing capabilities and commercial operations, or destruction, loss, or temporary shutdown of our manufacturing facilities;

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- concerns regarding the perceived safety, reliability or cybersecurity of any of our products, or any component thereof, particularly in connection with the launch of additional mobile application features and functionality and other software products; and
- claims that any of our products, or any component thereof, infringes on patent rights or other intellectual property rights of third parties.

Furthermore, any disruption in our supply chain could negatively impact our ability to manufacture or otherwise supply sufficient product quantities to meet demand. For example, sales of any of our current or future insulin delivery device products with CGM integration are subject to the continuation of our applicable agreements with DexCom, Abbott Diabetes Care Inc. (Abbott), or other third parties which, under some circumstances, may be subject to termination, with or without cause, on relatively short notice. Sales of our current or any future products may also be negatively impacted in the event of any regulatory or legal actions relating to CGM products that are compatible with our pumps, or in the event of any disruption to the availability of the applicable CGM-related supplies, such as sensors or transmitters, in a given market in which our products are sold. Sales of our products may also be adversely impacted if the CGM products that are compatible with our pumps are not viewed as superior to competing CGM products in markets where our products are sold, or if the price of these products is not competitive with similar products available in the market.

Because we currently rely on sales of our iLet and related single-use products to generate all of our revenue, any factors that negatively impact sales of these products (or negatively impact the products or components integrated with these products) could adversely affect our business, financial condition and results of operations.

Even if we consummate this offering, we may need to raise additional funds in the future, and these funds may not be available on acceptable terms, if at all.

The development of medical devices is capital-intensive. Our operations have consumed substantial amounts of cash since inception. As of September 30, 2024, our cash, cash equivalents and short-term investments were \$ million. Based on our planned use of the net proceeds of this offering and our current cash, cash equivalents and short-term investments, we estimate that our funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through . This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control.

Our capital requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the cost of maintaining FDA clearance for the iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older;
- the cost of obtaining and maintaining FDA marketing authorization or clearance for other future indications or other product candidates, including for the iLet for T1D using both insulin and glucagon (a bihormonal configuration), the iLet for T2D and the patch pump;
- future revenue generated by sales of the iLet and any future product candidates, if approved;
- expenses we incur in manufacturing and selling the iLet;
- costs associated with scaling up and expanding our manufacturing capacity;

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- costs associated with building and expanding our sales and marketing efforts in the United States and, in the future, internationally;
- costs associated with conducting research and development efforts for future improvements to the iLet;
- costs associated with conducting research and development efforts for future product offerings, such as the bihormonal iLet and patch pump;
- the cost of complying with regulatory requirements;
- costs associated with capital expenditures;
- the costs associated with hiring additional personnel as our business grows;
- the costs of operating as a public company;
- costs associated with any future litigation; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

We may require additional capital beyond the proceeds of this offering, which we may raise through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development, manufacturing and commercialization efforts.

Our ability to raise additional funds may also be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from geopolitical tensions, such as the ongoing war in Ukraine, the Israel and Palestine conflict, government actions implemented as a result of either of the foregoing, as well as tensions with and economic uncertainty in China, inflation, interest rates, and liquidity concerns at, and failures of, banks and other financial institutions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in economic growth, increases in inflation rates, higher interest rates and uncertainty about economic stability. If the equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Market volatility may further adversely impact our ability to access capital as and when needed.

If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or manufacturing or commercialization efforts. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or iLet.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our iLet, we expect to finance our future cash needs through

public or private equity offerings, debt financings, strategic collaborations and other strategic arrangements with third parties, or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of our common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities and harm our development, manufacturing and commercialization efforts.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or investigational devices or grant licenses on terms that may not be favorable to us.

Risks Related to Our Business, Strategy and Industry

The failure of our iLet and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.

Our current business and growth strategy is highly dependent on our insulin delivery device and related products achieving and maintaining market acceptance. For us to sell our products to people with insulin-dependent diabetes, we must demonstrate to them, their caregivers and HCPs that our products are an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative diabetes monitoring, treatment or prevention methodologies. Market acceptance and adoption of our products depends on educating PWD as well as their caregivers and HCPs, about the distinct features, ease-of-use, beneficial treatment outcomes and other perceived benefits of our products as compared to competing products. If we are not successful in convincing existing and potential customers of the benefits of our products, or if we are not able to achieve the support of caregivers and HCPs for our products, our sales may decline or we may achieve sales below our expectations.

Market acceptance of our products could be negatively impacted by many factors, including:

- the failure of our products to achieve and maintain wide acceptance among people with insulin-dependent diabetes, their caregivers, HCPs, third-party payors and key opinion leaders in the diabetes treatment community;
- PWD experience and satisfaction of our products;
- PWD preference for management of T1D;
- lack of evidence supporting the safety, effectiveness, ease-of-use or other perceived benefits of our products over competing products or other currently available insulin treatment methodologies;
- perceived risks or uncertainties associated with the use of our products, or components thereof, or of similar products or technologies of our competitors;

- adverse regulatory or legal actions or developments relating to our insulin delivery device product or to similar products or technologies; and
- results of clinical trials relating to our existing product or product candidates or to similar competitive products.

In addition, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements or breakthroughs, or the perception that advancements or breakthroughs could occur, in our products or the products offered by our competitors. It is also possible that consumer interest in our product candidates may lead consumers to delay the purchase of our current products.

If our insulin delivery device products do not achieve and maintain widespread market acceptance, we may fail to achieve sales consistent with our projections, in which case our business, financial condition and operating results could be materially and adversely affected.

The market opportunities for our iLet for the treatment of diabetes may be smaller than we anticipated.

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of T1D and T2D, including the patient population using intensive insulin therapy for treatment, which is derived from a variety of sources including scientific literature and third-party estimates. Our projections may prove to be incorrect and the number of potential patients may turn out to be lower than expected. Even though we have obtained a significant market share for our iLet, because the potential target populations could be smaller than we expect, we may never achieve profitability without obtaining regulatory clearance for the iLet in additional indications.

We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration and which may allow them to develop additional products for the treatment of diabetes that compete with our iLet.

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, or other market activities of industry participants. We compete with a number of companies that manufacture insulin delivery devices, including manufacturers of prefilled insulin syringes and insulin pens, such as Abbott, Eli Lilly, Medtronic, and Novo Nordisk A/S. In the United States, we expect our primary competitors for insulin infusion to be companies that manufacture insulin pumps, including Medtronic, Tandem and Insulet. However, the market for insulin pumps is currently undergoing significant changes and it is difficult to predict the potential impact of these changes on our competitive landscape.

Our current primary competitors are publicly traded companies that have several competitive advantages over us, including significantly greater name recognition, greater financial resources for sales and marketing and product development, established relationships with HCPs and third-party payors, and larger and more established distribution networks. Most of these competitors are large, well-capitalized companies with significantly more market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we may be able to. In some instances, our competitors also offer products that include features that our iLet does not include. For instance, Insulet offers a tubeless insulin delivery system which integrates the pump and infusion set in a single, disposable unit. The introduction of new products by competitors may create market saturation that may make it difficult to differentiate the potential benefits of the iLet over other products in development or approved products.

In addition, we may face competition from a number of medical device and pharmaceutical companies and academic and government-sponsored medical researchers that are pursuing new delivery devices, delivery

technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and prevention of diabetes.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for the iLet. The inability to compete with existing or subsequently introduced devices would have an adverse impact on our business, financial condition and prospects. In addition, the reimbursement structure of approved devices by other companies could impact the anticipated reimbursement structure of the iLet and our business, financial condition, results of operations and prospects.

Our results of operations will be harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

To ensure adequate supply of our products, we must forecast the inventory needs of our current and prospective customers, and manufacture our products based on our estimates of future demand. Our ability to accurately forecast demand for our products could be negatively affected by many factors, many of which are beyond our control, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast market acceptance of new products and changes in general market conditions or regulatory matters.

We seek to maintain sufficient levels of inventory of our products to protect ourselves from supply interruptions. We rely in part on our distributors and pharmacy customers to supply forecasts of anticipated product orders in their respective territories. If we fail to accurately estimate customer demand for our products, our inventory forecasts may be inaccurate, resulting in shortages or excesses of inventory. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and negatively impact our business, prospects, financial condition and results of operations. Conversely, if we underestimate customer demand for our products, we may not be able to deliver products in a timely manner or at all, and this could result in reduced revenue and damage to our reputation and customer relationships. For example, in the first 12 months after the release of the iLet, we faced demands that exceeded our existing supply of the iLet, which resulted in backorders. In addition, if we experience a significant increase in demand, we may not have adequate manufacturing capacity to meet such demand, and additional supplies may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity to meet our increased requirements, all of which would negatively affect our business, financial condition and results of operations. If we are unable to meet customer demand, we could lose our existing customers or lose our ability to acquire new customers, which would also negatively impact our business, financial condition and results of operations.

Competing products, therapeutic techniques or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable.

Our ability to grow our business and achieve our strategic objectives will depend on, among other things, our ability to develop and commercialize products for the treatment of diabetes that offer distinct features and functionality, are easy-to-use, provide superior treatment outcomes, receive adequate coverage and reimbursement from third-party payors, and are otherwise more appealing than available alternatives. Our primary competitors, as well as a number of other companies and medical researchers are pursuing new delivery devices, delivery technologies, therapeutic techniques, sensing technologies, treatment techniques, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for our products or render our products obsolete altogether, which would significantly reduce our sales or cause our sales to grow at a slower rate than we currently expect. In addition, even the perception that new products may be introduced, or that technological or treatment advancements could occur, could cause consumers to delay the purchase of our products.

Because the insulin-dependent diabetes market is large and growing, we anticipate companies will continue to dedicate significant resources to developing competing products and technologies, including potentially competitive learning algorithms. The introduction of products by competitors that are or claim to be superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, some of our competitors employ aggressive pricing strategies, including the use of discounts, rebates, low-cost product upgrades or other financial incentives that could adversely affect sales of our products. If a competitor develops a product that competes with or is perceived to be superior to our products, or if competitors continue to utilize strategies that place downward pressure on pricing within our industry, our sales may decline, our operating margins could be reduced and we may fail to meet our financial projections, which would materially and adversely affect our business, financial condition and operating results.

Moreover, we have designed our hardware products to resemble modern consumer electronic devices to address certain functionality concerns consumers have raised with respect to traditional pumps. Similarly, our newer mobile software applications are being designed to incorporate features and functions that are common to other consumer-oriented applications. These consumer industries are themselves highly competitive, and characterized by continuous new product introductions, rapid developments in technology and subjective and changing consumer preferences. If, in the future, consumers cease to view our products as contemporary or convenient as compared to then-existing consumer technology, our products may become less desirable.

The diabetes treatment market is subject to rapid technological change and product innovation. Our products are based on our proprietary technology, but a number of companies, medical researchers, and pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs, and other therapeutics for the monitoring, treatment, and/or prevention of insulin-dependent diabetes. In addition, we face competition from a number of companies, medical researchers and pharmaceutical companies that either offer or are pursuing competing delivery devices, technologies and procedures, such as smart insulin pens and inhalable insulin products, as well as companies with approved therapeutics or in-development therapeutic candidates impacting diabetes.

Any breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for our products or render our products obsolete altogether, which would significantly reduce our sales or cause our sales to grow at a slower rate than we currently expect. In addition, even the perception that new products may be introduced, or that technological or treatment advancements could occur, could cause consumers to delay the purchase of our products or impact our stock price.

We currently have a limited marketing and sales organization and have limited experience as a commercial-stage company marketing devices. If we are unable to successfully expand our marketing and sales capabilities or enter into additional agreements with third parties to market and sell devices, we may not be able to generate product revenue, and our business may be adversely affected.

We currently have limited sales marketing and distribution capabilities, and we have limited experience as an organization in marketing medical devices. Our continued sales will depend, in large part, on our ability to expand our sales infrastructure, particularly if we receive regulatory clearance in other jurisdictions. We will have to compete with other pharmaceutical and biotechnology companies and expend additional capital in order to recruit, hire, train and retain additional marketing and sales personnel.

Identifying and recruiting qualified personnel with sufficient industry experience and training them requires significant time, expense and attention. We have limited experience in training our personnel to successfully market and sell our iLet. If we provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop broad brand awareness in a cost effective manner, our business may be harmed. In addition, if our efforts to expand do not generate a corresponding increase in revenue or result in a decrease in our operating margin, our financial results will be adversely impacted. If we are unable to hire, develop and

retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

We may also decide to pursue collaborative arrangements regarding the sales and marketing of our products, if licensed. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our investigational devices ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our investigational devices.

There can be no assurance that we will be able to successfully expand our distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or in other jurisdictions for which we are able to obtain regulatory clearance.

If our information technology systems or those third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, process sensitive information. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including, but not limited to, social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. It may be difficult and/or costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third

parties with whom we work to detect, investigate, mitigate, contain and remediate a security incident could result in outages, data losses and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, manufacturing, employee email, content delivery to customers and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective.

In addition to the risks regarding our information systems and processing of sensitive information, our iLet insulin pumps rely on software, some of which is developed by third-party service providers, that could contain unanticipated vulnerabilities, which could make our products subject to computer viruses, cyber-attacks, or failures. These risks are further increased because we enable users to control insulin boluses through the mobile app using our iLet product.

The FDA has warned that insulin pumps may have cybersecurity vulnerabilities and could be manipulated by hackers, causing danger to PWD. Successful exploitation of any security vulnerabilities in our iLet products may allow attackers to gain access to the iLet to intercept, modify or interfere with the wireless radio frequency communications to or from our iLet products which could allow attackers to read sensitive data, change pump settings or control insulin delivery.

While we take steps designed to detect, mitigate, and remediate vulnerabilities in our iLet product and information systems (such as our hardware and/or software, including that of third parties with whom we work), we may not detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us

to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our products, deter new customers from using our products and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and, even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We may expend our resources to pursue the development of new potential indications or other modifications to commercialized products, and forgo the opportunity to capitalize on other potential indications or modifications that may ultimately be more profitable or for which there is a greater potential likelihood of success.

We have limited financial and personnel resources and are placing significant focus on the commercialization of our iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older, and the development of a bihormonal configuration for the treatment of T1D. We also intend to pursue expanded use of our iLet to treat people with insulin-dependent T2D. These changes will require the successful completion of additional trials, submission of and the FDA's clearance, approval or granting of marketing authorization applications and significant resources, which may not result in authorization for these uses and configurations. Over time, we may also seek future marketing authorizations or clearances for the use of our iLet in the treatment of a number of related conditions including gestational diabetes, monogenic diabetes, cystic fibrosis-related diabetes, congenital hyperinsulinism, insulinoma syndrome, post-bariatric surgery and metabolic syndrome. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable future investigational devices.

We will need to expand our organization, and we may experience challenges in managing this growth as we build our capabilities, which could disrupt our operations.

As of September 30, 2024, we had full-time employees. We expect to experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of

regulatory and clinical affairs and sales, marketing and distribution. To manage our growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. As we expand our organization, we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of investigational devices. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow product revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our investigational devices and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We expect to continue to increase our manufacturing capacity and our personnel, and we will need to develop additional capabilities to support our U.S. and international sales and marketing efforts. This growth, as well as any other growth that we may experience in the future, will pose challenges to our organization and may strain our management and operations resources. In order to manage future growth, we will be required to improve existing, and implement new, sales and marketing efforts and distribution channels. The form and function of our enterprise information technology systems will need to change and be improved upon as our business needs change. We will need to manage our supply chain effectively, including the development of our U.S. manufacturing, our relationship with single source suppliers as well as other suppliers going forward. We may also need to partner with additional third-party suppliers to manufacture certain components of the iLet and complete additional manufacturing lines in the future. A transition to new suppliers may result in additional costs or delays. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business, or we may not be able to manufacture sufficient inventory, or attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver the iLet in a timely manner and our results of operations may be adversely affected.

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

We are dependent on our executive officers, as well as the other members of our management, scientific and clinical teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time and, for certain of our executive officers, entitle them to receive severance payments in connection with their voluntary resignation of employment for good reason, as defined in the employment agreements. Additional details regarding these arrangements can be found in the section titled “Executive and Director Compensation—Employment Arrangements with Our Named Executive Officers.” We do not currently maintain key person life insurance policies for any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense, and we cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. The loss of the services of certain members of our senior management or key employees could prevent

or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Each member of senior management, as well as our key employees, may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein. Our future success depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

We may acquire other companies or technologies, which could fail to result in a commercial product or revenue, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our business.

Although we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so, we may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our offering of products, enhance our technical capabilities or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition and results of operations may be negatively affected.

If we were to be sued for product liability, we could face substantial liabilities that exceed our resources, limit sales of our iLet and limit commercialization of any products that we may develop.

The marketing, sale and use of our iLet could lead to the filing of product liability claims where someone may allege that our products identified inaccurate or incomplete information or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability claim could result in substantial damages and be costly and time-consuming for us to defend. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- substantial litigation costs;

- distraction of management's attention from our primary business;
- the inability to commercialize our products or new products;
- decreased demand for our products;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- loss of sales; or
- termination of existing agreements by our partners and potential partners failing to partner with us.

We maintain product liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability claims. Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also harm our reputation with customers, which could negatively affect our business, financial condition and results of operations.

Risks Related to the Development, Regulatory Approval and Commercialization of our iLet Bionic Pancreas and Product Candidates

We are highly dependent on the success of our iLet for the treatment of T1D, which is cleared by the FDA for commercial sale in the United States for the treatment of T1D, and we do not have any other commercial products. If we are unable to obtain and maintain regulatory clearance or approval for planned modifications to the iLet or for new indications, or for any future development-stage products, or if we are unsuccessful in our efforts to continue to commercialize our cleared version of the iLet, our business will be materially harmed.

We only have one commercialized device, the iLet, which is an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older. Our business primarily depends on the successful commercialization of the iLet. We currently have no other products cleared for sale and may never be able to develop other marketable products. Our iLet will require additional clinical development, testing and marketing authorization or regulatory clearance before we are permitted to commercialize it in a bihormonal configuration for the treatment of T1D or for any future indications we may pursue. Further, as we develop a bihormonal configuration of the iLet, which is designed to use both insulin and glucagon for the treatment of T1D, we will need to develop and obtain approval for our glucagon product candidate as a drug in order to successfully commercialize our iLet in a bihormonal configuration. In addition, we are developing an insulin pump, also commonly referred to as a "patch pump," for which we have engaged with the FDA in pre-submission interactions. The future regulatory and commercial success of our iLet, patch pump and any other product candidate is subject to a number of risks, including the following:

- completion of preclinical studies with favorable results;
- successful enrollment in, and completion of, planned and future clinical trials with favorable results;

- sufficiency of our financial and other resources to complete the necessary clinical trials and regulatory activities;
- successful patient enrollment in clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile in the intended populations;
- whether we are required by the FDA to conduct additional clinical trials or to modify the design of current or planned trials to support any future application seeking marketing authorization or clearance of the iLet in a bihormonal configuration for the treatment of T1D or for other indications we may pursue, or seeking initial marketing authorization or clearance for any of our other product candidates;
- receipt and maintenance of marketing authorizations or clearances from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our iLet;
- making arrangements with third-party manufacturers and ensuring such third-party manufacturers supply sufficient quantities of components of our products and product candidates;
- scaling up our manufacturing capabilities, for both commercial and clinical supplies of our products and product candidates;
- entry into collaborations to further the development of our iLet's capabilities;
- expanding sales, marketing and distribution capabilities as we continue our commercialization efforts of the iLet, whether alone or in collaboration with others;
- successfully launching commercial sales of the iLet, patch pump and any other product candidate, if authorized for marketing or cleared;
- acceptance of our products by PWD, the medical community and third-party payors;
- maintaining a continued acceptable safety profile following marketing authorization or clearance;
- maintaining regulatory compliance;
- effectively competing with other treatment options and the availability, perceived advantages, relative cost, relative safety and relative effectiveness of alternative and competing treatments;
- the emergence of competing technologies and other adverse market developments, and our need to enhance existing products and/or develop new products to maintain market share in response to such competing technologies or market developments;
- maintaining healthcare coverage and adequate reimbursement from third-party payors;
- continuing to build and maintain an organization of people who can successfully develop our products; and
- enforcing and defending intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are not successful in commercializing our iLet or obtaining marketing authorization or clearance for the iLet in its bihormonal configuration for the treatment of T1D or in other indications, such as T2D, the investigational glucagon product, the patch pump, or any other product candidate, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

Furthermore, even though we have received clearance for our iLet for insulin-only delivery for the treatment of T1D, any other configuration for the treatment of T1D such as a bihormonal configuration using both insulin and glucagon or other indications we may pursue for which we receive marketing authorization or clearance may be subject to limitations on the patient populations for which we may market the product. Even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that we will successfully develop, obtain marketing authorization or clearance for, and commercialize our iLet in its bihormonal configuration for the treatment of T1D or for any future indication we may pursue, the patch pump, the investigational glucagon product, or any other development-stage products. If we are unable to continue commercializing the iLet for T1D, or if we are unable to develop, or obtain marketing authorization or clearance for, or, if authorized for marketing or cleared, successfully commercialize the iLet for the treatment of any future indications, we may not be able to generate sufficient revenue to continue our business.

We are subject to a post-market surveillance order issued by the FDA for our iLet. If the FDA determines that our iLet does not perform as anticipated, or if the FDA identifies new concerns related to the safety and effectiveness of the device, we may need to make changes to or recall or withdraw the iLet from the field, which could harm our business.

The FDA has notified us that the iLet is subject to a mandatory post-market surveillance order under Section 522 of the FDCA, which authorizes the FDA to require a manufacturer to conduct post-market surveillance for devices that meet certain criteria. Relevant here, the FDA determined that the failure of the iLet would be reasonably likely to have serious adverse health consequences, and that the device is expected to have significant use in pediatric populations. The FDA issued this 522 Order based on its concerns with the limited safety and effectiveness data for the iLet Dosing Decision Software in certain intended use populations, incidence rates of rare adverse events associated with device use, and the limited safety and effectiveness data for specific design features (i.e., lack of conventional open-loop mode, the BG-run feature, body weight only initialization, handling of unannounced meals, and use of lower and higher glucose targets for the device).

To address these issues, the FDA has asked that we conduct a 1-year, prospective single-arm cohort study with a sample size that is statistically justified (based on study hypotheses, where applicable, and with appropriate distribution through different user groups) for T1D patients ages six years and older. The FDA has asked that we complete the study and submit a final report to the FDA by June 2027. We are currently making progress to initiate a single-arm prospective observational study anticipated to begin before the end of 2024. We expect this study will enroll a total of 1,875 users who will be followed for one year. Once we are able to commence, conduct and complete our study, we will be required to submit a final report to the FDA. Should the FDA decide that use of the iLet identifies new concerns related to the safety and effectiveness of the product, or if the FDA determines that the requirements of the 522 Order are otherwise unmet, we may be required to make additional changes to our iLet, for which we may need to submit new marketing authorization applications; we may be required to conduct additional studies or collect additional information; we may need to withdraw or recall the iLet from the market; and may be subject to other enforcement action, which in each case could harm our business. Failure to comply with these requirements in a timely manner could result in the revocation of the 510(k) clearance for our iLet that is the subject of the Section 522 Order, as well as the recall or withdrawal of the product, which in each case, could prevent us from generating sales from the iLet in the United States.

The regulatory authorization process of the FDA, or any comparable foreign regulatory authorities, is lengthy, time-consuming and inherently unpredictable. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain marketing authorization or clearance for any of our product candidates. Modifications to our currently commercialized version of the iLet may require new marketing authorizations or clearance.

We have developed a medical device that is subject to extensive regulation by the FDA. These regulations relate to testing, manufacturing, labeling, sale, promotion, distribution and shipping. Before we can market or sell a new product regulated as a medical device in the United States, we must obtain marketing authorization or clearance under one of the three following regulatory pathways: (i) Section 510(k) of the federal Food, Drug, and Cosmetic Act, (ii) a premarket approval application (PMA), or (iii) de novo classification of our product. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data are sometimes required to support substantial equivalence. In the second pathway, the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical study, clinical trial, manufacturing and labeling data. The PMA process is typically required for products that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, and is significantly more involved than the 510(k) process. The third pathway is called de novo classification, which is generally used for low- to moderate-risk products that have not previously been classified by the FDA and therefore no predicate device is available. Devices not previously classified by the FDA are automatically placed into Class III; through the de novo process a manufacturer may request reclassification as a Class I or II device. If the FDA agrees to reclassify the device, it will then clear the device through the de novo process, and future devices of a similar nature may use the device cleared through the de novo process as a predicate device for a 510(k) submission.

The PMA approval, 510(k) clearance and de novo classification processes can be expensive, lengthy and uncertain. The FDA’s 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Clinical data may also be required in connection with an application for 510(k) clearance or a de novo classification request. Despite the time, effort and cost, a device may not obtain marketing authorization or clearance by the FDA. Any delay or failure to obtain necessary marketing authorizations or clearances could harm our business. Furthermore, even if we are granted such marketing authorizations or clearances, they may include significant limitations on the indicated uses for the device, which may limit the potential commercial market for the device.

We pursued the 510(k) pathway for the iLet and ultimately received clearance from the FDA for insulin-only delivery for the treatment of T1D in adults and children six years of age and older. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer’s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified the iLet subsequent to obtaining 510(k) clearance, and have determined based on our review of the applicable FDA guidance that in these instances new 510(k) clearances or pre-market approvals were not required. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our iLet or any other product for which we may obtain 510(k) clearance in the future, and for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Moreover, we have planned modifications to our iLet for which we plan to seek new marketing authorization, such as the proposed bihormonal configuration. The FDA may ultimately determine that the

510(k) pathway is not appropriate for the bihormonal configuration of the iLet for the treatment of T1D, or for any other indications we may pursue, and may require us to obtain a PMA or seek de novo classification in order to commercialize the iLet for such uses in the United States. In particular, there are currently no authorized pump therapies that utilize both insulin and glucagon to treat T1D. As such it is difficult to accurately predict the developmental and regulatory challenges we may experience for our iLet in its bihormonal configuration if it proceeds into a pivotal trial. Obtaining a PMA is generally more costly and uncertain than the 510(k) clearance process or the de novo classification process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained, if ever. Additionally, even though the FDA determined that the 510(k) pathway was appropriate for the iLet for insulin-only delivery, different components of the system will require individual marketing authorizations and review of individual components can vary. For example, our iLet Dosing Decision Software utilized in the iLet required a separate 510(k) clearance. If the FDA requires us to go through a lengthier, more rigorous examination for our product candidates or for modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business. The FDA can delay, limit or deny marketing authorization or clearance of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our product candidates are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA with the design or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse effects experienced by participants in our clinical trials;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance, de novo classification or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Further, if the FDA determines that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at a particular clinical trial site or the utility of the clinical trial itself, we could encounter delays or difficulties in obtaining any future marketing authorizations or clearances. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any submitted marketing applications, or the data contained therein. Any such delay or rejection could prevent us from obtaining marketing authorization or clearance and commercializing any of our product candidates.

Clinical trials are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical trials.

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The results of preclinical studies and clinical trials of our products conducted to date and

ongoing or future studies and trials of our current, planned or future products or product candidates may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The data and results from our clinical trials does not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials, or have viewed such data in different ways than regulators do. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and nonclinical testing in addition to those we have planned.

Moreover, any delays in conducting clinical trials could materially affect our development costs and delay marketing authorization or clearance of our product modifications and product candidates, including our efforts to develop the iLet for the treatment of T1D using both insulin and glucagon, or for any other indication we may pursue, the patch pump, or any other product candidate. We do not know whether clinical trials will begin on time, will need to be redesigned, will be subject to delay, will be halted due to safety or other concerns, or will be completed on schedule, if at all. A clinical trial can be delayed for a variety of reasons, including:

- we may be required to submit an investigational device exemption application (IDE) or investigational new drug (IND) to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices and drugs, respectively, and the FDA may reject our IDE or IND and notify us that we may not begin clinical trials, or place restrictions on the conduct of such trials;
- regulators may disagree as to the design or implementation of our clinical trials;
- delays or failures in obtaining the required allowance, clearance, approval or authorization to commence a trial because of safety concerns;
- delays or failures in obtaining components of our products and manufacturing sufficient quantities for use in clinical trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites or other contract research organizations (CROs);
- delays or failures in obtaining approval of the clinical trial protocol from an institutional review board (IRB), to conduct a clinical trial at a prospective study site;
- delays in recruiting or enrolling participants for clinical trials;
- failure of a clinical trial or clinical investigators to be in compliance with Good Clinical Practices (GCPs);
- unforeseen safety issues;
- malfunctioning of devices;
- inability to monitor subjects adequately during or after treatment;
- difficulty monitoring multiple trial sites;

- the FDA requiring alterations to any of the study designs, our nonclinical strategy or our manufacturing plans;
- failure of third-party clinical trial sponsors conducting studies of our products or clinical trial vendors to satisfy their contractual duties, comply with regulations, or meet expected deadlines; and
- determination by regulators that the design of a clinical trial is not adequate.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing authorization or clearance.

Patient enrollment in clinical trials and completion of patient follow up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be authorized for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post treatment procedures or follow up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our product candidate. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by the trial sponsor, the FDA, the IRBs that are overseeing a trial, or a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or the clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen safety issues, including adverse events, or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices and drugs produced under current good manufacturing practices (cGMPs). Furthermore, we rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, conducting clinical trials in various countries may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non U.S. CROs and other third party contractors, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

If we are required to conduct additional clinical trials or other testing beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing, if the results of these trials or tests are not positive or are not as positive as we expect or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

Interim, “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line or preliminary results that we report may differ from future results of the same trial, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line or preliminary data we previously announced. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available.

In particular, we may disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, or the approvability or potential for commercialization of the particular product candidate. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Use of our commercial or development-stage products may cause adverse events or undesirable side effects or present other safety concerns which may cause us to suspend or discontinue clinical trials, delay or prevent marketing authorization, limit the commercial profile of labeling for any product that has received marketing authorization, or result in significant negative consequences following marketing authorization.

The use of the iLet and any of our product candidates could be associated with adverse events or serious adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics associated with our products and product candidates. Undesirable side effects, whether observed in clinical trials or in connection with the commercial use of our products, could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. The risks are associated with hypoglycemia and hyperglycemia. We report all severe hypoglycemia and all DKA events that we are aware of. Our rates of severe hypoglycemia and DKA are similar to those reported for other

AID systems currently on the market and to the rates that were observed in the investigator-initiated iLet Bionic Pancreas Pivotal Trial. Unacceptable safety concerns caused by our commercial or development-stage products could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label, or the delay or denial of required marketing authorizations or clearances.

In addition, if we, or others, discover safety concerns with our cleared iLet, or for any other product we may develop and for which we may obtain marketing authorization, that were not previously identified, a number of potentially significant negative consequences could result, including:

- regulatory authorities may seek to reclassify a 510(k)-cleared device, potentially triggering the need for a PMA submission or de novo request, withdraw marketing authorizations or clearances, seize the product, or seek an injunction against its manufacture or distribution;
- we, or any future collaborators, may be required to recall the product, change the way such product is administered to or used by patients or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or impose distribution or use restrictions;
- we, or any future collaborators, may be required to issue safety alerts or other mandatory communications to physicians and patients;
- we, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive;
- our reputation may suffer; and
- we could face decreased demand for our products as a result of PWD, caregivers and HCPs losing confidence in our products.

Any of the foregoing could prevent us from achieving and/or maintaining market acceptance of our products, which would significantly harm our business, results of operations and prospects, and could adversely impact our financial condition, results of operations or the market price of our common shares.

We are developing our iLet in combination with other therapies and devices, which requires additional development time and exposes us to additional risks.

The ability to obtain marketing authorization and to commercialize our iLet in its bihormonal configuration requires FDA approval of a glucagon product for chronic use and to obtain marketing authorization of the Bihormonal configuration setting of our iLet. In May 2024, we entered into an exclusive collaboration and license agreement with Xeris to facilitate development of a dual-hormone pump for individuals with T1D, whereby Xeris will develop a glucagon product utilizing Xeris’ XeriSol technology for use in our iLet in its bihormonal configuration. We will be responsible for obtaining regulatory approval of the glucagon product to be utilized in our iLet, if the bihormonal configuration is authorized for marketing by the FDA. We are highly dependent on the approval of such glucagon product to be able to successfully commercialize our iLet in its bihormonal configuration for the treatment of T1D, if authorized for marketing by the FDA.

We have also designed and received clearance of our iLet for use with prefilled insulin cartridges with multiple, commonly dosed analog insulins. Even with these clearances, we continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the drug therapy used in combination with our iLet or that safety, effectiveness, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

Similarly, we will initially seek clearance of our iLet for use with any approved iCGM models that are compatible with our iLet. Currently, the only iCGM models that are compatible with our iLet are DexCom's G6 and G7 iCGM devices and Abbott's FreeStyle Libre 3 Plus CGM sensor. Although we are actively working to expand the compatibility of our iLet with other iCGM models, there is no assurance we will be successful in our efforts. This exposes us to similar risk in the event the DexCom G7, Abbott's FreeStyle Libre 3 Plus, or any other marketed iCGM device that may be compatible with our iLet in the future, has its marketing authorization revoked or encounters other difficulties which could negatively affect the public's perception and use of such product and have a corresponding adverse effect on the use and public perception of the iLet. Furthermore, our agreements with certain iCGM manufacturers do not require such iCGM manufacturers to indefinitely support compatibility of their older generation iCGM devices with our iLet as they introduce new generations. As such, PWD may be unwilling to buy or continue to use our iLet if they are unwilling or unable to purchase newer generations of iCGM devices as they are developed and commercialized. If such difficulties occur with the iCGM devices with which the iLet is integrated or future generations of iCGM devices at a time when our iLet is not compatible with any other iCGM devices, or if any such compatible devices are or are perceived to be inferior to such iCGM devices, sales of the iLet would be adversely affected.

If the FDA does not conclude that our glucagon product candidate satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of our glucagon product candidate under Section 505(b)(2) are not as we expect, the approval pathway for our glucagon product candidate will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for our glucagon product candidate that we plan to develop for use with our development of a bihormonal configuration of the iLet for the treatment of T1D, as described in this prospectus. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of a new drug application (NDA) where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our glucagon product candidate as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our glucagon product candidate, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, it is possible that third parties may file citizens' petitions with the FDA in an attempt to persuade the FDA that our glucagon product candidate, or the clinical studies that we submit in our applications seeking approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2), which would substantially harm our business and could have a material adverse effect on our ability to pursue marketing authorization for the bihormonal configuration of our iLet.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products from being developed, authorized or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and authorize the sale of new products can be affected by a variety of factors, including government budget and funding levels; its ability to hire and retain key personnel and accept the payment of user fees; statutory, regulatory, and policy changes; and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or authorized for marketing by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our long-term growth depends, in part, on our ability to develop and enhance the iLet, expand our indications and commercialize the iLet in a timely manner. If we fail to do so we may be unable to grow our business or compete effectively.

It is important to our business and our long-term growth that we continue to develop and enhance the iLet, including in a bihormonal configuration. For example, we have completed over 20 pre-pivotal trials testing the iLet algorithms in order to enhance its learning capabilities. We intend to continue to invest in research and development activities focused on improvements and enhancements to the iLet. Additionally, we intend to pursue marketing authorization or clearance for other indications in the United States in the future.

Developing enhancements to the iLet can be expensive and time-consuming and could divert management's attention away from the commercialization of the iLet and divert financial resources from other operations. The success of any new product enhancements, including marketing authorization or clearance of the iLet for additional indications, will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs, and develop enhancements to meet those needs;
- demonstrate, if required, the safety and effectiveness of new enhancements to the iLet, including additional indications, with data from preclinical studies and clinical trials;
- obtain in a timely manner the necessary marketing authorization or clearance for new enhancements to the iLet, product modifications or expanded indications;
- avoid infringing upon the intellectual property rights of third parties;
- comply with all applicable laws and regulations, including those governing the marketing of new devices or modified products;
- develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users of the iLet; and
- receive adequate coverage and reimbursement for procedures performed with the iLet.

While we have commercialized the iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older, we may not be successful in expanding the

configurations or indications and developing and commercializing new product enhancements. This could negatively impact our ability to achieve and maintain market share and increase our revenue, which could have a material adverse effect on our business, financial condition and results of operations.

Maintaining regulatory clearance for our iLet as an automated insulin dosing system for the treatment of T1D and obtaining and maintaining marketing authorization or clearance for a bihormonal configuration for T1D or other indication in one jurisdiction does not mean that we will be successful in obtaining marketing authorization of the iLet in any configuration or indication in other jurisdictions.

Maintaining regulatory clearance for our iLet as an automated insulin dosing system for the treatment of T1D and obtaining and maintaining marketing authorization or clearance for a bihormonal configuration for T1D or other indication in one jurisdiction does not mean that we will be successful in obtaining or maintaining marketing authorization of the iLet in any configuration or indication in any other jurisdiction. For example, even if the FDA grants marketing authorization or clearance, this does not mean that comparable regulatory authorities in foreign jurisdictions would similarly grant marketing authorization or clearance in those countries. Procedures for obtaining marketing authorization or clearance vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, products must be approved for reimbursement before they can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign marketing authorization or clearance and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing authorizations or clearances, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

Risks Related to Reimbursement and Pricing

Coverage and reimbursement may be limited or unavailable in certain market segments for our iLet, which could make it difficult for us to sell any investigational devices profitably.

The success of our iLet for the treatment of T1D depends on the availability of adequate coverage and reimbursement from third-party payors. In the United States and markets in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new device acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and devices they will cover and the amount of reimbursement. Coverage may be more limited than the purposes for which the drug or device is approved by the FDA or comparable foreign regulatory authorities. In the United States, private health insurers and other third-party payors in the U.S. often follow the coverage and reimbursement policies of government payors, including the Medicare or Medicaid programs. The Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS) that administers the Medicare program, decides whether and to what extent a new medicine or device will be covered and reimbursed under Medicare. However, no uniform policy of coverage and reimbursement for products exists among third-party payors. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;

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- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for our iLet, in either its cleared use as a treatment for T1D adults and children six years of age and older, or other indications for which we may obtain marketing authorization or clearance in the future, the resulting reimbursement payment rates might not be adequate for us to maintain pricing sufficient to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use our devices that have received marketing authorization or clearance unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our devices. There is a risk that coverage and reimbursement rates may be inadequate for us to achieve profitability. There is significant uncertainty related to insurance coverage and reimbursement of products that are newly authorized for marketing. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement.

We are pursuing a multi-channel coverage and reimbursement strategy. If covered, the iLet is currently reimbursed through traditional medical benefit channels. As a medical device company, reimbursement from government and/or commercial third-party healthcare payors, including Medicare and Medicaid, is an important element of our success. CMS provides coverage for our product as DME eligible for coverage under Medicare Part B. Coverage criteria for DME is determined by CMS under national coverage determinations as well as by local Medicare Administrative Contractors under local coverage determinations. Therefore, Medicare reimbursement for the iLet is subject to various coverage conditions.

We are working with payors to establish coverage and reimbursement under both the DME and PBP channels as we believe that this strategy increases access and optimizes the potential for better medical outcomes for PWD through the adoption of the iLet.

The commercial opportunity in the PBP channel may be limited unless a substantial portion of the sales price for the iLet is covered by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, federal and state government healthcare agencies, intermediaries, Medicare, Medicaid and other managed care providers. Medicare Part D plan sponsors may provide coverage for the iLet under the Medicare Part D prescription drug program, which requires negotiating with third-party payors in order to provide iLet through the PBP channel in the United States. These payor contracts can generally be terminated by the third-party payor without cause. If our efforts to enter into additional contracts with intermediaries and third-party payors are not successful, our ability to offer iLet through the PBP channel may be limited.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly authorized products and, as a result, they may not cover or provide adequate payment for our commercialized devices. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We

may experience pricing pressures in connection with the sale of any of our products due to the shift toward value-based healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and legislative changes.

If we are not able to successfully implement our multi-channel coverage and reimbursement strategy, secure or retain adequate coverage or reimbursement for the iLet and our product candidates, if authorized, by third-party payors, or face delays in processing approvals by those payors, our business, financial condition and operating results could be adversely affected.

If we experience pricing pressure for our products and we are unable to reduce our expenses, including the per unit cost of producing our products, there may be a material adverse effect on our business, financial condition, results of operations and cash flows.

We may experience pricing pressure or decreasing prices for our products as a result of actions or negotiations by managed care organizations and other third-party payors, increased market power of payors, increased competition within our industry, and increased competition among suppliers, including manufacturing services providers, as the medical device and biotechnology industries consolidate. If the prices for our products decrease and we are unable to reduce our expenses, including the cost of sourcing materials, logistics and the cost to manufacture our products, our business, financial condition, results of operations and cash flows will be adversely affected.

Healthcare reform measures could hinder or prevent the commercial success of our solutions.

The United States and some foreign jurisdictions have enacted or are considering a number of health reform measures to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. There have been executive, judicial and congressional challenges, and a number of health reform measures by the Biden administration that have impacted certain aspects of the Affordable Care Act. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. It is possible that the Affordable Care Act and the IRA will be subject to additional challenges in the future.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Risks Related to Manufacturing and Our Reliance on Third Parties

We are substantially dependent on various third parties for the development and potential commercialization of our iLet and product candidates. Certain of our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the development of the investigational devices or other development-stage candidates, such as glucagon, we develop. If our collaborations are terminated or are not successful, our ability to successfully develop and commercialize our iLet and product candidates may be adversely affected.

Our iLet is currently only compatible with DexCom's G6 and G7 iCGM devices and Abbott's FreeStyle Libre 3 Plus CGM sensor. Although we are actively working to expand the compatibility of our iLet with other iCGM models, there is no assurance we will be successful in our efforts. Our development agreement with DexCom provides us with non-exclusive licenses to integrate the currently available generation of DexCom's iCGM technology with our iLet. Under our current commercialization agreement with DexCom, we and DexCom have agreed to commercialize an AID system comprised of our iLet and DexCom's G6 or G7 iCGM. We also have a development and commercialization agreement with Abbott, under which we and Abbott have agreed to commercialize an AID system comprised of our iLet and Abbott's iCGM. These agreements may be terminated by the other party upon certain conditions. If our existing agreements are terminated and/or DexCom or Abbott enter into an exclusive partnership with one of our competitors, our ability to commercialize the iLet would be disrupted, which would have a material adverse impact on our business, financial condition and results of operations, negatively impact our ability to compete and cause the price of our common stock to decline.

Additionally, we entered into an exclusive collaboration and license agreement with Xeris to facilitate the development of a dual-hormone pump for PWD, whereby Xeris will develop a glucagon drug product candidate utilizing Xeris' XeriSol technology for use in our iLet in its bihormonal configuration (if such configuration is authorized for marketing). We will be responsible for obtaining regulatory approval of such glucagon product candidate. We also entered into collaboration agreements with certain third-party producers of insulin, pursuant to which we have agreed to work with such parties to support the development of the iLet by researching and incorporating certain proprietary insulins in our iLet. Although we have been successful in obtaining clearance of our iLet with the use of these insulins, we are dependent upon the continued cooperation and collaboration of these parties. If any of these agreements are terminated, we would be required to purchase the applicable party's approved insulin and fill empty insulin cartridges fitted for the iLet to evaluate such party's insulin in trials, which would increase our costs and could delay the timing of trials. Although there are other producers of insulin, there is no assurance we could enter into agreements with them on commercially reasonable terms, if at all, and receive marketing authorizations or clearances for the use of their insulin in the iLet.

Additional details regarding these agreements can be found in the sections titled "Business—License and Collaboration Agreements" and "Business—Development and Commercial Agreements."

Our current collaboration agreements pose, and potential future collaborations involving our iLet may pose, the following risks to us:

- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development and commercialization of our products;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our iLet;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation;

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- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the investigational device, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may experience financial difficulties;
- our collaborators may experience legal difficulties with respect to FDA regulations or regulations of other government agencies that jeopardize their ability to continue supporting the development and commercialization of our products;
- collaborators could terminate our existing or future agreements or allow them to expire, which would delay the development and may increase the cost of developing our products;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and
- collaboration agreements may restrict our right to independently pursue new investigational devices.

If we enter into collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any investigational device or other development-stage product we develop could delay the development and commercialization of our investigational devices or other development-stage products, which would harm our business prospects, financial condition and results of operations.

We have limited experience manufacturing our products and, if we are unable to manufacture our products in high-quality commercial quantities successfully and consistently to meet demand, our growth will be limited.

We have limited experience manufacturing our products. We currently manufacture our iLet and its accompanying ready-to-fill insulin cartridges at our single manufacturing facility in Irvine, California. To manufacture our products in the quantities that we believe will be required to meet the currently anticipated market demand beyond the next several years, we will need to increase manufacturing capacity, which will subject us to numerous risks related to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers, including the suppliers of our infusion sets, pump motors and cartridge connectors used in the iLet;
- our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand;

- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently develop and manufacture new products or implement any necessary or desired changes in response to regulatory requirements; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facilities.

As we continue the commercial production of our products and increase our manufacturing capacity, we may encounter quality issues that could result in product defects, errors or recalls. Since launching the iLet in May 2023, we have experienced manufacturing issues related to screen breakage. To resolve these issues, we improved the screen bonding and durability of the glass. While we believe we have remediated these issues, there is no assurance we will not encounter similar or other unanticipated issues in the future. Manufacturing delays related to quality control could negatively impact our ability to bring our products to market, harm our reputation and decrease our revenue. Any defects, errors or recalls could be expensive and generate negative publicity, which could impair our ability to market or sell our products, and adversely affect our results of operations.

Following FDA clearance of the iLet as an automated insulin dosing system for the treatment of T1D in adults and children six years of age and older, we have had to invest additional resources in purchasing components, hiring and training employees and enhancing our manufacturing processes and quality systems. We have also needed to increase our utilization of third parties to perform contracted manufacturing services for us, and have acquired additional custom designed equipment to support the expansion of our manufacturing capacity. If we fail to adequately meet commercial requirements while also maintain product quality standards, we may fail to maintain our regulatory clearance and efficiently manage costs, and our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

Further, we perform all of our manufacturing activities at our single manufacturing facility in Irvine, California. Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in delays in meeting commercial demand and in conducting our clinical trials, the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our products, changes to labor costs or less favorable terms with third-party suppliers. There can be no assurance that we will not encounter such problems in the future.

Furthermore, the current lease for our manufacturing facility expires in May 2027, and we may be unable to renew our lease or find a new facility on commercially reasonable terms, or at all. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure investors that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business, financial condition and results of operations.

We obtain some of the components and subassemblies included in our iLet from single source suppliers, and the partial or complete loss of one or more of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

We rely on a number of suppliers who manufacture the components of the iLet. We have a supply agreement with Unomedical, an affiliate of ConvaTec Group Plc, for the production of infusion sets for our iLet, a contract manufacturing agreement with PMC SMART Solutions LLC (PMC) for the manufacture of our cartridge connectors and a supplier quality agreement with Maxon Precision Motors, Inc. (Maxon) for the supply of pump motors for our iLet. Unomedical, PMC and Maxon are our only suppliers of infusion sets, cartridge connections and pump motors, respectively. If any of Unomedical, PMC or Maxon were to terminate its contract with us, or be unable to provide infusion sets, manufacture cartridge connectors or supply pump motors to us in the quantities ordered, we would need to identify and qualify a new supplier.

Although there are other manufacturers of infusion sets, cartridge connectors and pump motors, we may not be able to identify a new manufacturer or enter into a contract with terms substantially the same as our current agreement in a timely manner, if at all. Any disruption in the supply of our infusion sets, cartridge connectors or pump motors, or any other key component of the iLet, could have a materially adverse impact on our clinical trials and commercial sales.

We do not currently have long-term supply agreements with the suppliers of most of our components, and, in most cases, we purchase these components on a purchase order basis. Although we are in active discussions to enter into long-term supply agreements for certain components, there is no assurance we will be able to enter into such agreements on commercially reasonable terms in a timely manner, if at all. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations and equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing components that could negatively affect the effectiveness or safety of the iLet or cause delays in shipment or in the conduct of our clinical trials;
- we may have difficulty locating and qualifying alternative suppliers for our single source supplies;
- switching components may require product redesign, and certain product redesigns or changes to the iLet or any other devices for which we receive marketing authorization or clearance may require additional regulatory applications or approvals;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- we may not be able to quickly establish additional or replacement suppliers, particularly for our single source components.

We generally use a small number of suppliers for our components and products, some of which are located outside the United States, including Switzerland, Mexico, China and Taiwan. Our dependence on a limited number of suppliers exposes us to risks, including limited control over costs, including tariffs, availability, quality and delivery schedules. Moreover, in some cases we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us at acceptable prices, or at all. We have in the past been, and we may in the future be, required to make significant “last time” purchases of component inventories that are being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. We are actively pursuing alternative suppliers of several existing components and qualifying new alternatives to existing select components, but there is no assurance that we will be able to identify alternative sources that meet our requirements and at comparable prices, or at all. Because of factors such as the proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires could harm our reputation and limit our ability to meet our sales projections, which could have a material adverse effect on our business, financial condition and operating results.

We place orders with our suppliers using our forecasts of customer demand, which are based on a number of assumptions and estimates, in advance of purchase commitments from our customers. As a result, we incur inventory and manufacturing costs in advance of anticipated sales, which sales ultimately may not materialize or may be lower than expected. If we overestimate customer demand, we may experience higher inventory carrying costs and increased excess or obsolete inventory, which would negatively impact our results of operations. By the same token, if we underestimate future demand, we may be unable to meet future production requirements, or our inventory of critical materials may be below our targeted stocking levels.

We may also have difficulty obtaining components from other suppliers that are acceptable to the FDA or other regulatory authorities and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination or interruption of distribution, operating restrictions, product seizures, delays in obtaining marketing authorization or clearance for our product candidates, suspension or withdrawal of clearances or certification, fines, civil penalties, or criminal prosecution. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional marketing authorizations or clearances. Any disruption of this nature, or any increased expenses associated with any such disruption, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and have a material adverse impact on our operating results.

Our iLet is complex in design and may contain defects that are not detected until use, which could increase our costs, including warranty costs, and reduce our revenue. If our iLet does not perform as expected or the reliability of the technology on which our products is based is questioned, our operating results, reputation and business will suffer.

Our iLet is complex in design and involves a complex and precise manufacturing process. As a result of the technological complexity of our systems, changes in our or our suppliers’ manufacturing processes or the inadvertent use of defective materials by us or our suppliers could result in an adverse effect on our ability to achieve acceptable manufacturing yields and product reliability.

To the extent that we do not achieve and maintain our projected yields or product reliability, our business, operating results, financial condition and customer relationships would be adversely affected. We provide warranties on our product sales, and reserves for estimated warranty costs are recorded during the period

of sale. The determination of such reserves requires us to make estimates of failure rates and expected costs to repair or replace the products under warranty. If actual repair and replacement costs differ significantly from our estimates, adjustments to cost of sales may be required in future periods which could have an adverse effect on our results of operations. Our customers may discover defects in our products only after initial use. In addition, some of our products include components from other vendors, which may contain defects. As a result, should problems occur, it may be difficult to identify the source of the problem. If we are unable to identify and fix defects or other problems, we could experience, among other things:

- loss of customers or orders;
- increased costs of warranty expenses;
- damage to our brand reputation;
- failure to attract new customers;
- diversion of development, engineering and manufacturing resources;
- regulatory actions by governmental authorities; and
- legal actions by our customers.

Our reputation and the public image of our iLet and any modifications to the iLet or any other products that may receive marketing authorization or clearance in the future may be impaired if our products fail to perform as expected. If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation and business will suffer, and we may also be subject to legal claims arising from product limitations, errors or inaccuracies. Any of the foregoing could have an adverse effect on our business, financial condition and results of operations. Although our products are tested prior to shipment, defects or errors could nonetheless occur. Our operating results depend on our ability to execute and, when necessary, improve our quality management strategy and systems and our ability to effectively train and maintain our employee base with respect to quality management. A failure of our quality control systems could result in problems with facility operations or preparation or provision of products. In each case, such problems could arise for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials or environmental factors and damage to, or loss of, manufacturing operations. Existing and future warranties place us at the risk of incurring future repair and/or replacement costs.

At the time revenue is recognized, we establish an accrual for estimated warranty expenses based on historical data and trends of product reliability and costs of repairing and replacing defective products. We exercise judgment in estimating the expected product warranty costs, using data such as the actual and projected product failure rates, estimated repair costs, freight, material, labor and overhead costs. While we believe that historical experience provides a reliable basis for estimating such warranty cost, unforeseen quality issues or component failure rates could result in future costs in excess of such estimates, or alternatively, improved quality and reliability in our products, including our single-use products, could result in actual expenses that are below those currently estimated. As of September 30, 2024, we have accrued approximately \$ so far in expenses relating to product warranty accruals. Substantial amounts of warranty claims could have an adverse effect on our business, financial condition and results of operations.

Even after any underlying concerns or problems are resolved, any lingering concerns in our target markets regarding our technology or any manufacturing defects or performance errors in our iLet could continue to result in lost revenue, delayed market acceptance, damage to our reputation and claims against us.

Performance issues, service interruptions or price increases by our shipping carriers could negatively affect our business, financial condition and results of operations and harm our reputation and our customer relationships.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our iLet and cartridges to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our solution and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders on a timely basis.

We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products or technologies, pursue new markets, or protect our intellectual property assets. We may also elect to amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process, and may subject us to business risks. For example, other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities, or may be the counterparty in any such arrangements. We may not be able to identify or complete any such collaboration in a timely manner, on a cost-effective basis, on acceptable terms or at all. In addition, we may not realize the anticipated benefits of any such collaborations that we do identify and complete. In particular, these collaborations may not result in the development of products or technologies that achieve commercial success or result in positive financial results, or may otherwise fail to have the intended impact on our business.

Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control or other licenses of intellectual property rights. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators, such as DexCom and Abbott, or any future collaborators devote to our arrangement with them or our product candidates. Disputes between us and our current, future or potential collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Our current or

future collaborators or strategic partners, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our investigational devices. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

We rely and will continue to rely on third parties to conduct clinical trials of our iLet, which means we do not have full control over the conduct of such trials.

We have relied and will continue to rely on third parties, such as medical institutions, clinical investigators and contract laboratories, to conduct clinical trials of our iLet and any modifications thereto or new uses thereof or other development-stage products, and some of the clinical trials of our iLet conducted to date have been sponsored by third parties. Our iLet has been studied in a number of trials sponsored by third parties, such as the pivotal trial for the iLet that supported our 510(k) clearance, sponsored by the Jaeb Center for Health Research Foundation, and earlier trials for our iLet, sponsored by the Massachusetts General Hospital. Third party-sponsored clinical trials pose similar risks as those set forth elsewhere in this section relating to clinical trials initiated by us. While third-party trials may provide us with clinical data that can inform our future development strategy, we do not have full control over the protocols, administration or our products, or conduct of the trials. As a result, we are subject to risks associated with the way such trials are conducted, and there is no assurance the clinical data from any future third-party clinical trials will be accepted by the FDA or other comparable regulatory authorities to support our submissions for marketing authorization. Third parties sponsoring such clinical trials may not perform their responsibilities for the clinical trials on our anticipated schedule or consistent with clinical trial protocols or applicable regulations. Further, any data integrity issues or patient safety issues arising out of any of these trials would be beyond our control yet could adversely affect our reputation and damage the clinical and commercial prospects for our iLet. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data. Third parties may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. As a result, our lack of control over the design, conduct and timing of, and communications with the FDA regarding such trials expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the prospects for our iLet.

We and third-party collaborators are required to comply with all applicable regulations governing clinical research, including good clinical practice (GCP) standards and regulations. The FDA and similar foreign regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our third-party collaborators fail to comply with GCP standards and regulations, the clinical trials may be delayed or the data generated in trials may be deemed unreliable and the FDA may require us to perform additional studies before granting us marketing authorization or clearance, if at all. We cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that any clinical trials of our products or product candidates comply or complied with applicable regulations, including GCPs. In addition, the FDA may require a large number of test subjects. Our failure or the failure of our third-party contractors to comply with the applicable regulations may require us to repeat studies or trials, which could delay or prevent us from obtaining marketing authorization or clearance for the iLet in other configurations or indications, or for the glucagon drug product candidate for which we will need to obtain approval in order to obtain marketing authorization for a bihormonal configuration of the iLet. Furthermore, our third-party collaborators may be delayed in conducting trials of our iLet for reasons outside of their control.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they

obtain is compromised due to the failure to adhere to clinical protocols or regulatory requirements or for other reasons, the non-clinical development activities or clinical trials for our iLet for other configurations or indications may be extended, delayed, suspended or terminated, and we may not be able to obtain marketing authorization or clearance for, or successfully commercialize, the iLet or any future investigational devices on a timely basis or other development-stage products, such as the glucagon product candidate, if at all, and our business, results of operations, financial condition and growth prospects may be adversely affected.

Risks Related to Government Regulation

We and our suppliers are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once we obtain marketing authorization or clearance for FDA-regulated products, such as our iLet and any future products, we and such products will be subject to continued and pervasive regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies governing, among other things, the manufacture, marketing, advertising, reporting, sale, promotion, import, export, registration, and listing of our products. For example, medical device manufacturers must submit periodic reports to the FDA as a condition of obtaining marketing authorization or clearance. These reports include information about failures and certain adverse events associated with the device after its marketing authorization or clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. In particular, unless exempt, we and our suppliers are required to comply with the FDA's Quality System Regulation (QSR) for medical device products and cGMPs for any approved drug products, such as glucagon if it is ultimately approved, and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. Regulatory bodies, such as the FDA, enforce the QSR and cGMPs and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions and/or other negative consequences:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;
- administrative detention by the FDA of medical devices believed to be adulterated or misbranded;
- operating restrictions, suspension or shutdown of production;
- refusing our requests for marketing authorization or clearance of new products, or new intended uses or modifications to the iLet;
- suspending or withdrawing marketing authorizations or clearances that have already been granted; and
- criminal prosecution.

If any of these actions were to occur, our reputation would be harmed and our product sales and profitability would be adversely impacted. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to manufacture our products on a timely basis and in the required quantities, if at all. Later discovery of previously unknown problems with our products, including manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In addition, the FDA may change its marketing authorization or clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization or clearance of any product candidate under development or impact our ability to modify any products authorized for market on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain marketing authorizations or clearances, increase the costs of compliance or restrict our ability to maintain any marketing authorizations or clearances we have obtained. For example, in February 2024, the FDA issued a final rule to amend and replace the QSR, which sets forth the FDA's current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, establishes the "Quality Management System Regulation," (QMSR), which among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. If we are unable to comply with the QMSR, once effective, or with any other changes in the laws or regulations enforced by the FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition and results of operations.

In addition, even after we have obtained marketing authorization or clearance for a product, the FDA has the power to require us to conduct post marketing studies, such as under a Section 522 Order, which is an order by the FDA to conduct a post-market study of an authorized or cleared medical device. *See Risk Factors, "We are subject to a post-market surveillance order issued by the FDA for our iLet. If the FDA determines that our iLet does not perform as anticipated, or if the FDA identifies new concerns related to the safety and effectiveness of the device, we may need to make changes to or recall or withdraw the iLet from the field, which could harm our business."* These studies can be very expensive and time-consuming to conduct. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if marketing authorization or clearance is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

Our iLet or any of its components may be subject to product recalls in the future. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our iLet, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation. Manufacturers may, on their own initiative, recall a product if any deficiency is found. A government-mandated or voluntary recall by us or one of our suppliers could occur as a result of an unacceptable health risk, component failures, failures in laboratory processes, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious

injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new marketing authorizations or clearances for the device before we may market or distribute the corrected device. Seeking such marketing authorizations or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future. Recalls of any of our products would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. A recall announcement by us could harm our reputation with customers and negatively affect our business, financial condition, and results of operations. In addition, the FDA or other agency could take enforcement action for failing to report the recalls when they were conducted.

If we initiate a recall, including a correction or removal, for our iLet, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our iLet, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

Our iLet is currently cleared only for the treatment of T1D in adults and children six years of age and older. If our iLet is authorized for marketing or cleared in a bihormonal configuration for the treatment of T1D or for any other indications, such marketing authorization or clearance will be limited by the FDA to the specific indication for which granted. We are prohibited from marketing the iLet for other indications, such as T2D.

We are currently commercializing our iLet for the treatment of T1D, and our iLet is only cleared as an automated insulin dosing system for the treatment of T1D in adults and children six years of age and older. Although T2D is also a disease stemming from excess glucose in the blood, we are prohibited from promoting the iLet for T2D or any other indication unless we receive marketing authorization or clearance for such indication. The FDA strictly regulates the promotional claims that may be made about medical devices, and the iLet may not be promoted for uses that are not authorized or cleared by the FDA as reflected in the device's FDA-authorized labeling. If we are not able to obtain FDA marketing authorization or clearance for the bihormonal configuration for the treatment of T1D or for any desired future indications, our ability to effectively market and sell our iLet may be reduced and our business may be adversely affected.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and authorized or cleared by the regulatory authorities, we are prohibited from marketing and promoting the products for indications that are not specifically cleared or approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biotechnology or medical device companies on off-label use. If the FDA determines that our promotional activities constitute

promotion of an off-label use, it could request that we modify our promotional materials and subject us to FDA regulatory or enforcement actions as well as actions by other agencies, such as the Federal Trade Commission and the Department of Justice, including issuance of warning letters or untitled letters, suspension or withdrawal of a product from the market, mandatory or voluntary recalls, civil fines, disgorgement of money, operating restrictions, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, injunctions or criminal prosecution, any of which could significantly harm our business.

Our relationships with HCPs and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

HCPs and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of products. Arrangements with third-party payors and customers can expose device manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the False Claims Act, laws and regulations related to the reporting of payments to physicians and teaching hospitals, and HIPAA (defined below), which may constrain the business or financial arrangements and relationships through which such companies research, sell, market and distribute products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to, the below.

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, paying or providing any remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.
- Federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. Moreover, a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the False Claims Act.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, which impose, among other things, requirements on certain covered HCPs, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The federal Physician Payment Sunshine Act created under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, ACA), which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to any payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Additional federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. For instance, state anti-kickback and false claims laws may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients. Laws related to insurance fraud may provide claims involving private insurers. State laws may require pharmaceutical or medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to HCPs and other potential referral sources. State and local laws may also require the licensure of sales representatives, and require drug or device manufacturers to report information related to payments and other transfers of value to physicians and other HCPs or marketing expenditures and pricing information. Analogous state and foreign laws may additionally govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to

authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and HCPs, which has led to a number of investigations, prosecutions, convictions and significant settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, guidance or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a device manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, the approval and commercialization of any of our investigational devices outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, insurance data, and payment data (collectively, sensitive information).

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information.

As another example, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (CAN-SPAM) and the Telephone Consumer Protection Act of 1991 (TCPA) impose specific requirements on communications with customers. For example, the TCPA imposes various consumer consent requirements and other restrictions on certain telemarketing activity and other communications with consumers by phone, fax or text message. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to \$1,500 per violation imposed through private litigation or by state authorities. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

For example, the California Consumer Privacy Act of 2018 (CCPA) applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to \$7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work, and our customers.

In addition, we may now or in the future be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act (MHMD) broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's GDPR (UK GDPR and together with the EU GDPR, the GDPR) impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Our employees and personnel may use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies may be subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI which may impact our ability to develop and use AI in our products and services, including our ability to use our data to train AI algorithms or for other use cases for this technology. Our use of this technology

could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Additionally, regulators are increasingly scrutinizing companies that process children's data. Numerous laws, regulations, and legally binding codes, such as the Children's Online Privacy Protection Act (COPPA), California's Age Appropriate Design Code, the CCPA, and other U.S. state comprehensive privacy laws impose various obligations on companies that process children's data, including requiring certain consents to process such data and extending certain rights to children and their parents with respect to that data. Some of these obligations have wide ranging applications, including for services that do not intentionally target child users (defined in some circumstances as a user under the age of 18 years old). These laws may be, or in some cases, have already been, subject to legal challenges and changing interpretations, which may further complicate our efforts to comply with these laws.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements, regarding data privacy and security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including, but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data, including restrictions on using personal data to train AI algorithms; orders to destroy or not use personal data, including algorithmic disgorgement; and imprisonment of company officials.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including, but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the U.S. Securities and Exchange Commission (SEC) and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm

our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to the iLet, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect the iLet. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made during the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, we do not have the first right to control the preparation, filing and prosecution of patent applications covering technology that we have in-licensed from BU and Xeris. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase the iLet and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, our agreements and/or security measures may be breached, and we may not have adequate remedies for any such breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and

proprietary information. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and financial condition.

If we fail to comply with our obligations in our current and future intellectual property licenses with third parties, we could lose rights, which may be important to our business.

We rely upon licenses to certain patent rights and proprietary technology for the development of the iLet and our other product candidates, in particular our license agreements with BU and Xeris. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these license agreements, our licensor may have the right to terminate our licenses, in which event we may not be able to develop, manufacture or market any product that is covered by the intellectual property licensed to us under such license agreement, in addition to damages and other penalties. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop, manufacture and/or commercialize our products.

In addition, the agreements under which we license or acquire intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed or acquired prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Licenses to additional third-party technology and materials that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. We do not have the first right to control the prosecution, maintenance and enforcement of our licensed intellectual property, and we thus require the cooperation of our licensor. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any product that is the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may license in the future.

In addition, intellectual property rights that we may in-license in the future may be sublicensed under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries could increase those uncertainties and costs and may diminish the value of our intellectual property or narrow the scope of our patent protection.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the U.S. Patent and Trademark Office (USPTO), the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, patent coverage in medical devices and technologies is a subject of evolution and differences between countries. This is especially true of the definition of patentable subject matter which affects both computer-related inventions and biological inventions. This evolution may cause current granted patents to be considered non-patent eligible or prevent us from protecting future inventions. U.S. Supreme Court and Federal Circuit decisions interpreting and/or limiting the scope of patentable subject matter under 35 U.S.C. § 101, in addition to examination guidelines from the USPTO, have made it more difficult for patentees to obtain and/or maintain patent claims in the United States that are directed to medical technologies involving computer-implemented applications. Several precedential decisions regarding patentable subject matter are of particular relevance to patents in the computer-implemented applications space. For example, the 2014 decision in *Alice Corporation Pty. Ltd. v. CLS Bank International* concerns a computer-implemented, electronic escrow service for facilitating financial transactions. The U.S. Supreme Court held that an abstract idea could not be patented just because it is implemented on a computer, thus providing guidance on the patentability of computer-implemented applications such as those used with our products. Our efforts to seek patent protection for our technologies and products may be impacted by the evolving case law and guidances or procedures issued by the USPTO or authorities in other jurisdictions based on such evolving case law.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of the new unitary patent system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the ability to opt out of the jurisdiction of the UPC and remain as national patents in the UPC countries. The UPC will provide our competitors with a new forum to centrally revoke European patents, and allow for the possibility of a competitor to obtain pan-European injunctions, since patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation.

challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States and Europe. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In certain circumstances it may not be practicable or cost effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity.

If we initiate legal proceedings against a third party to enforce a patent covering the iLet, its components or algorithms, the defendant could counterclaim that our patent(s) are invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover their technology. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose some, and perhaps all, of the patent protection covering the iLet. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

We may not be able to detect or prevent, alone or with our future licensors, infringement, misappropriation or other violation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and, even if successful, may result in substantial costs and distract our management and other employees. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by

disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. Companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of the relevant program or products, which could have a material adverse effect on our business.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future products or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability or business risk;

- collaborations may be terminated, which may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products or products;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and, in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

The intellectual property or technology licensed from various third parties may be subject to retained rights.

Our current or future licensors, including BU, may retain certain rights under the relevant agreements with us, including the right to use the licensed intellectual property for academic and research use and to publish general scientific findings from research from the use of such intellectual property or technologies. It is difficult to monitor whether any of our licensors limit their use of the licensed intellectual property or technologies to these permitted uses, and we could incur substantial expenses to enforce our rights in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). For examples, certain patents and patent applications licensed from BU were made with financial assistance from the federal government. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. If we choose to collaborate with academic institutions to accelerate our preclinical research or development, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell the iLet and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The medical device industry is characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding the manufacture, use or sale of the iLet. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize the iLet and any product candidates we may develop. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

In order to successfully challenge the validity of a U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Foreign courts will have similar burdens to overcome in order to successfully challenge a third-party claim of patent infringement.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other medical device companies. In addition, we use publications that are subject to copyright, as well as proprietary information and materials from third parties in our research. Some of the information and materials we use from third parties may be subject to agreements that include restrictions on use or disclosure. Although we strive to ensure proper safeguards, we cannot guarantee strict compliance with such agreements, nor can we be sure that our employees, consultants and advisors do not use proprietary information, materials or know-how of others in their work for us. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and, to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patent applications, our future patents or other intellectual property, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of consultants, contractors or others who are involved in developing our products. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We currently and in the future may employ individuals who were previously employed at other medical device companies. Although we endeavor to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work

for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of a former employer or another third party. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these claims, and there is no guarantee of success. If we fail in defending these claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, if such intellectual property rights are found to incorporate or be derived from the trade secrets or other proprietary information of third parties. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed to others.

If we rely on third parties to manufacture or commercialize our product candidates, or if we collaborate with additional third parties for the development of our products, we may need to, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our trade secrets and other proprietary technology in part by entering into confidentiality agreements with third parties prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets, and we may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where enforcement rights are not as strong as those in the United States or Europe. These products may compete with the iLet, and our future patents or other intellectual property rights may not be effective or sufficient to defend our rights adequately.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to methods of treatment.

While we seek to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the

United States over the lifetime of our patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

The terms of our patents may not be sufficiently long to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, but can be shorter due to terminal disclaimers or similar term reductions in other jurisdictions. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Even if patents covering our technologies or products are obtained, once the patent term has expired, we may be open to competition. In addition, although upon issuance in the United States, a patent's term can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of products, patents protecting such product candidates might expire before or shortly after such products are commercialized. If we do not have sufficient patent life to protect our technologies and products, our business and results of operations will be adversely affected.

If we are not successful in obtaining patent term extensions for our future products, our business may be harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our future products, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to one patent that covers the approved product, the approved use of the product or a method of manufacturing the product. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in some foreign countries upon obtaining the applicable regulatory approval for any future products. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries or areas, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension due to failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements, among other reasons. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, as applicable, our competitors and other third parties may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

We rely on trademarks as one means to distinguish the iLet from the systems of our competitors and market ourselves and our products. We may select new trademarks and apply to register them, but our trademark applications may not be approved in the United States or any other relevant jurisdiction. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand the iLet, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Competitors or other parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion.

Our competitors may also infringe or otherwise violate our trademarks, and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our issued or future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, our business, results of operations and prospects could be significantly harmed.

Risks Related to This Offering and Ownership of Our Common Stock

An active trading market for our common stock may not develop or be sustained.

Prior to this offering, there has been no public market for our common stock. We have applied for listing of our common stock on under the symbol “ ”. We believe that upon the completion of this offering, we will meet the standards for listing on and the closing of this offering is contingent upon such listing. An active trading market for our shares may never develop or be sustained following this offering. In addition, the initial price for our common stock in this offering will be determined through negotiations with the underwriters and may vary from the market price of our common stock following this offering. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. Further, an inactive trading market for our shares may also impair our ability to raise capital by selling shares of our common stock or enter into strategic partnerships and transactions by issuing our shares of common stock as consideration. If an active trading market for our common stock does not develop, or is not sustained, you may not be able to sell your shares quickly or at the market price, or at all, and it may be difficult for you to sell your shares without depressing the market price for our common stock.

The trading price of our common stock may be volatile and you could lose all or part of your investment.

The trading price of our common stock after this offering is likely to be volatile. As a result of this volatility, you may not be able to sell your shares of common stock at or above the initial public offering price. The market price for our common stock may be influenced by those factors discussed in this “Risk Factors” section and many other factors, including:

- actual or anticipated fluctuations in our financial and operating results from period to period;
- market acceptance of our current product and product candidates under development, and the recognition of our brand;
- introduction of proposed products, technologies or treatment techniques by us or our competitors, including the ongoing adoption of diabetes drugs;
- announcements of significant contracts, acquisitions, divestitures or partnerships by us, our competitors or our collaboration partners;
- regulatory marketing authorizations or clearance received for our current product or product candidates, or the products of our competitors or collaboration partners, or the failure to obtain such marketing authorizations or clearance on the projected timeline or at all;
- the announcement of a product recall, suspension or other safety notice associated with our products or the products of our competitors, or other similar regulatory enforcement actions;

- financial and operating results relative to the expectations of securities analysts and other market participants and the issuance of securities analysts' reports or recommendations;
- threatened or actual litigation, regulatory proceedings or government investigations;
- the costs and timing of manufacturing for our product, including developing our own manufacturing capabilities;
- the success of existing or new competitive therapies, products or technologies;
- development of new products that may address our markets and make our product less attractive;
- failure or discontinuation of any of our research or development programs;
- changes in the level of expenses related to any of our research or development programs;
- developments related to any existing or future collaborations;
- the recruitment or departure of key personnel;
- regulatory or legal developments in the United States and other countries;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in the structure of healthcare payment systems;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the medical device sector;
- general political, economic, industry and market conditions;
- changes in accounting principles; and
- the other factors described in this "Risk Factors" section and elsewhere in this prospectus.

Following price volatility, holders of securities may institute securities class action litigation against the issuer. If any holders of our common stock were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our board of directors and senior management would be diverted

from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities. Further, a decline in the financial markets and related factors beyond our control may cause the price of our common stock to decline rapidly and unexpectedly. If the market price of our common stock following this offering does not exceed the initial public offering price, you may not realize any return on, or you may lose some or all of your investment. Broad market and industry factors such as these could materially and adversely affect the market price of our stock, regardless of our actual operating performance.

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Upon the closing of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates will, in the aggregate, hold approximately % of our outstanding common stock (based on the number of shares of common stock outstanding as of September 30, 2024 and assuming no purchase of shares in this offering by any of this group). As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination that other stockholders may desire. The interests of these stockholders may not always coincide with your interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock. Any of these actions could adversely affect the market price of our common stock.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of stockholders intend to sell shares of our common stock, could reduce the market price of our common stock. After this offering, we will have shares of common stock outstanding (assuming no exercise of the underwriters' option to purchase additional shares of our common stock). This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Substantially all of the remaining shares of common stock initially will be restricted as a result of securities laws, market standoff provisions or lock-up agreements, but will become eligible to be sold after this offering as described in the section titled "Shares Eligible for Future Sale."

Moreover, after this offering, holders of an aggregate of shares of common stock will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act of 1933, as amended (the Securities Act), or until the rights terminate pursuant to the terms of the stockholder agreements between us and such holders. We also intend to register all shares of common stock subject to equity awards issued or reserved for future issuance under our equity compensation plans on a registration statement on Form S-8. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates under Rule 144 under the Securities Act and the market standoff provisions and lock-up agreements described above. Any sales of securities by these stockholders could have a negative impact on the trading price of our common stock.

If you purchase common stock in this offering, you will suffer immediate and substantial dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our outstanding common stock immediately after the closing of this offering. Based on an assumed initial public offering price of \$ per share (the midpoint of the price range set forth on the cover page of this prospectus), you will experience immediate dilution of \$ per share as of September 30, 2024, representing the difference between our pro forma as adjusted net tangible book value per share, after giving effect to this offering and the assumed initial public offering price. This dilution is due to our investors who purchased shares prior to this offering having paid a price for their shares that is substantially less than the price offered to the public in this offering, as well as the exercise of stock options granted to our employees. To the extent any outstanding options are exercised, you will experience further dilution. As a result of this dilution, investors purchasing stock in this offering may receive significantly less than the full purchase price that they paid for the shares purchased in this offering in the event of a liquidation. See the section titled “Dilution” for additional information.

Future sales and issuances of our securities, including pursuant to our equity incentive plans, may cause dilution to our stockholders or decrease our stock price.

We expect that significant additional capital may be necessary to continue our planned operations, including to expand product development and commercialize our products. We may seek additional capital through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of our product candidates and commercialization of our current products. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

Pursuant to our 2025 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2025 Plan will automatically increase on January 1 of each calendar year, beginning on January 1, 2026 and continuing through and including January 1, 2035, by % of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2026 and continuing through and including January 1, 2035, by the lesser of (i) % of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of the automatic increase and (ii) shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

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We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.235 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act allows us as an “emerging growth company” to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies.

We have taken advantage of the reduced reporting burdens in this prospectus and the information we provide to stockholders will be different than the information that is available with respect to other public companies that are not emerging growth companies. For example, in this prospectus we have only included two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. It is possible that this may cause investors to find our common stock less attractive. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be reduced or more volatile.

Even following the termination of our status as an emerging growth company, we may be able to take advantage of the reduced disclosure requirements applicable to “smaller reporting companies,” as that term is defined in Rule 12b-2 of the Exchange Act, and, in particular, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. To the extent that we are no longer eligible to use exemptions from various reporting requirements, we may be unable to realize our anticipated cost savings from these exemptions, which could have a material adverse impact on our operating results.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our

common stock. We expect that we will use the net proceeds of this offering as set forth in the section titled “Use of Proceeds.” However, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline and delay the development and commercialization of our product candidates and current products. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future. See the section titled “Dividend Policy” for additional information.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect at the completion of this offering could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the completion of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- divide our board of directors into three classes, with each class serving staggered three-year terms;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder’s notice;

- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; and
- provide that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law (Section 203). These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult or costly for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

For information regarding these and other provisions, see section titled “Description of Capital Stock.”

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware and any appellate court therefrom will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action that is based upon a violation of a duty owed by any current or former director, officer, other employee or stockholder, to us or our stockholders; (iii) any claim or cause of action against us or any current or former director, officer or other employee, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any current or former director, officer or other employee, governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by applicable law and subject to the court having personal jurisdiction over the indispensable parties named as defendant; provided, however, that if the designation of such court as the sole and exclusive forum for a claim or action referred to in foregoing clauses (i) through (vi) would violate applicable law, then the United States District Court for the District of Delaware shall be the sole and exclusive forum for such claim or cause of action. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive

jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits and result in increased costs for investors to bring a claim. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

General Risk Factors

Adverse changes in general economic conditions in the United States and outside of the United States could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions. A U.S. or global recession, could negatively impact our current and prospective customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our ability to pay our expenses and ability to obtain financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures.

Healthcare spending in the United States could be negatively affected in the event of a downturn in economic conditions. For example, U.S. patients who have lost their jobs or healthcare coverage may no longer be covered by an employer-sponsored health insurance plan and patients reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the iLet to a new PWD will be generally dependent on the availability of third-party reimbursement and will require the patient to make a significant co-payment, an economic downturn on our potential customers could reduce the referrals generated by our sales force and thereby reduce our customer orders. Similarly, existing customers at such time could cease purchasing the iLet and return to other types of intensive insulin therapy, such as MDI, or other less-costly therapies, which would cause our attrition rate to increase. Any decline in new customer orders or increase in our customer attrition rate would reduce our revenue.

Our ability to use our net operating loss (NOL), carryforwards and certain other tax attributes may be limited.

As of December 31, 2023, we had U.S. federal NOL carryforwards of \$158.3 million, which may be available to reduce future taxable income, of which \$11.5 million expire at various dates beginning in 2035 while the remaining \$146.8 million do not expire but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2023, we had state NOL carryforwards of \$33.9 million, which may be available to reduce future taxable income, of which \$31.9 million expire at various dates beginning

in 2029, while \$2.0 million do not expire. As of December 31, 2023, we also had U.S. federal and state research and development tax credit carryforwards of \$3.0 million and \$2.7 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2032, respectively, with \$2.3 million of state research and development tax credits carrying forward indefinitely. For state income tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state NOLs to offset taxable income and certain business credits to offset California state tax liabilities in tax years beginning after 2023 and before 2027.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards, research and development credits and other tax attributes to offset its post-change income or taxes may be limited. The completion of this offering, together with any private placements and other transactions that have occurred since our inception, may trigger such ownership changes pursuant to Section 382 of the Code. We have not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards or research and development credits is materially limited, it would harm our future results of operations by effectively increasing our future tax obligations.

We may be subject to adverse legislative or regulatory changes in tax laws, and there are uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations, any of which could materially affect our tax obligations and effective tax rate.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service (IRS) and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made. New income or other tax laws or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act made many significant changes to U.S. tax laws. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our or our stockholders’ tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. Further, existing tax laws and regulations could be interpreted, modified or applied adversely to us. In the United States, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets and could increase our future worldwide tax expense.

We will incur increased costs and become subject to additional regulations and requirements as a result of becoming a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices, which could impact our financial condition and results of operations and make it more difficult to run our business.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act, and related rules implemented by the SEC and . The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any

degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation. Accordingly, increases in costs incurred as a result of becoming a publicly-traded company may adversely affect our business, financial condition and results of operations.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Section 404(a) of the Sarbanes-Oxley Act requires that, beginning with our second annual report following our initial public offering, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an emerging growth company or smaller reporting company.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the closing of this offering, we will be subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Additionally, the increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, business automobile, workers' compensation, clinical trials/products liability, cybersecurity liability, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. For example, although we maintain product liability insurance coverage that also covers our clinical trials, this insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our headquarters and manufacturing facility are located in Southern California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or manufacturing facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Although we do have a disaster recovery plan in place, we may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster

recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance (ESG) matters, may expose us to reputational and other risks.

Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or that are perceived to have not responded appropriately, may suffer from reputational damage, which could result in the business, financial condition and/or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in new regulations and/or third-party requirements that could adversely impact our business, or certain shareholders reducing or eliminating their holdings of our stock. Additionally, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements.” As an emerging growth company, the JOBS Act allows us to delay adoption of new or revised accounting standards applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. However, we may elect to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. We may take advantage of these exemptions up until the time that we are no longer an emerging growth company.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will” or “would,” or the negative of these words or other similar terms or expressions.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus, regarding, among other things:

- our expected future growth;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- our ability to accurately forecast demand for our products;
- the rate and degree of market acceptance of our products;
- the expected future growth of our sales and marketing organization;
- our ability to implement our multi-channel coverage and reimbursement strategy;
- the performance of, and our reliance on, third parties in connection with the commercialization of our products, including single source suppliers;
- our ability to accurately forecast and manufacture appropriate quantities of our products to meet commercial demand;
- regulatory developments in the United States;
- our ability to maintain regulatory approval for our products or obtain regulatory approval for new products in the United States;
- our research and development for existing products and any future products;
- the development, regulatory approval and commercialization of competing products;
- our ability to retain and hire senior management and key personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our expectations regarding the impact of global health pandemics, geopolitical conflicts and economic uncertainty, including rising interest rates and inflation on our business and operations;
- our financial performance and capital requirements;

- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others; and
- our use of the net proceeds from this offering.

These risks are not exhaustive. Other sections of this prospectus may include additional factors that could harm our business and financial performance. We operate in a very competitive and rapidly changing environment where new risk factors may emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. These forward-looking statements speak only as of the date of this prospectus. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this prospectus. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

MARKET, INDUSTRY AND OTHER DATA

Certain market, industry and competitive data included in this prospectus were obtained from our own internal estimates and research, as well as from publicly available information, reports of governmental agencies and industry publications and surveys conducted by third parties. In some cases, we do not expressly refer to the sources from which this data is derived. All of the market and industry data used in this prospectus is inherently subject to uncertainties and involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information.

The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our capital stock for the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately \$ million (or approximately \$ million if the underwriters exercise their option to purchase additional shares in full) based on the assumed initial public offering price of \$ per share of common stock, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Similarly, each one million share increase (decrease) in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming that the assumed initial offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. . We do not expect that a change in the initial price to the public or the number of shares by these amounts would have a material effect on the uses of the proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as follows:

- approximately \$ million to ; and
- the remaining amounts for working capital and general corporate purposes.

We may use a portion of the net proceeds for strategic investments in complementary businesses, services, products or technologies. However, we do not have agreements or commitments to enter into any such acquisitions or investments at this time.

Based on our current operating plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as well as cash generated from sales of our products, will be sufficient to fund our projected operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect.

We cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in applying the net proceeds of this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending their application, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade investments, certificates of deposit or guaranteed obligations of the U.S. government.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and our capitalization as of September 30, 2024 on:

- an actual basis;
- a pro forma basis to give effect to (i) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock as of September 30, 2024 into shares of our common stock upon the closing of this offering, (ii) the conversion of shares of our convertible preferred stock outstanding as of September 30, 2024 into shares of our common stock upon the closing of this offering and the related reclassification of the carrying value of our convertible preferred stock to permanent equity in connection with the closing of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering; and
- a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale of shares of common stock in this offering at the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our cash, cash equivalents and short-term investments and capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with our financial statements and related notes included elsewhere in this prospectus and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other financial information contained in this prospectus.

	As of September 30, 2024		
	Actual	Pro Forma	Pro Forma As Adjusted ⁽¹⁾
	(in thousands, except share and per share data)		
Cash, cash equivalents and short-term investments	\$	\$	\$
Convertible preferred stock (Series A, A-2, B, B-2, C and D), \$0.0001 par value; shares authorized, shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$	\$	\$
Stockholders’ equity (deficit):			
Preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, \$0.0001 par value; no shares authorized issued or outstanding, actual; shares authorized, pro forma and pro forma as adjusted; shares issued and outstanding, pro forma as adjusted			

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	As of September 30, 2024		
	Actual	Pro Forma	Pro Forma As Adjusted ⁽¹⁾
(in thousands, except share and per share data)			
Class A common stock, \$0.0001 par value; shares authorized issued or outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Class B common stock, \$0.0001 par value; shares authorized issued or outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Class C common stock, \$0.0001 par value; shares authorized issued or outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders' equity (deficit)			
Total capitalization	\$	\$	\$

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of our cash, cash equivalents and short-term investments, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each one million share increase (decrease) in the number of shares offered by us at the assumed initial public offering price per share of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of our cash, cash equivalents and short-term investments, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately \$ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The information in the table above excludes:

- shares of our Class B common stock issuable upon the exercise of options to purchase shares of our common stock issued under our 2016 Plan and outstanding as of September 30, 2024, with a weighted-average exercise price of \$ per share;
- shares of our Class B common stock issuable upon exercise of stock options granted under our 2016 Plan subsequent to September 30, 2024 and before , 2025, with a weighted-average exercise price of \$ per share;
- shares of our common stock reserved for future issuance under our 2025 Plan, which will become effective upon the execution and delivery of the underwriting agreement for this offering (which shares include new shares plus the number of shares (not to exceed shares) (i) that remain available for the issuance of awards under the 2016 Plan at the time the 2025 Plan becomes effective, and (ii) any shares underlying outstanding stock awards granted under the 2016 Plan that, on or after the 2025 Plan becomes effective, terminate or expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled "Executive and Director Compensation—Equity Incentive Plans"), as well as any automatic increases in the number of our common stock reserved for future issuance under the 2025 Plan; and

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- shares of our common stock reserved for future issuance under our ESPP, as well as any annual automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP, which will become effective upon the execution and delivery of the underwriting agreement for this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock immediately after the completion of this offering.

As of September 30, 2024, we had a historical net tangible book value (deficit) of approximately \$ million, or \$ per share of common stock based on shares of common stock outstanding as of such date. Our historical net tangible book deficit per share represents the amount of our total tangible assets less our total liabilities and convertible preferred stock, which is not included within permanent equity, divided by the number of shares of our common stock outstanding as of September 30, 2024.

After giving effect to (i) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock into shares of our common stock, in connection with the closing of this offering and assuming the occurrence of such conversion on September 30, 2024 and (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity in connection with the closing of this offering and assuming the occurrence of such conversion on September 30, 2024, our pro forma net tangible book value as of September 30, 2024, would have been approximately \$ million, or approximately \$ per share of our common stock.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after closing of this offering. After giving further effect to the sale of shares of our common stock that we are offering at the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2024 would have been \$ million, or approximately \$ per share. This amount represents an immediate increase in pro forma net tangible book value of \$ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$ per share to new investors participating in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution:

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of September 30, 2024	\$
Pro forma increase in historical net tangible book value per share as of September 30, 2024	
Pro forma net tangible book value per share as of September 30, 2024, before this offering	
Increase in pro forma net tangible book value per share attributed to investors purchasing shares in this offering	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution per share to investors in this offering	\$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the

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assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$ _____, and dilution in pro forma net tangible book value per share to new investors by approximately \$ _____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

We may also increase or decrease the number of shares we are offering. Each increase of one million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by approximately \$ _____ and decrease the dilution to investors participating in this offering by approximately \$ _____ per share, assuming that the assumed initial public offering price remains the same, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us. Similarly, each decrease of one million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by approximately \$ _____ and increase the dilution to investors participating in this offering by approximately \$ _____ per share, assuming the assumed initial public offering price of \$ _____ per share remains the same, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

If the underwriters exercise their option to purchase up to _____ additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be \$ _____ per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$ _____ per share and the dilution per share to new investors would be \$ _____ per share, in each case assuming an initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

To the extent that outstanding options with an exercise price per share that is less than the pro forma as adjusted net tangible book value per share are exercised, or outstanding warrants with an exercise price per share that is less than the pro forma as adjusted net tangible book value per share are exercised, new investors will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The following table summarizes, on the pro forma as adjusted basis described above, as of September 30, 2024, the differences between the number of shares of common stock purchased from us by our existing stockholders and common stock by new investors purchasing shares in this offering, the total consideration paid to us in cash and the weighted-average price per share paid by existing stockholders for shares of common stock issued prior to this offering and the price to be paid by new investors for shares of common stock in this offering. The calculation below is based on the assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	\$	%	\$
New investors					\$
Total		100.0%	\$	100.0%	

Each \$1.00 increase in the assumed initial public offering price of \$ _____ per share would increase total consideration paid by new investors, total consideration paid by all stockholders and the weighted-average

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price per share paid by all stockholders by \$ million, \$ million and \$, respectively, while each \$1.00 decrease in the assumed initial public offering price of \$ per share, would decrease total consideration paid by new investors, total consideration paid by all stockholders and the weighted-average price per share paid by all stockholders by \$ million, \$ million and \$, respectively, and assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Similarly, each one million share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the total consideration paid by investors participating in this offering, total consideration paid by all stockholders and the weighted-average price per share paid by all stockholders by approximately \$ million, \$ million and \$, respectively, while each one million share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the total consideration paid by investors participating in this offering, total consideration paid by all stockholders and the weighted-average price per share paid by all stockholders by approximately \$ million, \$ million and \$, respectively, assuming the assumed initial public offering price of \$ per share remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Except as otherwise indicated, the discussion and the tables above assume no exercise of the underwriters' option to purchase additional shares of our common stock and excludes:

- shares of our Class B common stock issuable upon the exercise of options to purchase shares of our common stock issued under our 2016 Plan and outstanding as of September 30, 2024, with a weighted-average exercise price of \$ per share;
- shares of our Class B common stock issuable upon exercise of stock options granted under our 2016 Plan subsequent to September 30, 2024 and before , 2025, with a weighted-average exercise price of \$ per share;
- shares of our common stock reserved for future issuance under our 2025 Plan, which will become effective upon the execution and delivery of the underwriting agreement for this offering (which shares include new shares plus the number of shares (not to exceed shares) (i) that remain available for the issuance of awards under the 2016 Plan at the time the 2025 Plan becomes effective, and (ii) any shares underlying outstanding stock awards granted under the 2016 Plan that, on or after the 2025 Plan becomes effective, terminate or expire or are repurchased, forfeited, cancelled or withheld, as more fully described in the section titled "Executive and Director Compensation—Equity Incentive Plans"), as well as any automatic increases in the number of our common stock reserved for future issuance under the 2025 Plan; and
- shares of our common stock reserved for future issuance under our ESPP, as well as any annual automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP, which will become effective upon the execution and delivery of the underwriting agreement for this offering.

We may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that stock options are exercised, warrants are exercised or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our planned investments in our research and development, sales and marketing and general administrative functions, and our current plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a commercial-stage medical device company engaged in the design, development, and commercialization of innovative solutions to improve the health and quality of life of insulin-requiring PWD by utilizing advanced adaptive closed-loop algorithms to simplify and improve the treatment of their disease. Diabetes is a serious, chronic and often lifelong condition with no known cure that is characterized by extended periods of elevated levels of glucose in the bloodstream (hyperglycemia), resulting from the body's inability to either produce or effectively utilize the hormone insulin. To treat their diabetes, PWD must undergo a rigorous regimen of daily insulin substitution as elevated levels of glucose in the blood over time can lead to serious and often life-threatening cardiovascular, metabolic and nervous system complications. Despite decades of innovation that have advanced the quality of care available, a significant unmet need remains as the vast majority of PWD still cannot manage their diabetes effectively. Our product, the iLet, is the first insulin delivery device cleared by the FDA to utilize adaptive closed-loop algorithms to autonomously determine every insulin dose without requiring a user to count carbohydrate intake. We believe this marks a significant advancement over other insulin delivery technologies by offering a differentiated combination of improved glycemic control and a vastly simplified experience for users and caregivers.

The iLet was specifically designed to provide improvements in glycemic control relative to currently available treatment options, such as insulin pumps, including partially AID systems (also known as hybrid closed-loop systems), and MDI, while also reducing the complexity and burden of achieving these improved results for PWD. It is enabled by adaptive closed-loop algorithms that continuously learn each person's unique and ever-changing insulin requirements and then autonomously delivers the correct insulin doses every five minutes throughout the day and night. Only the user's body weight is required for device initialization and the autonomous determination of all insulin doses, unlike insulin pumps and hybrid closed-loop systems, which require a complex host of parameters to configure.

Our initial commercialization efforts for the iLet are focused on the T1D market. T1D is an autoimmune disorder that often develops during childhood or adolescence, but can occur at any age, and arises from a person's immune system attacking and destroying the insulin-producing beta cells in the pancreas. There are approximately 1.8 million people with T1D currently in the United States, all of whom require daily insulin replacement to manage their disease. We believe that one of the principal causes of suboptimal outcomes as it relates to disease management is the complexity of the user experience with most currently available insulin pumps and hybrid closed-loop systems, which has kept the majority of PWD from adopting them despite the improved disease management they can offer. These systems require PWD to set and to periodically adjust several insulin pump parameters, to quantify daily carbohydrate intake, and to frequently calculate proper doses of insulin for their pump to deliver. We believe this complexity, and the constant engagement that is required in order to enjoy the full therapeutic benefits that these systems can offer, limits their uptake to a subset of PWD

and to subspecialty HCPs. Currently, approximately one-third of people with T1D in the United States utilize insulin pumps or hybrid closed-loop systems, while the majority receive their daily insulin via MDI, which is less complex, but often less effective. Our initial commercial results suggest that the iLet's value proposition is resonating strongly within the MDI population as approximately 51% of the iLet's adoption through December 31, 2023 came from PWD who were previously utilizing MDI.

We have also partnered with Dexcom and Abbott—global leaders in popular and easy to use CGM technology—to integrate the iLet with the Dexcom G6 and G7 CGMs and with Abbott's FreeStyle Libre 3 Plus CGM sensor. The CGM is a crucial component of AID systems, and by partnering with these leading global CGM platforms, we believe we leverage all of the benefits that these CGMs offer in an elegant solution for PWD.

In addition to the iLet, we sell single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, as well as infusion sets that connect the insulin pump to a user's body. We also offer a mobile application that includes a share/follow feature which allows data to be shared in real time with a trusted "Bionic Circle" of friends and family members. The mobile application receives information from the iLet and displays that information discreetly to the user. This user-friendly, intuitive mobile application provides real-time glucose readings, trends and graphs. It also allows for cloud-based data storage.

To maximize the commercial value of the iLet opportunity, we have assembled a team across our organization with broad experience in the successful commercialization of innovative technologies in the field of diabetes disease management. We are promoting sales of the iLet through an internal sales organization where our initial direct sales efforts are focused on high volume endocrinology practices and then, over time, the larger, but more diffuse, multispecialty practices in primary care. These PCP treat an estimated one-half of the T1D population in the United States but do so among a much more diversified patient base than the endocrinologists. We believe that the iLet's core value proposition of marrying effective glycemic control with the simplicity of use that is brought about by adaptive closed-loop algorithm insulin-dose determination may resonate particularly well among PCP who do not have the subspecialty-level of expertise, the resources, or the clinical bandwidth that is needed to initiate insulin-pump or hybrid closed-loop therapy or for the continual demand those systems place on clinical practices in follow-on care.

We are also optimizing our direct sales efforts by growing, in parallel, an internal customer support team. All of this has been supplemented with strategic marketing initiatives and a targeted campaign we call the "Bionic Universe," which is built around a community of iLet users, caregivers, and key opinion leaders (KOLs) who share their stories to inspire others.

Our primary customers are DME distributors and pharmacies who sell the iLet and single-use products that are used together with the iLet. PWD acquire our products through the DME channel and the PBP channel. Currently, the majority of our new patient starts are reimbursed through the DME channel.

We are pursuing a multi-channel coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device and provide PWD with advantageous coverage and reimbursement terms. We are working with payors to establish coverage and reimbursement under both the DME and PBP channels as we believe this strategy increases access and optimizes the potential for better medical outcomes for PWD through the adoption of the iLet.

The DME and PBP reimbursement channels for the iLet and its single-use products entail different payment outlays and therefore differentially impact PWD and our financial results. DME reimbursement requires the user and insurance carrier to make a large, upfront payment and reimbursement, respectively, for the iLet, which is typically in the thousands of dollars. In order to use the iLet, the user must purchase our single-use products, which are generally sold in a 30-day supply. While a PWD using the iLet does not have a minimum commitment for the purchase of single-use products, the iLet is not compatible with other infusion sets or insulin cartridges.

By contrast, PBP reimbursement requires the user and insurance carrier to make a small upfront payment and reimbursement, respectively, for the iLet, allowing for a potentially higher rate of adoption by PWD. The insurance carrier then makes larger reimbursement payments for the purchase of single-use products, with the user's payments for the single-use products being generally consistent with what the user would likely pay for single-use products in DME reimbursement. As a result, we recognize a small amount of revenue at or around the date the iLet is sold in the PBP channel and we absorb initial negative gross margin. iLet sales in the PBP channel are generally expected to then start generating cumulative positive gross margin for us following the third month the user utilizes the iLet and continues to purchase single-use products. For the year ended December 31, 2023, PBP channel sales were immaterial.

When considering the overall economics over the lifetime of each iLet, sales through the DME channel generally result in higher upfront cash flows from the large upfront payment and reimbursement for the iLet, but lead to lower cash flows as the user purchases the necessary single-use products. By contrast, sales through the PBP channel generally result in lower upfront cash flows from the small payment and reimbursement for the iLet, but lead to higher cash flows as the user purchases the necessary single-use products. This is because single-use products through the PBP channel are sold at a much higher per unit cost than through the DME channel. When comparing sales through the DME and PBP channels, we expect sales through the PBP channel will have a more favorable economic impact on our financial results over the expected life of the iLet, which we generally expect to be four years. As such, our current strategic priority is to direct demand to the PBP reimbursement channel.

In addition to our commercialized product and to maintain our competitive position in the marketplace, we intend to continue investing in disruptive technologies through our experienced research and development team. We are developing an insulin pump that adheres directly to the skin and administers insulin without the need for tubing, commonly known in the diabetes industry as a "patch pump." We are also developing a first-of-its-kind bihormonal configuration of the iLet, which combines automated delivery of insulin and glucagon, the BG-raising hormone that protects against low blood sugar, or hypoglycemia, with adaptive closed-loop algorithms where all doses of both hormones are autonomously determined. We also intend to pursue the development of the iLet for expanded patient populations and indications, such as people with T2D, as we believe the size and composition of this population make it a compelling opportunity.

License and Collaboration Agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see the sections titled "Business—License and Collaboration Agreements."

Device License Agreement with Boston University

In December 2015, we and BU entered into a device license agreement, which was amended in December 2017, September 2020 and February 2022 (collectively, the Device License Agreement). Under the Device License Agreement, we received a royalty-bearing license (with the right to sublicense) under certain of BU's patent rights related to a system and individual components thereof for delivering multiple medicaments to a patient without medicament mis-channeling to make, use, sell, and import products, and practice processes covered by the licensed patent rights (collectively, the Licensed Products and Licensed Processes). The rights granted to us by BU under the Device License Agreement are exclusive, subject to certain reserved rights, including BU's right to practice and/or use the licensed patent rights for non-profit purposes such as sponsored research and collaborations, government rights and other third party rights. Furthermore, at BU's request, we will be required to negotiate a sublicense in good faith with a third party if we are unable or unwilling to use the patent rights licensed to us under the Device License Agreement to address the unmet needs of neglected people or geographic areas that such party is willing and able to address. The exclusivity may be terminated by BU if we fail to meet a specified percentage of the applicable minimum royalty amount for a given calendar year. The minimum royalty amount is a non-material amount.

Pursuant to the Device License Agreement, we agreed to use commercially reasonable efforts to market Licensed Products in the United States and elsewhere in the world. Additionally, we are obligated to meet certain diligence milestones under the Device License Agreement. We have satisfied all the milestones set forth under the Device License Agreement required to be achieved to date, with specified regulatory milestones remaining to be achieved in connection with our development of the Licensed Products and Licensed Processes.

In consideration for the licensed patent rights and other rights granted to us under the Device License Agreement, we issued 2,286 shares of our Class B common stock to BU, representing a specified ownership percentage on a fully diluted basis at the time of entering into the Device License Agreement, subject to anti-dilution adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock. We are also required to pay (i) quarterly royalties of a mid-single-digit percentage based on net sales of all Licensed Products and Licensed Processes by us or our affiliates, (ii) quarterly royalties of a low double-digit percentage based on net sales by our sublicensees (in each case (i) and (ii), which royalties are creditable against the minimum royalty amount) and (iii) agreed to make quarterly lump sum payments of a low-double-digit percentage based on certain non-royalty sublicensing revenue received by us from our sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. We also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if we assign the Device License Agreement in connection with the sale of all or substantially all of our assets relating to the licensed patent rights, we will be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment.

Control Algorithm License Agreement with Boston University

In December 2015, we and BU entered into a control algorithm license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the Control Algorithm Agreement). Under the Control Algorithm Agreement, we received a royalty-bearing license (with the right to sublicense) to (i) make, use, sell, and import products, and practice processes, covered by certain of BU's patent rights related to automated control systems for treatment of T1D and similar conditions, involving monitoring and/or delivering insulin, glucagon, and glucose (collectively, the Automated Control System Technology); and (ii) use, reproduce, prepare derivative works, perform, display, and distribute all or any part of the software, source code, object code and/or related documentation, covered by certain copyright rights, and related to (a) the Automated Control System Technology and (b) the iLet control algorithm. The licenses granted by BU to us pursuant to the Control Algorithm Agreement are exclusive, subject to certain reserved rights including BU, BU's third party licensors' and other not-for profit institutions' rights to practice and/or use the patent rights for non-profit purposes such as sponsored research and collaborations and to permit other academic, government and not-for-profit institutions to make use of the same for educational purposes. Furthermore, at BU's request, we will be required to negotiate a sublicense in good faith with a third party if we are unable or unwilling to use the technology licensed to us under the Control Algorithm Agreement to address the unmet needs of neglected people or geographic areas that such third party is willing to address. The exclusivity may be terminated by BU if we fail to meet a specified percentage of the applicable minimum royalty amount for a given calendar year. The minimum royalty amount is a non-material amount. Additionally, under the Control Algorithm Agreement, we granted a perpetual, non-exclusive, royalty-free license back to BU with respect to the copyrights and patents covering any derivative works of the licensed software for BU's educational and academic purposes and to practice their reserved rights.

Pursuant to the Control Algorithm Agreement, we agreed to use commercially reasonable efforts to market Licensed Products in the United States and elsewhere in the world. Additionally, we are obligated to meet certain diligence milestones under the Control Algorithm Agreement. We have satisfied all the milestones set forth under the agreement required to be achieved to date.

In consideration for the licensed patent rights and other rights granted to us under the Control Algorithm Agreement, we issued 2,247 shares of our Class B common stock to BU, representing a specified ownership percentage on a fully diluted basis at the time of entering into the license agreement, subject to anti-dilution

adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock to BU. We are also required to pay BU (i) quarterly royalties of a mid-single-digit percentage based on net sales by us and our affiliates, and royalties of a low double-digit percentage of net sales by sublicensees, (in each case (i) and (ii), which royalties are creditable against the minimum royalty amount), and (iii) agreed to make quarterly lump sum payments of a low double-digit percentage of the non-royalty sublicensing revenue received by us from our sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. We also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if we undergo a change of control (as defined in the Control Algorithm Agreement) we will owe BU a one-time change of control payment of \$65,000. We will also be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment if we assign the Control Algorithm License Agreement in connection with the sale of all or substantially all of our assets relating to the licensed patent rights and copyright.

Collaboration and License Agreement with Xeris Pharmaceuticals, Inc.

In May 2024, we and Xeris entered into a collaboration and license agreement (Collaboration and License Agreement). Under the Collaboration and License Agreement, we received a worldwide, exclusive, royalty-bearing, sublicensable license under certain patent rights and know-how related to Xeris' proprietary non-aqueous formulation technology and technology developed during the collaboration (Xeris Technology) to develop and commercialize glucagon products that are reformulated using the Xeris Technology and developed by Xeris under a development plan under the Collaboration and License Agreement, for use in a pump product or system for glycemic control (Glucagon Products) in the field of chronic glycemic control in diabetes mellitus, excluding single-dose, one-time use form for treatment of severe hypoglycemia and diagnostic uses (Field). We also received a worldwide, exclusive, sublicensable manufacturing license under the Xeris Technology to manufacture Glucagon Products in the Field following a future manufacturing transfer date to be agreed with Xeris and subject to a separate commercial supply agreement.

We and Xeris will conduct certain development activities for the Glucagon Products in accordance with the mutually agreed development plan. Xeris will be responsible for the cost of completing the activities under the development plan up to a certain development stage, and we will reimburse Xeris for any later-stage or additional work required under the development plan.

We and Xeris each agree not to directly or indirectly develop, commercialize or otherwise exploit any drug product comprising glucagon or a glucagon analogue, other than a Glucagon Product, for use with a pump system in the Field worldwide for the duration of the Collaboration and License Agreement, subject to certain specified exceptions.

Pursuant to the Collaboration and License Agreement, we agreed to use commercially reasonable efforts to develop and seek regulatory approval for, a Glucagon Product in certain specified countries.

In consideration for the licenses and other rights granted to us under the Collaboration and License Agreement, we paid Xeris a one-time payment of \$0.5 million, and we will pay Xeris a one-time milestone payment of \$3.0 million upon our achievement of a certain development milestone event. In addition, we are required to pay Xeris tiered royalties of low double-digit percentages based on net sales of Glucagon Products by us or our sublicensees, subject to certain customary reductions.

Development and Commercial Agreements

Below is a summary of the key terms for certain of our development commercial agreements. For a more detailed description of these agreements, see the sections titled "Business—Development and Commercial Agreements."

Commercialization Agreement with DexCom, Inc.

In July 2023, we and DexCom, Inc. (DexCom), entered into a commercialization agreement (the Commercialization Agreement). Under the Commercialization Agreement, we and DexCom agreed to commercialize an AID system that is comprised of our system and DexCom's G6 or G7 iCGM (integrated continuous glucose monitoring) system (the Combined Platform), which we and DexCom developed under a separate development agreement executed in December 2016. We and DexCom will use commercially reasonable efforts to commercialize the Combined Platform in accordance with an agreed commercialization plan, in the territories specified in the commercialization plan. We and DexCom will conduct certain development activities for the Combined Platform in accordance with an agreed development plan.

We granted DexCom a limited license to use certain of our trademarks in connection with commercialization of the Combined Platform under the Commercialization Agreement. DexCom granted us (a) a limited license to use the specifications and communication protocol integrating our system with DexCom's G6 and G7 iCGM devices and (b) a limited license to use certain of DexCom's trademarks, in each case (a) and (b), in connection with the development and commercialization of the Combined System. On termination of the Commercialization Agreement, each party's license will terminate, subject to any wind down period. We and DexCom also granted each other limited licenses to use certain data generated by the other's devices in the Combined System.

Development and Commercialization Agreement with Abbott Diabetes Care Inc.

In April 2024, we and Abbott entered into a development and commercialization agreement (Development and Commercialization Agreement). Under the Development and Commercialization Agreement, we and Abbott agree to develop and commercialize an automated insulin delivery system comprised of our subcutaneous insulin infusion delivery system combined with Abbott's glucose monitoring system (Libre-Beta System).

Under the Development and Commercialization Agreement, we and Abbott agreed to jointly prepare a development plan setting forth each party's responsibilities in developing the Libre-Beta System in the United States. We are responsible for all development and clinical trials for the Libre-Beta System, and Abbott is responsible for all development for the continuous glucose monitoring system. We and Abbott agreed to jointly develop a regulatory plan for the Libre-Beta System, setting out the regulatory activities to be performed by each party. We and Abbott also agreed to jointly prepare a commercialization plan for the Libre-Beta System to launch the Libre-Beta System in the United States.

Abbott granted us a limited license under Abbott's existing background intellectual property and any intellectual property developed solely by Abbott under the Development and Commercialization Agreement for us to perform our obligations under the Development and Commercialization Agreement. Abbott also granted us a limited license to use Abbott's trademarks for the purpose of developing and marketing the Libre-Beta System.

We granted Abbott a limited license under our existing background intellectual property and any intellectual property developed solely by us under the Development and Commercialization Agreement for Abbott to perform its obligations under the Development and Commercialization Agreement. We also granted Abbott a limited license to use our trademarks for the purpose of developing the Libre-Beta System and marketing the continuous glucose monitoring system for use with the Libre-Beta System.

Key Business Metrics

We regularly review the following key business metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate financial projections and make strategic decisions. We believe that the following metrics are representative of our current business:

	Year Ended December 31,	
	2022	2023
New patient starts	—	2,304
New patient starts from MDI as a percentage of total new patient starts	—	51%
Installed customer base	—	2,304

As we began commercializing the iLet in May 2023, these key business metrics were not applicable for the year ended December 31, 2022.

New Patient Starts

Our ability to add new patients is a key indicator of the market's adoption of the iLet and a key growth driver for the business. We grow our patient base through our own internal sales organization, which drives most of our new patient growth. We define a new patient as an individual making their initial purchase of an iLet during the period presented, excluding replacements. This metric highlights our capability to identify and attract new users, illustrating the number of new iLet product users during each period presented.

New Patient Starts from MDI as a Percentage of Total New Patient Starts

The percentage of new patient starts from MDI is a valuable metric for us, as it demonstrates a user's willingness to transition from an MDI therapy to the insulin delivery mechanism provided by the iLet. Percentage of new patient starts from MDI helps us understand our patient profile and quantifies our expansion of the insulin pump market. We believe a higher percentage of new patient starts from MDI indicates that the iLet's value proposition is resonating with patients who have historically chosen to not wear an insulin pump. New patient starts from MDI as a percentage of total new patient starts is calculated by dividing the number of new patient starts from MDI by the total number of new patient starts.

Installed Customer Base

The installed customer base represents all new patient starts, over a rolling four-year period basis. This period reflects our in-warranty customer base under the typical four-year reimbursement cycle and helps us understand the total number of patients using the iLet.

Non-GAAP Financial Measures

In addition to our financial results determined in accordance with generally accepted accounting principles in the United States (GAAP), we believe the following non-GAAP measures are useful in evaluating our operating performance. We use the following non-GAAP financial measures to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that these non-GAAP financial measures, when taken together with the corresponding GAAP financial measures, provide meaningful supplemental information regarding our performance by excluding certain items that may not be indicative of our business, results of operations, or outlook. In particular, we believe that the use of adjusted gross profit, adjusted gross margin, and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) are helpful to our investors as they are metrics used by management in assessing the health of our business and our operating

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performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. A reconciliation is provided below for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with GAAP. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business.

Adjusted Gross Profit and Adjusted Gross Margin

Adjusted gross profit and adjusted gross margin are key performance measures that we use to assess our overall performance. We define adjusted gross profit as GAAP gross profit, excluding depreciation and amortization expense and stock-based compensation expense. For purposes of calculating adjusted gross profit, we do not consider gross profit earned from collaboration agreements. We define adjusted gross margin as our adjusted gross profit divided by our revenue from contracts with customers. We believe adjusted gross profit and adjusted gross margin provide consistency and comparability with our past financial performance and facilitates period-to-period comparisons of operations, as these metrics eliminate the effects of depreciation and amortization and stock-based compensation from period-to-period as factors unrelated to overall operating performance.

The following table presents a reconciliation of adjusted gross profit and adjusted gross margin from the most comparable GAAP measure, gross profit, for the year ended December 31, 2023:

	Year Ended December 31, 2023 (in thousands, except percentages)
Gross profit	\$ 6,308
Add:	
Depreciation and amortization expense	390
Stock-based compensation expense	239
Adjusted gross profit	<u>\$ 6,937</u>
Adjusted gross margin (as a percentage of revenue)	58%

During the year ended December 31, 2022, we had no adjusted gross profit or adjusted gross margin, as the only revenue generated was related to upfront consideration received under a collaboration agreement, for which any related costs were included within research and development expense.

Adjusted EBITDA

Adjusted EBITDA is a key performance measure that we use to assess our operating performance. Because adjusted EBITDA facilitates internal comparisons of our historical operating performance on a more consistent basis, we use this measure for business planning purposes.

We calculate adjusted EBITDA as net loss adjusted to exclude (i) depreciation and amortization expense, (ii) stock-based compensation expense, (iii) interest income, (iv) provision for state taxes and (v) change in fair value of warrant liabilities.

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The following table presents a reconciliation of adjusted EBITDA from the most comparable GAAP measure, net loss, for the years ended December 31, 2022 and 2023:

	Year Ended December 31,	
	2022	2023
	(in thousands)	
Net loss	\$(64,751)	\$(44,099)
Add:		
Depreciation and amortization expense	1,345	1,226
Stock-based compensation expense	6,100	5,658
Interest income	(196)	(1,777)
Provision for state taxes	14	13
Change in fair value of warrant liabilities	(911)	9,958
Adjusted EBITDA	<u>\$(58,399)</u>	<u>\$(29,021)</u>

Some of the limitations of adjusted EBITDA include: (i) adjusted EBITDA does not properly reflect capital commitments to be paid in the future; and (ii) although depreciation and amortization expense are non-cash charges, the underlying assets may need to be replaced and adjusted EBITDA does not reflect these capital expenditures. Our adjusted EBITDA may not be comparable to similarly titled measures of other companies because they may not calculate adjusted EBITDA in the same manner as we calculate the measure, limiting its usefulness as a comparative measure. In evaluating adjusted EBITDA, you should be aware that in the future we will incur expenses similar to the adjustments in this presentation. Our presentation of adjusted EBITDA should not be construed as an inference that our future results will be unaffected by these expenses or any unusual or non-recurring items. When evaluating our performance, you should consider adjusted EBITDA alongside other financial performance measures, including our net loss and other GAAP results.

Key Factors Affecting Our Performance

We believe that our financial performance has been and in the foreseeable future will continue to be primarily driven by the following factors. While each of these factors presents significant opportunities for our business, they also pose important challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in the section titled “Risk Factors.”

New Patient Adoption and iLet Sales

Our financial performance has largely been driven by, and in the future will continue to be impacted by, the rate of sales of our products to new patients. Management focuses on new patient starts as a key indicator of current business success. We expect our new patient starts to continue to grow as we increase penetration in our existing markets and expand into, or offer new features and solutions that appeal to, new markets.

We plan to grow our sales in the coming years through multiple strategies, including expanding our sales efforts to focus on more diffuse, multispecialty practices in primary care over time, expanding our marketing initiatives including via the Bionic Universe, leveraging our partnerships with global leaders in CGM technology like Dexcom and Abbott, growing our internal customer support team, continuing to enhance our product offerings and pursuing a multi-channel coverage and reimbursement strategy.

Third-Party Payor Reimbursement and Impact of Our Multi-Channel Reimbursement Strategy

As a medical device company, our revenue and results of operations may be impacted by the failure to obtain adequate coverage or reimbursement for our current and future products from third-party payors, as well as changes in reimbursement structures in line with our strategy.

We are pursuing a multi-channel coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device and provide PWD with advantageous coverage and reimbursement terms. We are working with payors to establish coverage and reimbursement under both the DME and PBP channels as we believe this strategy increases access and optimizes the potential for better medical outcomes for PWD through the adoption of the iLet. The DME and PBP channels for the iLet and its single-use products entail different payment outlays and therefore differentially impact PWD and our financial results. When considering the overall economics over the lifetime of each iLet, sales through the DME channel generally result in higher upfront cash flows from the large, upfront payment and reimbursement for the iLet, but lead to lower cash flows as the user purchases the necessary single-use products. By contrast, sales through the PBP channel generally result in lower upfront cash flows from the small payment and reimbursement for the iLet, but lead to higher cash flows as the user purchases the necessary single-use products. This is because single-use products under the PBP channel are sold at a much higher per unit cost than under the DME. As a result of the a small amount of revenue recognized at or around the date the iLet is sold in the PBP channel, we absorb initial negative gross margin. iLet sales in the PBP channel are generally expected to start generating cumulative positive gross margin for us following the third month the user utilizes the iLet and continues to purchase single-use products. For the year ended December 31, 2023, PBP channel sales were immaterial. When comparing sales through the DME and PBP channels, we expect sales through the PBP channel will have a more favorable economic impact on our financial results over the lifetime of the iLet. To the extent that our mix of channel reimbursement fluctuates, our financial results may vary from period to period.

Continued Investment In Growth and Innovation

Our revenue growth has been driven by rapid innovation and quick adoption of our products by our customer base. We intend to continue to make focused investments to increase revenue and grow our business, and therefore expect expenses in this area to increase.

We have invested, and will continue to invest, significantly in our manufacturing capabilities and commercial and customer support infrastructure. We expect that our 50,000 square foot facility in Irvine, California, which commenced operations in 2020, will have sufficient production capacity to support our anticipated clinical and commercial demand for the foreseeable future. We also plan to invest in sales and marketing activities, expect to incur additional general and administrative expenses and to have higher stock-based compensation expenses as we support our growth and our transition to becoming a publicly traded company.

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies. We expect our business to be impacted by the introduction of new diabetes devices and treatments by us or our competitors. In order to maintain our competitive position in the marketplace, we intend, through our experienced research and development team, to continue investing in disruptive technologies, such as a patch pump and bihormonal configuration of the iLet, as well as pursuing the development of the iLet for expanded patient populations and indications such as people with T2D.

As cost of revenue, operating expenses and capital expenditures fluctuate over time, we may experience short-term, negative impacts to our results of operations and cash flows, but we are undertaking such investments in the belief that they will contribute to long-term growth. Moreover, introduction of new products may negatively impact aspects of our financial performance such as our overall gross margins.

Regulatory Approvals and Actions

The medical devices we manufacture are subject to laws and regulation by numerous regulatory bodies, including the FDA. The laws and regulations govern, among other things, the research and development, design, testing, manufacture, packaging, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Any adverse event involving any products

that we distribute could result in future corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. In the future, we also intend to pursue additional products, such as a patch pump and bihormonal configuration of the iLet, as well as pursue the development of the iLet for expanded patient populations and indications such as people with T2D, which will increase our expenses and subject us to increased regulatory-related risks.

Seasonality

We anticipate that the revenue generated from our product sales will vary from quarter to quarter as we continue to commercialize the iLet. Specifically, we expect to typically experience lower sales in the first quarter of each year compared to the preceding fourth quarter. This seasonal sales pattern in the United States is associated with the annual insurance deductible resets and coinsurance requirements of the medical insurance plans providing coverage to PWD using the iLet.

Macroeconomic Factors, Global Supply Chain Disruption and Inventory

Our costs are subject to fluctuation, and we continue to evaluate contributing factors, specifically those leading to inflationary cost increases in logistics, price of raw materials, cost of labor, transportation and operating supplies. While we are experiencing higher raw material, labor, transportation, and operating supply costs, we intend to continue to work to improve productivity to help offset these costs as we navigate these global macroeconomic challenges.

In addition, it is possible that we may be negatively affected from unexpected delays resulting from global supply chain disruptions and other adverse global conditions. To date, we have been able to successfully mitigate this disruption and ensure uninterrupted supply to our customers by increasing our inventory levels and taking other measures, however, there is no guarantee of future performance. There may be times in which we determine that our inventory does not meet our product requirements or we maintain an insufficient level of inventory. We may also over- or underestimate the quantities of required components, in which case we may expend extra resources or be constrained in the amount of end product that we can procure. These factors subject us to the risk of obsolescence and expiration, which may lead to impairment charges.

Components of Results of Operations

Revenue

Our revenue consists of (i) net sales and (ii) collaboration revenue.

Net Sales

In May 2023, the iLet was cleared by the FDA for the treatment of T1D and we began commercializing the iLet in the United States. We generate product revenue from the sale of the iLet and single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. We are able to recognize revenue when control of the promised goods and services is passed to the customer, which we have identified as our distributor and pharmacy partners. Revenue is recognized in the amount of the consideration received net of any estimated returns and estimated variable consideration adjustments, including rebates, chargebacks and patient assistance. Revenue is recognized either over time or at a point in time, depending on when control of the associated performance obligation is transferred to the customer.

Collaboration Revenue

Prior to commercialization of the iLet, all of our revenue was derived from a collaboration agreement with Novo Nordisk A/S (Novo Nordisk), entered into in 2017 and subsequently modified in December 2019,

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February 2021 and April 2021. Our collaboration revenue included the amortization of an upfront payment and milestone payments received upon achieving specified clinical and regularly milestones, which we recognized over the expected performance period. We recognized collaboration revenue from our collaboration agreement with Novo Nordisk ratably over the estimated period because our efforts to satisfy our obligation have been, and were expected to be, consistent throughout the period. The work outlined in the agreement was completed in November 2022.

Cost of Sales

Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, royalties, freight, import tariffs, scrap and reserves for expected warranty costs and excess and obsolete inventory. Manufacturing overhead expenses include expenses relating to manufacturing engineering, material procurement, inventory and quality control, facilities, depreciation, amortization, information technology and operations supervision and management.

Gross Profit and Gross Margin

Gross profit and gross margin, or gross profit as a percentage of revenue, has been and will continue to be affected by various factors, including the timing of new patient adoption, iLet and associated single-use product sales, reimbursement, length of product usage, our introduction of new products, including the costs associated with producing and bringing those new products to market, cost reduction and operational efficiency. As a result of the small revenue recognized at or around the date the iLet is sold in the PBP channel, we absorb initial negative gross margin. iLet sales in the PBP channel are generally expected to start generating cumulative positive gross margin for us beyond the third month the user uses the iLet and continues to purchase single-use products. For the year ended December 31, 2023, PBP channel sales were immaterial. Given the differences in the timing and amount of outlays which correlate directly to revenue between the DME and PBP channels, changes in our future sales mix may also impact our gross profit and gross margin.

Operating Expenses

Our operating expenses consist of (i) research and development expenses, (ii) sales and marketing expenses and (iii) general and administrative expenses.

Research and Development

Our research and development expenses primarily consist of engineering and research expenses related to the iLet clinical trials, regulatory expenses and personnel-related expenses, such as salaries, bonuses, stock-based compensation expense and benefits for our employees in the research and development function. We also incur research and development expenses for payments made under third-party licensing agreements, supplies, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trial costs, and other indirect costs. We expense research and development costs as incurred.

Investigational devices in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly for the foreseeable future as we advance our current clinical development activities, develop the bihormonal configuration of the iLet, develop the patch pump, and if we pursue the development of the iLet for expanded patient populations and indications such as people with T2D. We expect our research and development expenses to also increase significantly for the foreseeable future as we hire and retain additional personnel, including research, clinical, development, manufacturing, regulatory and scientific personnel; remit payments to third parties through license arrangements; and develop, establish and validate our commercial-scale and manufacturing process.

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Sales and Marketing

We are in the early commercialization stages of the iLet and are focused on driving awareness and adoption among new customers. Sales and marketing expenses are primarily related to the market development and post-commercial launch activities for the iLet, including the design of infrastructure to support the customer experience, and marketing and branding strategy. Market development and post-commercial launch activities account for a significant portion of our overall operating expenses and are expensed as they are incurred. We expect our sales and marketing expenses to increase significantly for the foreseeable future to support the continued commercialization of the iLet.

Our sales and marketing expenses primarily consist of personnel-related expenses, such as salaries, sales incentive compensation, stock-based compensation expense and benefits for our sales representatives, field clinical specialists, and other sales and marketing personnel, the cost of healthcare conference exhibits and market research, market access expenses, including payor education to support the future commercialization of the iLet, costs for secondary data purchases of patient claims and prescription data, website development and consulting fees; and facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities as well as travel expenses.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, such as salaries, bonuses, stock-based compensation expense and benefits for our personnel in executive, legal, finance and accounting, human resources, information technology, quality assurance and other administrative functions. Patent costs including costs related to filing and pursuing patent applications are also included in general and administrative expenses. General and administrative expenses also include legal fees relating to patent and corporate matters, professional fees paid for accounting, auditing, consulting and tax services, insurance costs, travel expenses, and facilities, depreciation and other expenses not otherwise included in research and development or sales and marketing expenses. We expect our general and administrative expenses to increase significantly for the foreseeable future, including as we incur increased expenses associated with operating as a public company, such as increased costs of accounting, audit, legal, regulatory and tax-related services, costs related to compliance with the rules and regulations of the SEC and exchange listing standards, director and officer insurance expenses, and investor and public relations costs.

Other Income (Expense), Net

Our other income (expense), net consists of (i) interest income, (ii) interest and other expense and (iii) change in fair value of warrant liabilities.

Interest Income

Interest income consists of cash interest earned on our cash, cash equivalents and short-term investment balances.

Interest and Other Expense

Interest and other expense consists of interest expense and other miscellaneous expenses unrelated to our core operations.

Change in Fair Value of Warrant Liabilities

In connection with our February 2022 Series C preferred stock financing, we granted warrants (Series C Warrants) to certain investors to purchase additional shares of our Series C convertible preferred stock.

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In connection with our August 2023 Series D preferred stock financing, we granted warrants to certain investors to purchase shares of our Class B common stock (Class B Warrants, and together with the Series C Warrants, the Warrants). These Warrants were classified as liabilities on our balance sheet and initially recorded at fair value on the grant date. They are subsequently remeasured to fair value at the end of each reporting period, with changes in the fair value recognized as a component of other income (expense), net. We will continue to recognize changes in fair value of the warrant liabilities until the warrants are exercised, expire, or qualify for equity classification. The Warrants are expected to be exercised prior to the completion of this offering and will no longer be outstanding subsequent to the offering. For additional information, see Note 4 of our audited financial statements included elsewhere in this prospectus.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2023

The following table summarizes our results of operations for the periods indicated:

	Year Ended December 31,		Change	
	2022	2023	\$	%
(in thousands, except percentages)				
Revenue:				
Net sales	\$ —	\$ 11,995	\$ 11,995	100%
Collaboration revenue	179	—	(179)	*
Total revenue	179	11,995	11,816	*
Cost of sales	—	5,687	5,687	100%
Gross profit	179	6,308	6,129	100%
Operating expenses:				
Research and development ⁽¹⁾	31,428	17,943	(13,485)	(43%)
Sales and marketing ⁽¹⁾	8,827	11,990	3,163	36%
General and administrative ⁽¹⁾	25,768	12,225	(13,543)	(53%)
Total operating expenses	66,023	42,158	(23,865)	*
Loss from operations	(65,844)	(35,850)	29,994	*
Other income (expense), net:				
Interest income	196	1,777	1,581	*
Interest and other expense	(14)	(68)	(54)	*
Change in fair value of warrant liabilities	911	(9,958)	(10,869)	*
Total other income (expense), net	1,093	(8,249)	(9,342)	*
Net loss	<u>\$ (64,751)</u>	<u>\$ (44,099)</u>	<u>\$ 20,652</u>	*

* Not meaningful

(1) Includes stock-based compensation expense as follows:

	Year Ended December 31,	
	2022	2023
(in thousands)		
Cost of sales	\$ —	\$ 239
Research and development	1,554	1,781
Sales and marketing	384	610
General and administrative	4,162	3,028
Total stock-based compensation expense	<u>\$ 6,100</u>	<u>\$ 5,658</u>

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Net Sales

The increase in net sales is attributable to the commercialization of the iLet, which received FDA approval in May 2023, and began being sold in May 2023 in the United States. Prior to May 2023, we had no revenue from contracts with customers. Our net sales in 2023 were generated from customers within our DME and PBP channels, which represented 94% and 6% of net sales, respectively.

Collaboration Revenue

The collaboration agreement with Novo Nordisk, related to the initial research and development of the iLet, resulted in collaboration revenue of \$0.2 million in 2022. The collaboration was completed in November 2022 and as such, no collaboration revenue was recorded in 2023.

Cost of Sales

The increase in cost of sales is attributable to the commercialization of the iLet, which received FDA approval in May 2023 and subsequently began being sold in the United States. Prior to May 2023, we had no cost of sales associated with contracts from customers.

Gross Profit and Margin

In 2022, we did not generate product revenue from contracts with customers and the only revenue generated was related to an upfront payment received related to our collaboration agreement with Novo Nordisk. As such, gross profit and margin was \$0 for the year ended December 31, 2022. For the year ended December 31, 2023, we generated gross profit of \$6.3 million attributable to the commercialization of the iLet beginning in May 2023, the majority of which resulted from sales within the DME channel. For the year ended December 31, 2023, sales within the PBP channel were immaterial. When the FDA approved the iLet for treatment of T1D in May 2023, we had \$2.3 million of inventory on hand which was previously charged to research and development expense and as a result had no cost basis. During 2023, \$1.9 million of this inventory was utilized to fulfill orders placed from our contracts with customers, resulting in a 16% positive increase to gross margin for the year.

Research and Development Expenses

Research and development expenses were \$31.4 million for the year ended December 31, 2022, compared to \$17.9 million for the year ended December 31, 2023. The decrease of \$13.5 million was primarily attributable to a \$12.3 million decrease in research and development activities and associated spend as a result of the commercialization of the iLet in May 2023. The remaining \$1.2 million decrease was attributable to a decrease in payroll and payroll related expenses associated with a reduction in headcount.

Sales and Marketing Expenses

Sales and marketing expenses were \$8.8 million for the year ended December 31, 2022, compared to \$12.0 million for the year ended December 31, 2023. The increase of \$3.2 million was primarily attributable to a \$2.0 million dollar increase in commissions incurred as a result of the implementation of our sales incentive plan in conjunction with the commercialization of the iLet in May 2023. The remaining \$1.2 million increase was primarily attributable to payroll and payroll related expenses as a result of changes in the composition of the sales and marketing team.

General and Administrative Expenses

General and administrative expenses were \$25.8 million for the year ended December 31, 2022, compared to \$12.2 million for the year ended December 31, 2023. The decrease of \$13.6 million was attributable

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to a decrease of \$7.2 million as a result of cost savings initiatives, including consolidation of our service provider relationships, and a decrease of \$6.4 million in payroll and payroll related expenses associated with reduction in headcount, including a \$1.1 million decrease in stock-based compensation expense.

Other Income (Expense), Net

Total other income, net was \$1.1 million for the year ended December 31, 2022, compared to total other expense, net of \$8.2 million for the year ended December 31, 2023. The decrease of \$9.3 million was primarily attributable to a \$10.9 million increase in expense associated with the change in fair value of warrant liabilities as a result of the issuance of the Class B Warrants in August 2023 and changes in the inputs associated with the Black-Scholes calculations used to determine the fair value of the warrant liabilities for both the Warrants as of December 31, 2023. This was partially offset by a \$1.6 million increase in interest income earned on short-term investments.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. To date, research and development, market development and commercial launch activities have accounted for a significant portion of our overall operating expenses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the commercialization of our iLet, including future development of the patch pump and bihormonal configuration of the iLet.

To date, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock, raising an aggregate of approximately \$296.6 million of gross proceeds, including net proceeds of approximately \$101.7 million from the issuance and sale of our Series D convertible preferred stock in August 2023. We have also received payments in connection with collaboration agreements and government grants, receiving \$6.1 million to date from these types of arrangements, as well as from the sale of the iLet and single-use products utilized with the iLet from our contracts with customers. As of December 31, 2023, we had cash and cash equivalents and short-term investments of \$96.7 million.

Cash Flows

The following table summarizes our cash flows for the periods presented:

	Year Ended December 31,	
	2022	2023
	(in thousands)	
Net cash used in operating activities	<u>\$ (60,208)</u>	<u>\$ (32,445)</u>
Net cash used in investing activities	<u>(769)</u>	<u>(69,693)</u>
Net cash provided by financing activities	<u>56,782</u>	<u>101,029</u>
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (4,195)</u>	<u>\$ (1,109)</u>

Operating Activities

During the year ended December 31, 2022, net cash used in operations was \$60.2 million, primarily attributable to our net loss of \$64.8 million and net cash used by changes in our operating assets and liabilities of \$2.8 million. This was partially offset by non-cash charges of \$6.1 million of stock-based compensation expense and \$1.3 million of depreciation and amortization expense. Net cash used related to changes in our operating assets and liabilities for the year ended December 31, 2022, and primarily consisted of a \$2.0 million decrease in

accrued expenses and other current liabilities related to a reduction in headcount resulting in a decrease in accrued bonuses and reduced project spend and \$0.7 million decrease in operating lease liabilities.

During the year ended December 31, 2023, net cash used in operations was \$32.4 million, primarily attributable to our net loss of \$44.1 million and net cash used by changes in our operating assets and liabilities of \$5.3 million. The net cash used by changes in our operating assets and liabilities was partially offset by non-cash charges of \$17.0 million, including \$10.0 million attributable to the change in the fair value of our preferred stock warrant liabilities due to the issuance of warrants to purchase shares of Class B common stock in 2023 and changes in the fair value of the warrant liabilities during the year, \$5.7 million in stock-based compensation expense and \$1.2 million in depreciation and amortization expense. For the year ended December 31, 2023, net cash used from changes in our operating assets and liabilities was primarily attributable to a \$4.5 million increase in accounts receivable and a \$1.2 million increase in inventories, both resulting from the launch of commercial sales of the iLet in May 2023. Additionally, there was a \$1.1 million decrease attributable to the extinguishment of the funded research and development liability, as a result of the FDA approval of the iLet in May 2023. These were partially offset by a \$0.7 million increase in accounts payable and a \$1.8 million increase in accrued expenses and other current liabilities attributable to additional raw materials purchases, changes in our bonus accrual and the establishment of sales related accruals such as warranty, returns, chargebacks, and rebates, all as a result of the commercialization of the iLet in 2023.

Investing Activities

During the year ended December 31, 2022, net cash used in investing activities was \$0.8 million, attributable to purchases of property and equipment associated with additional manufacturing equipment.

During the year ended December 31, 2023, net cash used in investing activities was \$69.7 million, primarily attributable to the purchase of short-term investments utilizing proceeds from the issuance and sale of the shares of our Series D convertible preferred stock as well as \$0.4 million in additional investment in property and equipment associated with additional manufacturing equipment.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was \$56.8 million, primarily attributable to \$56.3 million of net proceeds from the issuance and sale of shares of our Series C convertible preferred stock and the exercise of \$0.4 million of options for shares of our Class B common stock.

During the year ended December 31, 2023, net cash provided by financing activities was \$101.0 million, primarily attributable to net proceeds from the issuance and sale of shares of our Series D convertible preferred stock.

Future Funding Requirements

We expect our expenses to increase significantly in connection with our ongoing activities. The timing and amount of our funding requirements will depend on many factors, including:

- the cost of maintaining FDA clearance for the iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older;
- the cost of obtaining and maintaining FDA marketing authorization or clearance for other future indications or other product candidates, including for the iLet for T1D using both insulin and glucagon (a bihormonal configuration), the iLet for T2D and the patch pump;
- future revenue generated by sales of the iLet and any future product candidates, if approved;

- costs associated with scaling up and expanding our manufacturing capacity;
- costs associated with building and expanding our sales and marketing efforts in the United States and, in the future, internationally;
- costs associated with conducting research and development efforts for future improvements to the iLet;
- costs associated with conducting research and development efforts for future product offerings, such as the patch pump and bihormonal configuration of the iLet;
- the cost of complying with regulatory requirements;
- costs associated with capital expenditures;
- the costs associated with hiring additional personnel as our business grows;
- the costs of operating as a public company;
- costs associated with any future litigation; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Based on our current operating plans, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as well as cash generated from sales of our products, will be sufficient to fund our projected operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

We expect to finance our operations through product revenue, as well as potentially through equity or debt financing, collaborations or strategic alliances. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or strategic alliances with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or investigational devices, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

Leases

We have entered into various non-cancelable operating leases for certain office, laboratory and manufacturing space. The leases have varying initial lease terms of approximately 2-7 years. For additional information, see Notes 2 and 17 of our audited financial statements included elsewhere in this prospectus.

Research and Development Costs

In May 2024, in connection with research and development activities, we entered into an exclusive worldwide License and Collaboration Agreement with Xeris which contains a number of contractual obligations. In consideration for the licenses and other rights granted to us under the License and Collaboration Agreement, we paid Xeris a one-time, non-refundable payment of \$0.5 million, and will pay Xeris an additional one-time non-refundable milestone payment of \$3.0 million upon the achievement of certain developmental milestones. In addition, we are required to pay tiered royalties of low double-digit percentages based on net sales of Glucagon Products, subject to certain reductions. For additional information, see the section titled “Business—Collaboration and License and Agreements.”

Royalty Obligations

In connection with the development, production and sale of the iLet, we have entered into certain agreements that obligate us to pay royalties based on specific production or net sales metrics. Among other obligations, certain license agreements with BU require us to pay quarterly royalties of a mid-single-digit percentage based on net sales (and royalties of a low double-digit percentage of net sales by sublicensees), of any products licensed under the agreements, which royalties are creditable against the minimum royalty amount. For additional information on these license agreements with BU, see the section titled “Business—License and Collaboration Agreements.”

Qualitative and Quantitative Disclosures About Market Risk

We are exposed to certain market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Interest Rate Risk

As of December 31, 2023, we had cash, cash equivalents and short-term investments of \$96.7 million, which consisted primarily of bank deposits, U.S. Treasury bills and money market funds. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We do not believe that a hypothetical immediate 10% increase or decrease in interest rates would have had a material impact on our financial statements included elsewhere in this prospectus.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, that would have been established to facilitate off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our audited financial statements, which are prepared in accordance with GAAP. The preparation of our audited financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our audited financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited financial statements included elsewhere in this prospectus, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our audited financial statements.

Revenue Recognition

Our revenue from contracts with customers is generated from the iLet and single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. Our primary customers are distributors and pharmacy partners who sell our products to insulin-requiring PWD. We recognize revenue when we transfer control of the promised goods or services to customers in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services, net of estimated returns and estimated variable consideration. Variable consideration is related to pharmacy rebates and chargebacks is accounted for as a reduction in revenue and is estimated based on contractual arrangements, actual sales of products qualifying for rebates or chargebacks, and historical payments made related to pharmacy rebates and chargebacks. Estimates associated with pharmacy rebates and chargebacks on products sold are the most significant component of our variable consideration estimates and most at risk for material adjustment because of the time delay between the recording of the provision and its ultimate settlement, an interval that generally ranges from 30 to 90 days. Due to this time lag, in any given period, our adjustments to reflect actual amounts can incorporate changes of estimates related to prior periods. The amount of variable consideration that is included in the transaction price is estimated and is included in revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. If the actual amounts of consideration that we receive differ from estimates, we adjust these estimates, which affects reported revenue, in the period that such variances become known or at the end of each reporting period.

We have identified the ability for a customer to access the mobile application and our promise to provide firmware upgrades to the iLet through the mobile application as distinct performance obligations, as access and support is provided throughout the standard four-year warranty period of the device. Accordingly, revenue related to the mobile application and firmware upgrades are deferred and recognized ratably over a four-year period. Given the access to the mobile application and unspecified software updates follow the same pattern of transfer to the customer and are provided over the same four-year period, we recognize revenue for these performance obligations as if they were a single performance obligation. As there is no observable standalone selling price for access to the mobile application or promise to provide firmware upgrades, we estimate standalone selling price by applying the expected cost plus a margin approach.

Stock-Based Compensation

We measure stock-based awards granted to employees, non-employees and directors based on their fair value on the date of the grant using the Black-Scholes option pricing model. Stock-based compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award for employees and directors and the period during which services are performed for non-employees. Stock-based compensation expense for non-employee awards is recognized in the same manner as if we had paid cash in exchange for the goods or services, which is generally the vesting period of the award. We have issued awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We have not issued any stock-based awards with performance-based or market-based vesting conditions.

We determined the assumptions for the Black-Scholes option pricing model as discussed below. Each of these inputs is subjective and generally requires significant judgment to determine. Forfeitures are accounted for as they occur.

- *Fair Value of Our Class B Common Stock*—Prior to this offering, our stock was not publicly traded, and therefore we estimated the fair value of our Class B common stock, as discussed in the

subsection title “Determination of Fair Value of Our Class B Common Stock and Series C Convertible Preferred Stock” below.

- *Expected Volatility*—Because we do not have a trading history of our common stock, the expected volatility was derived from the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or the simplified method.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to expected term of the stock options.
- *Expected Dividend Yield*—The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

See Note 13 of our audited financial statements included elsewhere in this prospectus for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of these assumptions involve inherent uncertainties and generally require significant analysis and judgment to develop. Changes in these assumptions can materially impact the fair value and ultimately how much stock-based compensation expense is recognized.

Determination of Fair Value of Our Class B Common Stock and Series C Convertible Preferred Stock

Given the absence of a public trading market to date, the fair value of our common stock has been determined by our board of directors at the time of each option grant, with input from management, considering contemporaneous valuations of common stock, and our board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant, including: the prices at which we sold shares of our convertible preferred stock to outside investors in arms-length transactions, and the superior rights, preferences and privileges of the convertible preferred stock relative to the common stock at the time of each grant; the progress of our research and development and commercialized programs, including their stages of development; our business strategy; operating and financial performance; the lack of liquidity of our common stock; trends in the broader economy and the medical device industry; the likelihood of achieving a liquidity event for our company’s securityholders, such as an initial public offering or a sale of the company; prevailing market conditions, the hiring of key personnel and the experience of management; and the analysis of initial public offerings and the market performance of peer companies in the medical device industry, as well as completed mergers and acquisitions of public peer companies.

These valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Auditing and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the Guide). The methodology to determine the fair value of our common stock included estimating the fair value of the enterprise using a market approach, which estimates the fair value of a company by including an estimation of the value of the business based on prior sales of our capital stock. The Guide identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date.

In accordance with the Guide, we considered the following methods:

- *Current Value Method*. Under the current value method, once the fair value of the enterprise is established, the value is allocated to the various series of preferred and common stock based on their respective seniority, liquidation preferences or conversion values, whichever is greatest.
- *Option Pricing Method (OPM)*. Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the convertible preferred stock and common stock are inferred by analyzing these options. This method is appropriate to use when the range of possible future outcomes is so difficult to predict that estimates would be highly speculative, and dissolution or liquidation is not imminent.
- *Probability-Weighted Expected Return Method (PWERM)*. The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Based on our early stage of development and commercialization, the difficulty in predicting the range of specific outcomes (and their likelihood), and other relevant factors, the OPM allocation method was considered most appropriate for valuations prior to December 31, 2023. For valuations prepared as of and after December 31, 2023, a hybrid method between the PWERM and OPM was used, where the equity value was probability-weighted across multiple scenarios but using the OPM to estimate the allocation of value within one or more of those scenarios, and in certain cases taking into account secondary sale transactions. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

As our Series C convertible preferred stock is convertible into shares of common stock, the fair value of our Series C convertible preferred stock is derived contemporaneously with each valuation of our common stock. Therefore, consistent valuation assumptions and allocation methodologies are utilized in order to determine the fair value of our Series C convertible preferred stock. In addition to the assumptions utilized in the determination of fair value of our common stock, the superior rights, preferences and privileges of the Series C preferred stock relative to the common stock at the time of each grant impact the valuation.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to complete an initial public offering or other liquidity event, and the determination of the appropriate valuation methods.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options or for any other such awards we may grant, as the fair value of our common stock will be determined based on the closing price of our common stock as reported on the date of grant on the stock exchange on which our common stock is traded.

Determination of Fair Value of Warrant Liabilities

Our common stock and preferred stock warrants require liability classification and accounting. The warrants are recorded at fair value upon issuance and are subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in other income, net in the statements of operations and

comprehensive loss. The fair value was estimated using a Black-Scholes option pricing model. The valuation model used incorporates significant assumptions and estimates, which include, but are not limited to, the fair value per share of the underlying shares, the remaining contractual term of the warrants, risk-free interest rate and expected volatility of the price of the underlying shares.

Recent Accounting Pronouncements

A description of recently issued accounting standards that may potentially impact our financial position, results of operations, and cash flows is included in Note 2 to our audited financial statements included elsewhere in this prospectus.

Emerging Growth Company and Smaller Reporting Company Status

We are an “emerging growth company” as defined in the JOBS Act. For as long as we remain an “emerging growth company”, we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to: (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act; (ii) reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and (iii) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and therefore, we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies; however, we may adopt certain new or revised accounting standards early. We may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.235 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

BUSINESS

Overview

We are a commercial-stage medical device company engaged in the design, development, and commercialization of innovative solutions to improve the health and quality of life of insulin-requiring people with diabetes (PWD) by utilizing advanced adaptive closed-loop algorithms to simplify and improve the treatment of their disease.

Diabetes is a serious, chronic, and often lifelong condition with no known cure that is characterized by extended periods of elevated levels of glucose in the bloodstream (hyperglycemia), resulting from the body's inability to either produce or effectively utilize the hormone insulin. To treat their diabetes, PWD must undergo a rigorous regimen of daily insulin substitution, as elevated levels of glucose in the blood over time can lead to serious and often life-threatening cardiovascular, metabolic and nervous system complications. Despite decades of innovation that have advanced the quality of care available, a significant unmet need remains as the vast majority of PWD still cannot manage their diabetes effectively.

Our product, the iLet Bionic Pancreas (iLet), was cleared by the U.S. Food and Drug Administration (FDA) for the treatment of T1D in adults and children six years of age and older in May 2023. The iLet autonomously determines and delivers every insulin dose without requiring a user to count carbohydrate intake, which we believe can make effective glycemic control easier to achieve. This unique ability of the iLet to determine 100% of all insulin dosing represents a new category in automated insulin delivery that is separate and apart from hybrid closed-loop devices, which only partially automate insulin delivery, making it more far-reaching than any other current technology on the market. Since we began commercializing the iLet, our installed base has grown , from 2,304 iLets as of December 31, 2023 to iLets as of September 30, 2024.

There are two principal types of diabetes within the overall population:

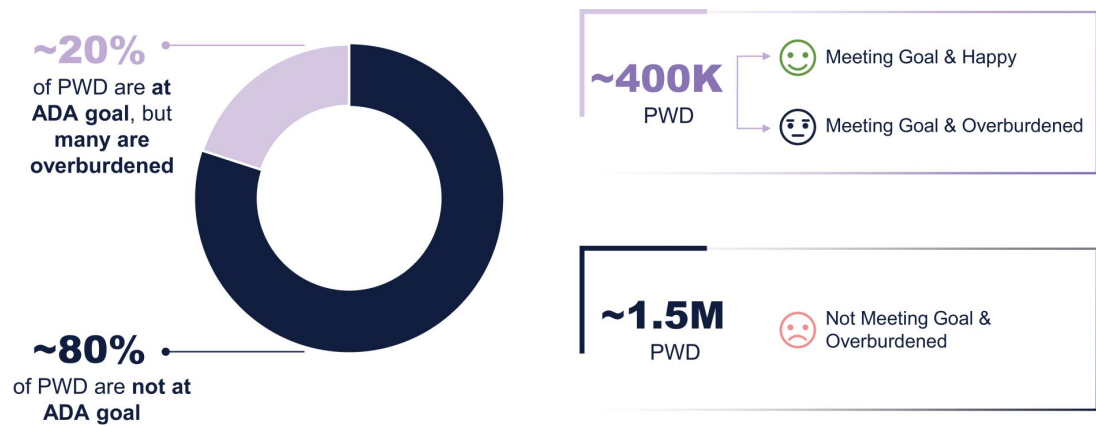
- Type 1 diabetes (T1D): an autoimmune disorder that often develops during childhood or adolescence, but can occur at any age, arising from a person's immune system attacking and destroying the insulin-producing beta cells in the pancreas leading to elevated blood-glucose (BG) levels. There are currently approximately 1.8 million people with T1D in the United States, all of whom require daily insulin replacement to manage their disease.
- Type 2 diabetes (T2D): a metabolic disorder that typically develops in adulthood, whereby the body becomes resistant to insulin, and, consequently, increased insulin production or replacement is needed to regulate BG levels. As T2D progresses, the body's beta cells cannot maintain the increased insulin levels needed to regulate BG. There are currently approximately 36 million people with T2D in the United States, of whom an estimated 1.8 million require daily intensive insulin therapy.

The dynamic evolution of care in the field of diabetes over the past several decades has been characterized by continuous cycles of innovation that have produced several generations of increasingly sophisticated and complex devices to help maintain BG levels within the normal range or achieve goal, as established by the American Diabetes Association (ADA). The capabilities of devices range from offering convenience features to allowing transformative improvements in efficacy. We believe that, while these new technologies have managed to remove or reduce some "twentieth-century burdens" of disease management (e.g., logbooks, fingerstick measurements, not knowing BG levels for large stretches of the day and night), they have also added new, "twenty-first-century burdens" (e.g., bombardment with overwhelming amounts of data, constant alerts and alarms, and 24/7 information overload). The psychological, emotional and cognitive burden imposed by the continuous need for user engagement to manage the disease is substantial, unsustainable by most

and unachievable by many. We believe that the iLet marks a significant breakthrough in the achievement of our ultimate goal, as it has been shown to enable clinically relevant improvements in glycemic control across broad populations of PWD, while dramatically reducing necessary user engagement.

Our initial commercialization efforts for the iLet have been focused on the T1D market. Currently, only about 20% of adults, and an even smaller percentage of children, with T1D meet or exceed the ADA goal for therapy for hemoglobin A1C (HbA1c), a measure of average BG levels over an extended period of time. Therefore, the remaining 80% are at elevated risk of developing an array of life-threatening cardiovascular, metabolic, and nervous system complications that arise as a result of chronic exposure to hyperglycemia. We believe that one of the principal causes of these suboptimal outcomes is the complexity of user experience of most currently available insulin pumps and partially automated insulin delivery (AID) systems, also known as hybrid closed-loop systems, which has kept the majority of PWD from adopting them despite the improved disease management these systems can offer. These systems require PWD to set and periodically adjust several insulin pump parameters, to quantify daily carbohydrate intake, and to frequently calculate proper doses of insulin for their pump to deliver. This complexity and the constant engagement required to achieve the full therapeutic benefits that these systems can offer limit the adoption of these systems to a subset of PWD and to subspecialty healthcare providers (HCPs). Currently, only approximately one-third of people with T1D in the United States utilize insulin pumps or hybrid closed-loop systems, while the majority receive their daily insulin via the self- administration of multiple daily injections (MDI) via a pen or syringe, a less complex, but often less effective, technique that is associated with higher HbA1c levels.

Figure 1. 80% of the T1D Market in the United States Is Not at ADA Goal for HbA1c



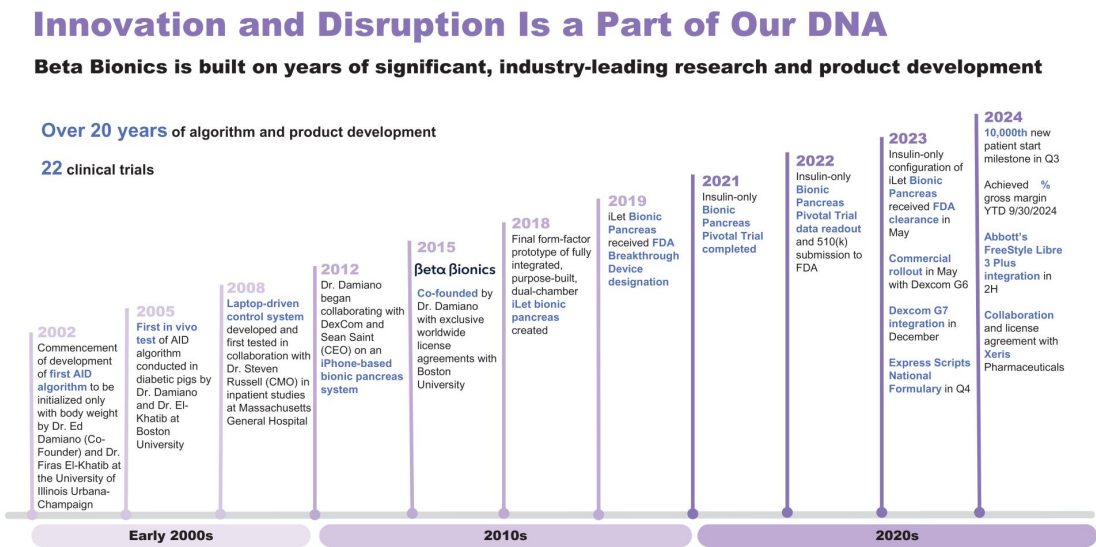
The iLet was specifically designed to provide improvements in glycemic control relative to insulin pumps hybrid closed-loop systems, and MDI therapy without the complexity and management burden of current insulin pumps and hybrid closed-loop systems. It is enabled by adaptive closed-loop algorithms that continuously learn each person’s unique and ever-changing insulin requirements and then autonomously delivers the correct insulin doses every five minutes throughout the day and night. Only the user’s body weight is required for initialization, unlike insulin pumps and hybrid closed-loop systems, which require a complex host of parameters to configure. The iLet autonomously determines all insulin doses. We believe this convenient product feature, coupled with improved glycemic control, will appeal to broad segments of PWD who are seeking a simpler path to improved disease management.

Figure 2. The iLet Bionic Pancreas



The iLet is the culmination of over 20 years of significant, industry-leading research and product development, as shown below. The iLet’s differentiated algorithms were first developed in 2002. To date, the iLet and its predecessor bionic pancreas devices have been evaluated in 21 pre-pivotal clinical trials and one pivotal trial. In total, over 800 individuals participated across all 22 trials.

Figure 3. Select Historical Achievements



The safety, effectiveness, and simplicity of the iLet were evaluated in the investigator-initiated iLet Bionic Pancreas Pivotal Trial (BPPT) of 440 people assessing the efficacy and safety of the iLet in people with T1D between the ages of six and 83 with starting HbA1c levels between 5.3% and 14.9%, which we believe is the largest and most diverse population ever studied in a pivotal clinical trial of an AID system. Participants were

randomized to either iLet therapy or standard of care (SC), which was defined as their own insulin delivery modality plus a DexCom G6 continuous glucose monitor (CGM) if they were not already using a DexCom G6 CGM as part of their own diabetes management regimen. As a group, the participants who randomized to iLet therapy experienced an average reduction in HbA1c from a baseline of 7.9% to 7.3% over 13 weeks, while participants who randomized to standard of care saw no change from a baseline of 7.7%. We believe the results of this trial validate the iLet's core value proposition of marrying effective glycemic control with the simplicity of use that is brought about by adaptive closed-loop algorithm insulin dose determination and delivery. The trial met its primary endpoint, finding that participants using the iLet demonstrated statistically significant and clinically relevant improvements in glycemic control versus the standard of care, both across the overall trial population and among important subgroups: adults only, children only, those with starting HbA1c levels greater than 7%, those on MDI, and those on insulin pump therapy without automation.

In addition, the improved glycemic control seen in the results of the BPPT has been supported by additional, "real-world" iLet data. Of the 5,190 iLet users who uploaded CGM readings to the Beta Bionics cloud over the first year after our commercial launch (May 19, 2023 to May 18, 2024), 3,675 of them had at least three-weeks' worth of iLet data (which affords at least one week of algorithm learning followed by two weeks to provide a reliable estimate of CGM outcomes). Of those 3,675 iLet users, 3,300 also had a pre-iLet baseline HbA1c value available. Data from these 3,300 users showed an overall improvement, from an average HbA1c of 8.5% to an average glucose management indicator (GMI)—a CGM surrogate for HbA1c—of 7.3%, which demonstrates a clinically meaningful improvement.

To maximize the commercial value of the iLet opportunity, we have assembled a team across our organization with broad experience in the successful commercialization of innovative technologies in the field of diabetes disease management. Our initial commercialization efforts have been focused on identifying the people with T1D most likely to adopt the iLet across multiple demographics, including age, level of glycemic control, current therapy, and HCP to create a multi-factor target-customer profile. Understanding how these factors interrelate with the decision to either adopt an AID system for the first time or to switch from an existing insulin pump or AID system will be key to identifying the people most likely to switch from their current therapy to the iLet and assisting with their transition. We have also partnered with DexCom, Inc. (DexCom) and Abbott Diabetes Care Inc. (Abbott)—global leaders in popular and easy to use CGM technology—to integrate the iLet with the DexCom G6 and G7 CGMs and with Abbott's FreeStyle Libre 3 Plus CGM sensor. The CGM is a crucial component of AID systems, and by partnering with these global leading CGM platforms, we believe we leverage all of the benefits that these CGMs offer in an elegant solution for PWD.

We promote sales of the iLet through an internal sales organization, where our initial direct sales efforts are focused on high volume endocrinology practices and, over time, the larger, but more diffuse, multispecialty practices in primary care. These primary care physicians (PCP) treat an estimated 50% of the T1D population in the United States but do so among a much more diversified patient base than the endocrinologists. We believe that the iLet's core value proposition of marrying effective glycemic control with the simplicity of use that is brought about by adaptive closed-loop algorithm insulin dose determination may resonate particularly well among PCP who do not have the subspecialty-level of expertise, the resources, or the clinical bandwidth that is needed to initiate insulin-pump or hybrid closed-loop therapy or for the continual demand those systems place on clinical practices in follow-on care.

We are also optimizing our direct sales efforts by growing, in parallel, an internal customer support team. All of this has been supplemented with strategic marketing initiatives and a targeted campaign we call the "Bionic Universe," which is built around a community of iLet users, caregivers, and key opinion leaders (KOLs) who share their stories to inspire others.

We are pursuing a multi-channel durable medical equipment (DME) and pharmacy benefit plans (PBP) coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device, provide PWD with advantageous coverage and reimbursement

terms and provide us with potential access to higher revenue streams. We are working with payors to expand the reach of coverage and reimbursement under both DME and PBP channels. We believe that utilizing a strategy between DME and PBP will make the iLet more accessible to PWD and the HCPs who recommend and initiate the device. We believe the PBP channel, in particular, reduces the administrative burden associated with DME reimbursement, minimizes the initial economic burden to PWD with little to no upfront cost, ensures faster and easier access for PWD to purchase the device, and, over time, is economically favorable to us.

In order to maintain our competitive position in the marketplace, we intend to continue investing in our research and development activities to expand the potential therapeutic applications of the iLet based on our scalable technology platform. We are currently developing the following products:

- **Patch Pump.** We are developing an insulin pump that is designed to adhere directly to the skin and administer insulin without the need for tubing, commonly known in the diabetes industry as a “patch pump.” Our patch pump features a two-component design: a durable component that contains the electronics and motor, and a disposable component that includes the insulin reservoir, adhesive, an insertion device, and a cannula. This design is intended to enable efficient manufacturing and provide a convenient pump-change experience. Our patch pump is intended to unlock a new pool of PWD who are looking to receive the many benefits of the iLet, but prefer the patch pump form factor.
- **Bihormonal iLet.** We are also developing a first-of-its-kind bihormonal configuration of the iLet, which combines automated delivery of insulin and glucagon, the BG-raising hormone that protects against low blood sugar (hypoglycemia), with adaptive closed-loop algorithms where all doses of both hormones are autonomously determined. Hypoglycemia, which can develop while a person is either awake or asleep, can lead to a range of acute medical complications, including tissue and organ damage, seizures, and coma; it can also be fatal. For people with T1D, the person’s immune system attacks and destroys the alpha cells in the pancreas that secrete glucagon. Consequently, people with T1D have a dual-hormone insufficiency, not just an insulin insufficiency. There are currently no commercially available devices capable of delivering both insulin and glucagon. We believe the ability to both proactively and reactively provide automated microdose administration of glucagon represents a large commercial opportunity and the next new paradigm in diabetes disease management—from automated insulin delivery to automated glycemic control. To advance this opportunity, we have entered into a collaboration and license agreement with Xeris Pharmaceuticals, Inc. (Xeris), whereby we have an exclusive license to commercialize a pump-compatible Xeris glucagon formulation.

In the future, we intend to pursue expanded use of the iLet to treat people with insulin-dependent T2D, as we believe the size and composition of this population make it a compelling opportunity. While there are certain differences in how T2D is treated relative to T1D, these differences primarily relate to the amount and rate of insulin delivered. Approximately 1.8 million PWD have T2D and require intensive insulin therapy, but fewer than 10% of this population has adopted pump technology to date. If the iLet is cleared for use in T2D, we believe that these individuals, who span socioeconomic and educational levels, and their HCPs, 90% of whom are PCP, may find the iLet’s combination of simplicity and efficacy particularly appealing.

We believe our financial and operating results and clinical and real-world data to date validate our opportunity, strategy, and execution. In the five full quarters since launching the iLet in May 2023, our quarterly revenue has grown over %—from \$3.1 million for the quarter ended September 30, 2023 to \$ million for the quarter ended September 30, 2024—while our operating expenses have grown only % during the same time period—from \$10.0 million to \$ million, respectively. Approximately % of the iLet’s adoption through September 30, 2024 came from PWD who were previously utilizing MDI, while the remainder came from PWD utilizing insulin pumps or hybrid closed-loop systems. We believe this split, which approximates the current share of the T1D population for each modality, demonstrates that the iLet’s value proposition is resonating across broad segments of the population of PWD and their HCPs.

Our revenue for the nine months ended September 30, 2024 was \$ million, more than that of our annual revenue of \$12.0 million for the year ended December 31, 2023. Our revenue for the nine months ended September 30, 2023 was \$3.6 million. Our net losses were \$ million for the nine months ended September 30, 2024 and \$25.3 million for the nine months ended September 30, 2023.

Our Strengths

We believe the success and continued growth of our company will be driven by the following strengths:

Highly Differentiated Technology Powered by Algorithmically Autonomous Insulin Dosing

Our novel iLet was developed to revolutionize the management of diabetes by offering meaningful clinical, ease-of-use, and quality of life improvements over the current standard of care. The iLet is the first FDA-cleared insulin delivery device that autonomously determines every insulin dose. Our system offers a significantly improved user experience by administering insulin without the need to count carbohydrate intake. The iLet was designed to maximize PWD's preference by integrating with leading CGM systems and allowing the use of either pre-filled or manually filled insulin cartridges. The iLet also represents a significant reduction in the setup and follow-on care burden currently borne by PWD and their caregivers. The initial setup of our device is designed to increase PWD and HCP accessibility by only requiring the input of the user's body weight, after which the iLet uses sophisticated proprietary algorithms to automate all insulin dosing. We believe that the combined innovative features of the iLet represent a meaningful breakthrough among other insulin delivery therapies to treat PWD, and may lead to improved disease management, quality of life, and penetration of the large and growing population of PWD.

Robust Compendium of Clinical and Real-World Data

We have developed a significant body of clinical data that demonstrates the safety, effectiveness, and simplicity of the iLet. Our BPPT of 440 volunteers with T1D between the ages of six and 83 years old with starting HbA1c levels between 5.3% and 14.9% represents what we believe is the largest and most diverse population ever studied in a pivotal trial of any AID device. The trial met its primary endpoint, finding a statistically significant and clinically meaningful improvement in HbA1c levels in participants randomized to use the iLet versus standard-of-care therapy across the overall trial population and among five clinically important subgroups: adults, children, those with starting HbA1c levels greater than 7%, those on MDI, and those on insulin pump therapy without automation. The results of this trial suggest that improved glycemic control can be achieved across delivery modalities without the burdens of frequent user engagement, and we believe these results validate the iLet's core value proposition. In addition, the improved glycemic control seen in the results of the BPPT has been supported by additional, "real-world" data generated from the CGM readings of 3,675 iLet users over the first year after our commercial launch (May 19, 2023 to May 18, 2024).

Significant New Product Pipeline

We have invested heavily in our research and development activities to expand the potential therapeutic applications of the iLet based on our scalable technology platform. Our proprietary algorithms have been developed and refined based on over a decade of clinical trials and real-world experience. We believe the continued advancement of our algorithms will be fundamental in improving health outcomes and quality of life for PWD. We are currently developing a smaller, semi-disposable patch pump that is intended to unlock a new pool of PWD who are looking to receive the many benefits of the iLet, but prefer the patch pump form factor. We are also advancing the development of our first-in-kind bihormonal iLet, which is designed to automatically deliver both insulin and glucagon. We believe the ability to both proactively and reactively automate glucagon administration would simultaneously improve HbA1c and reduce hypoglycemia.

Extensive Intellectual Property Portfolio

Our technology is supported by an extensive intellectual property portfolio which includes patents, know-how, and trade secrets. As of August 20, 2024, we own or have rights in 57 issued U.S. patents, 18 pending U.S. nonprovisional patent applications, three pending U.S. provisional patent applications, two pending Patent Cooperation Treaty (PCT) patent applications, 68 issued foreign patents, and 59 pending foreign patent applications (including three which are allowed), certain of which relate to various current or prospective aspects of the iLet, and related prospective bihormonal and adjunct products and methods. We also have exclusive, worldwide sublicensable licenses from the Trustees of Boston University (BU) to a portfolio of U.S. and international patents directed at the algorithms and other components of the iLet and an exclusive collaboration and license agreement with Xeris to commercialize a pump-compatible glucagon formulation.

Highly Efficient Business Model

Our goal is to continue to drive fiscally responsible revenue growth through enhanced patient access and vertically-integrated manufacturing. We are pursuing a multi-channel DME and PBP coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device, provide PWD with advantageous coverage and reimbursement terms and provide us with potential access to higher revenue streams. We are working with payors to expand the reach of coverage and reimbursement under both DME and PBP channels. As an alternative to DME, the PBP channel provides a lower upfront cost to PWD and potentially greater economic value to us over the life of the iLet. We believe utilizing this strategy optimizes medical and economic outcomes for key stakeholders and may result in enhanced user adoption. In addition, we have designed the various hardware, software, and electronics platforms of the iLet to maximize scalability, reliability, serviceability, and manufacturability from initial development, including multi-sourcing components to support production efficiencies. As a result, our gross margin was % for the nine months ended September 30, 2024.

Experienced Management Team

Our senior management team has extensive experience, including lived experience, in the diabetes and medical technology industry. Specifically, our team has extensive operating experience in commercialization, product development, clinical research, regulatory approval, and reimbursement of innovative medical technology products at well-regarded companies such as Medtronic plc (Medtronic), Tandem Diabetes Care, Inc. (Tandem), and Companion Medical, Inc. in insulin pump therapy, and DexCom in CGM. Since our founding, we have been supported by a seasoned board of directors with extensive industry and public company experience.

Our Strategy

Our mission is to grow our business by successfully commercializing our innovative solutions for safe, simple, and effective autonomous glycemic control and to reach as many people living with insulin-requiring diabetes as we can. Our goal is to establish the iLet as the standard of care for insulin delivery. The key elements of our growth strategy are as follows:

Continue our commercialization efforts by utilizing our sales force to educate PWD and HCPs on the compelling potential benefits of the iLet and to drive awareness

To fully realize the commercial opportunity presented by the iLet, we have developed an integrated commercial strategy to drive adoption across the T1D population and establish and maintain customer loyalty through customer service and educational programs. We promote sales of the iLet through an internal sales organization, where the initial direct sales efforts have been focused on high-volume endocrinology practices. Over time, we plan to expand our commercial focus to the larger, but more diffuse, market of PCP in multispecialty practices. We believe that the iLet's core value proposition of marrying effective glycemic control

with the simplicity of use that is brought about by adaptive closed-loop algorithm insulin dose determination may resonate particularly well among PCP who we believe service an estimated 50% of the T1D population in the United States but who do not possess the subspecialty-level of expertise, the resources, or the clinical bandwidth that is needed for insulin-pump or hybrid closed-loop therapy or for the continual demand those systems place on clinical practices in follow-on care.

Build our commercial and customer support infrastructure to maximize access to the iLet and maximize customer retention

We have an integrated customer-support strategy designed to efficiently fulfill orders, educate both new users and their caregivers during device initialization and follow-on care, and respond promptly to inquiries throughout the life of the product. Our commercialization efforts are supplemented with strategic marketing initiatives and a targeted campaign we call the “Bionic Universe,” which is built around a community of iLet users, caregivers, and KOLs who share their stories to inspire others. We utilize both direct media and social media communications strategies to build the Bionic Universe. We leverage feedback from this community to continuously upgrade both current and future device generations.

Leverage our in-house manufacturing capabilities to optimize production efficiency and maintain quality

We manufacture the iLet and the ready-to-fill insulin cartridges at our facilities located in Irvine, California. By assembling and testing the iLet in-house, we believe that we can maintain better quality control and compliance with our own internal specifications and with applicable regulatory standards. We expect that our 50,000 square foot facility in southern California, which commenced operations in 2020, will have sufficient production capacity to support our anticipated clinical and commercial demand for the foreseeable future.

Obtain third-party coverage and reimbursement from payors under both DME and PBP channels

We are pursuing a multi-channel DME and PBP coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device, provide PWD with advantageous coverage and reimbursement terms and provide us with potential access to higher revenue streams. We are working with payors to expand the reach of coverage and reimbursement under both the DME and PBP channels. We believe that utilizing this strategy between DME and PBP will make the iLet more accessible to PWD and the HCPs who prescribe the device. The PBP channel reduces the administrative burden associated with DME reimbursement, minimizes the initial economic burden with little to no upfront cost, ensures faster and easier access for PWD to purchase the device, and, over time, is economically favorable to us.

Increase our addressable market by developing a patch pump and bihormonal iLet, as well as seeking expansion into the treatment of T2D

We are leveraging our algorithms to develop two additional products in our pipeline: the patch pump and the bihormonal iLet. The patch pump is an insulin pump that is designed to adhere directly to the skin and administer insulin without the need for tubing. Our patch pump features a two-component design: a durable component that contains the electronics and motor, and a disposable component that includes the insulin reservoir, adhesive, an insertion device, and a cannula. This design is intended to enable efficient manufacturing and provide a convenient pump-change experience. The bihormonal iLet is being designed and configured to administer both insulin and glucagon—the hormone responsible for raising BG levels—in a fully closed-loop system in which all doses of both hormones would be determined and delivered autonomously. We believe this bihormonal capability would offer a meaningful additional benefit to PWD as it would allow the proactive raising of glycemic levels as needed to reduce the risk of hypoglycemia.

In addition, we intend to pursue expanded use of the iLet to treat people with insulin-dependent T2D, as we believe the size and composition of this population make it a compelling opportunity. While there are certain

differences in how T2D is treated relative to T1D, these differences primarily relate to the amount of insulin delivered. Approximately 1.8 million PWD have T2D and require intensive insulin therapy, but fewer than 10% of this population has adopted pump technology to date. We designed the iLet to serve both the T1D and T2D populations.

Diabetes Overview

Insulin-deficient diabetes can lead to chronic, life-threatening diseases for which there are no known cures. Over its typically multi-decade course, diabetes can lead to many serious and often life-threatening complications, including cardiovascular disease, kidney disease, stroke, blindness, neuropathy and cognitive impairment.

Diabetes is a complex, multisystemic disease characterized by sustained and prolonged elevated BG levels, or hyperglycemia, that results from the body's inability to either produce the hormone insulin, which is responsible for the proper metabolization of glucose, or properly utilize it. In the absence of insulin, ketones rise in the blood, which becomes acidotic. Insulin insufficiency leads to catabolism (in which the body begins to waste fat and muscle), which in the extreme, leads to diabetic ketoacidosis (DKA), and, ultimately, death. PWD also face the daily risk of low blood sugar, or hypoglycemia, which has multiple causes, including receiving excess exogenous insulin in the course of disease management. Hypoglycemia, which can strike without warning, starves the brain of needed glucose and can result in cognitive impairment, loss of consciousness, seizures, and death.

As diabetes has no known cure, its treatment paradigm entails an arduous daily regimen of disease management and insulin substitution whereby PWD must maintain constant vigilance regarding both their BG levels and the amount of insulin they receive. The long disease course, daily management requirements, and potentially catastrophic consequences of mismanagement each represent a significant burden to PWD, their caregivers, and society at large. Despite decades of innovation that have advanced the quality of care available, the vast majority of PWD cannot currently manage their diabetes effectively. The ramifications of this suboptimal treatment are substantial. Diabetes is estimated to shorten overall life expectancy by 7-10 years on average. According to the ADA, PWD are estimated to spend 2.5 times more on healthcare than people without it throughout their lifetime. In addition to the clinical burden of diabetes, the financial burden is substantial with an estimated annual cost to the U.S. healthcare system of over \$400 billion.

According to the Centers for Disease Control (CDC), in 2021 there were an estimated 29.7 million people in the United States who had been diagnosed with diabetes, representing approximately 9% of the overall U.S. population. The two most prevalent subtypes of diabetes are referred to as type 1 and type 2 diabetes.

- Type 1 diabetes is an autoimmune disorder that usually develops during childhood or adolescence, but can occur at any age, and arises from the inability of the body to produce insulin due to the destruction of insulin-producing beta cells in the pancreas. People with T1D are also deficient in the hormone glucagon, which serves as the body's natural protection for low blood sugar, or hypoglycemia. In the United States, it is estimated that 1.8 million people have T1D and rely on intensive insulin therapy.
- Type 2 diabetes is a metabolic disorder that typically develops in adulthood as the body becomes resistant to insulin and, consequently, more insulin is needed to manage BG levels. As a result, the pancreas needs to produce more insulin than it normally would, which results in excess stress on beta cells. As the disease progresses, the beta cells cannot produce sufficient insulin for the increased needs. In many cases, daily insulin replacement becomes required despite the availability of other classes of medications. About 1.8 million or about 8% of the overall T2D population require intensive insulin therapy.

Our focus has been on the T1D population, but over time, we may expand our focus to include people with T2D who require intensive insulin therapy. In the coming decades, the total prevalence of PWD in the United States is expected to continue to increase meaningfully. The number of people with T1D is expected to grow in line with overall population growth, while those with T2D are currently expected to grow at a significantly faster rate due to the growth in risk factors for developing T2D, such as obesity.

The Current T1D Disease Management Paradigm

According to the ADA, the central objectives for disease management in the treatment of T1D are sustaining HbA1c levels at or below 7% over time while maintaining daily BG levels between 70 and 180 mg/dL, near the range experienced by healthy individuals, for 17 or more hours per day. Those accomplishing these goals have been shown to significantly reduce their risk of developing the long-term complications of diabetes. These guidelines were established based on the results of the landmark Diabetes Control and Complications Trial (DCCT). These results demonstrated that failure to maintain BG near an acceptable range had long-term negative health consequences for PWD, exacerbating the complications of the disorder. The achievement of glycemic goals, however, is a daunting task due to the lifelong, daily requirements and the complex and dynamic nature of the factors that drive BG levels. Currently, only about 20% of adults in the United States with T1D meet these established therapy goals for HbA1c. We believe that one of the principal reasons for these suboptimal outcomes is that, despite decades of innovation and clinical data demonstrating their superiority to alternatives, insulin pumps have only been adopted by approximately one-third of people with T1D. We believe that one reason for this relatively low adoption rate is the demands placed on users to perform the complex tabulations and calculations required for even the most advanced pumps (other than the iLet) to function optimally.

Current Treatment Strategies

The current day-to-day strategy for T1D disease management is a two-step process comprised of monitoring one's BG level and administering appropriate amounts of insulin, both to satisfy baseline needs and to adjust as glycemic levels change throughout the day, primarily due to food intake and physical activity. PWD have multiple options available to perform both the monitoring and administration functions, ranging from a fully manual process to nearly complete automation. The primary means of performing each function are as follows:

Monitoring

Glucose Meters and Test Strips

First introduced in the 1970s, this technique requires a PWD to take a blood sample, typically from their finger, several times a day to measure BG directly from the bloodstream. Monitoring BG in this fashion can be extremely accurate at the time of measurement but is limited in its overall utility by the large variations in BG that can occur between measurements. In order for this technique to be an effective diabetes management tool, measurements must be performed in regular intervals as often as several times a day and before or after various activities. It is estimated that 30% of people with T1D in the United States utilize glucose meters and test strips as their primary means of determining their BG level.

Continuous Glucose Monitor (CGM)

A continuous glucose monitor (CGM) is a wearable device that provides regular estimates of BG based on levels present in the interstitial fluid, a thin layer of fluid that surrounds the cells of tissue below the skin. CGM devices enable the constant monitoring of BG levels via a catheter or sensor typically inserted subcutaneously in the back of the arm or abdomen. The sensor tracks changes in glucose levels throughout the day and night, as often as every five minutes, and provides glucose readings through wireless data transfer to a receiver.

A CGM typically contains three components:

- a small electrode that is placed under the skin

- a transmitter that sends readings from the electrode to a receiver at regular intervals (every one to 15 minutes)
- a separate receiver that shows the glucose level on a display

Since receiving FDA approval in 2005, real-time CGMs have been adopted by an estimated 70% of people with T1D in the United States, with most of the adoption occurring since 2018, when the first CGM that no longer required calibration from blood samples received FDA approval.

Insulin Delivery

MDI

MDI insulin therapy is the most widely used method of insulin delivery as it requires minor training and has a lower relative cost to users. MDI consists of the delivery of insulin via several discrete subcutaneous injections, typically four or five, per day by either syringe or pen. This typically includes one injection of long-acting insulin per day and an injection of rapid- or short-acting insulin before each meal. The long-acting insulin (basal insulin) is designed to release slowly and evenly in the bloodstream for about 24 hours after it is injected and act as the background insulin would in a person without diabetes. The short-acting insulin (bolus insulin) is intended to act like the insulin released by the pancreatic beta cell around mealtimes in a person without diabetes. Since the inception of exogenous insulin therapy in 1922, MDI has been the standard of care for the majority of PWD. Currently, of the approximately 1.8 million people with T1D in the United States, approximately two-thirds of the population utilize MDI. Although MDI requires minimal training, a great deal of sophistication and vigilance on the part of the user is required to achieve good results with this approach.

Insulin Pumps

Insulin pumps, first introduced in 1974, perform continuous subcutaneous insulin infusion and typically involve the use of a tethered programmable pump that administers insulin through an infusion set into a person's body. Insulin pumps deliver continuous small doses of rapid-acting insulin to fulfill both basal (to reproduce long-acting insulin) and mealtime requirements, which more closely resembles the physiologic function of a healthy pancreas. Current-generation pumps offer a number of potential advantages relative to MDI, including the elimination of MDI, more precise insulin administration, greater glycemic control, and greater lifestyle flexibility. More recent innovations have enabled the direct integration of insulin pumps with data from a wearable CGM sensor to form hybrid closed-loop systems which incorporate algorithms that modulate pump settings to adjust the insulin delivery. Since their introduction, approximately one-third of the overall population with T1D have adopted an insulin pump.

Limitations of Current Insulin Delivery Devices

Both MDI and insulin pumps exhibit limitations either in convenience, glycemic control, or both, and neither has eliminated the need for substantial user engagement to achieve adequate glycemic control. The primary limitations of each modality are as follows:

MDI

The primary drawback of MDI is its inherent imprecision, as it delivers insulin in large quantities at four to five discrete intervals throughout the day on average, and therefore does not mimic the natural insulin utilization patterns of a healthy metabolic system. Because dosages cannot be corrected, slowed, or withdrawn once given, this fundamental mismatch leads to wider variability in overall glycemic levels, inferior long-term outcomes for users, and a higher risk of dangerous hypoglycemic episodes. MDI also requires users to count the carbohydrates they consume, manually self-calculate the correct dosage and administer multiple dosages each day. This process can be complicated, burdensome, prone to error and incompatible with many lifestyles.

Insulin Pumps

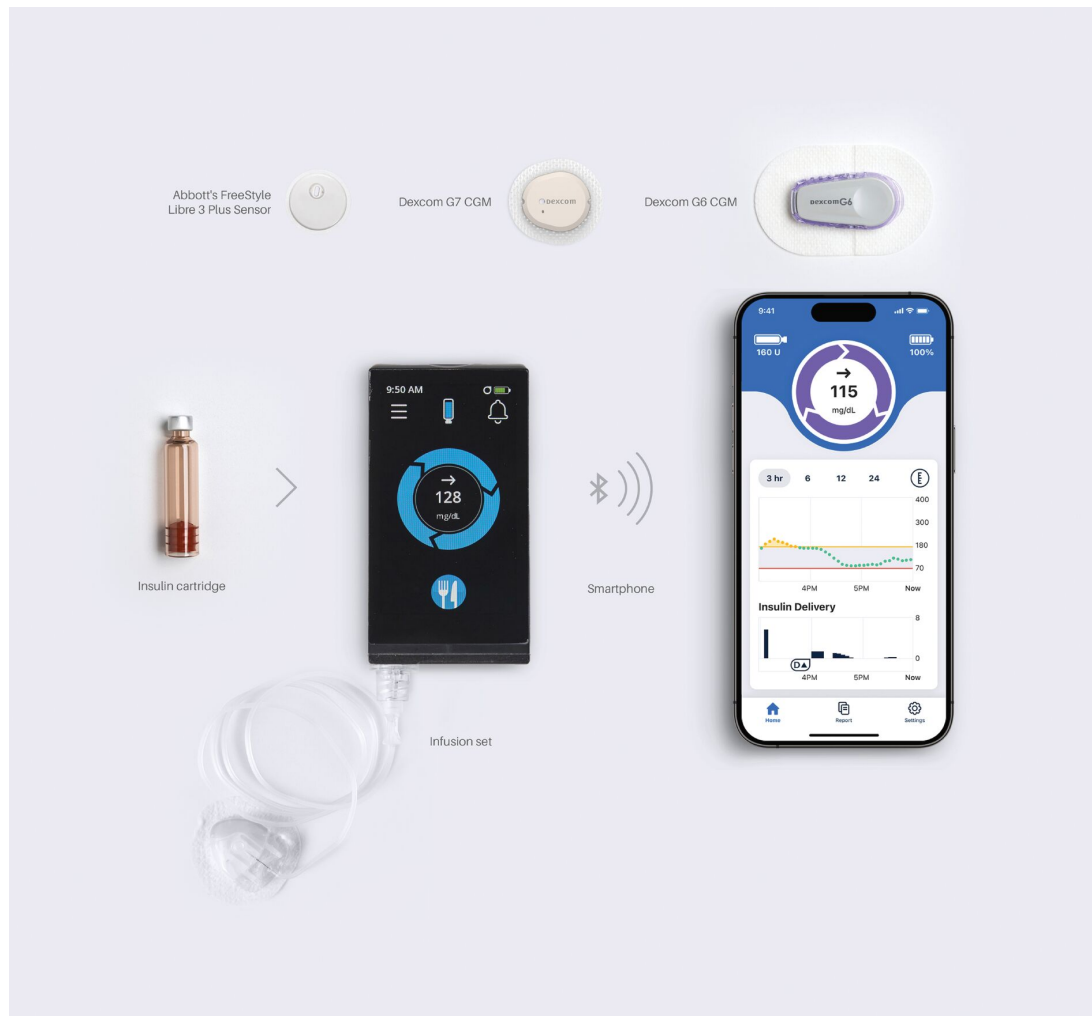
Insulin pumps, when utilized optimally, represent a significant medical advance relative to MDI. To achieve this optimal functionality, however, the user of a currently available pump (other than the iLet) must make several manual adjustments throughout the day. Properly making these adjustments requires ongoing tabulation of food intake and calculation of the correct food-to-insulin ratios. All calculations and adjustments are based on a comprehensive understanding of absolute levels of glucose at a given time, whether levels are static or changing, and, if changing, how rapidly they are doing so. The proper operation of an insulin pump, therefore, requires extensive education and training for both users and caregivers. As such, the recognized clinical advantages provided by pumps have been insufficiently compelling to the majority of people with T1D to warrant adoption. The primary requirements for optimizing the effectiveness of current-generation pumps are:

- ***Initialization of and Ongoing Intervention for Insulin Dosing Regimen.*** All current technologies, except iLet, rely on a process of trial and error with physician intervention over many months to determine a user's basal insulin rates, insulin correction factors, and carbohydrate-to-insulin ratios. This process requires the expertise of a clinician specially trained in the use of insulin pump therapy and vigilant participation by the user. Once calibrated to the individual, current pump technologies require iterative manipulation of user-specific variables that must be revisited several times a year by the HCP, which adds to the burden of diabetes management.
- ***Carbohydrate Counting.*** All current technologies, except iLet, require the user to quantitatively estimate the amount of carbohydrates they will be consuming (i.e., the number of grams of carbohydrate) and manually enter meal bolus dosing specifics to prevent BG from rising too high.
- ***Manual Calculation of Correction Dosages.*** All current solutions, except iLet, require the user to input the necessary treatment adjustment calculations to function optimally and deliver insulin to bring BG down.
- ***Manual Filling of Insulin Cartridges.*** None of the systems currently available on the market in the United States, except iLet, are compatible with prefilled insulin cartridges. Non-iLet users are required to handle an insulin vial and use a syringe with a needle to fill either a pump cartridge or reservoir.

Our Solution: The iLet Bionic Pancreas

We believe the iLet addresses the significant limitations of current insulin delivery and benefits a significant community of PWD living with T1D. FDA-cleared in May 2023, the iLet is the first adaptive closed-loop algorithm insulin dosing system that does not require T1D users to keep a daily tabulation of their carbohydrate intake or perform calculations to determine the correct dose of insulin to take. Its compact size and integration with the leading CGMs via Bluetooth make it well suited for those people living with T1D who prefer a discreet and convenient approach to personalized disease management with adaptive closed-loop algorithm insulin dosing and delivery. The iLet's convenient form factor is augmented by a user interface that presents all relevant data in a familiar app-based format, allowing users to receive real-time updates on any adjustments the iLet is making. The iLet's share/follow feature allows data to be shared in real time with a trusted "Bionic Circle" of friends and family members. This feature can be particularly helpful in the pediatric setting, where PWD and their parents are learning the nuances of T1D.

Figure 4. The Suite of Components of the iLet



As shown above, the iLet includes:

- a pumping platform, which consists of the pump itself and related single-use products, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. The pumping platform is designed to deliver analog insulin alone using either a prefilled cartridge or an empty cartridge that the user fills using an external insulin source of their choice;
- a suite of adaptive control algorithms that autonomously analyze and administer the delivery of insulin doses based on CGM data;
- an intuitive touchscreen display that enables user interactions through a custom graphical user interface embracing smartphone simplicity; and

- a wirelessly rechargeable battery and wireless software update capabilities.

The iLet integrates with the user's CGM device (either DexCom G6 or G7 or Abbott's FreeStyle Libre 3 Plus), which measures the user's glucose levels. The iLet's suite of three adaptive algorithms then work together to understand the user's distinct patterns of food intake and insulin needs, allowing the iLet to make all insulin dosing decisions with minimal human intervention. The three algorithms described below, refined over more than a decade, are the key enabling innovation of the iLet.

Basal Algorithm

The proportional-derivative (PD) basal algorithm determines daily basal insulin requirements and autonomously adapts to the user's changing insulin needs. Our adaptive basal insulin algorithm obviates the need for the user to set, or even know, their basal-rate profile. The algorithm has been optimized to continuously update the user's basal-rate profile throughout 288 segments each day.

Corrections Algorithm

Running in parallel with the basal algorithm, the model-predictive control (MPC) correction algorithm automatically modulates insulin delivery in addition to basal insulin delivery by either adding (to reduce risk of hyperglycemia) or reducing (to reduce the risk of hypoglycemia) dosage levels of insulin dynamically based on changing needs throughout the day. We incorporate insulin pharmacokinetics into the MPC algorithm by augmenting it with a mathematical formulation for estimating current concentration of insulin in the blood and predicting future concentrations. Our algorithm takes into consideration the slow absorption rate of insulin analogs and is designed to help prevent the iLet from delivering excess insulin which often occurs in MDI, insulin pump, or hybrid closed-loop systems due to user error. Furthermore, our correction algorithm automatically adjusts its insulin dosing aggressiveness in real time to accommodate the different insulin needs between individuals and the variable needs within the same person. Our adaptive correction insulin algorithm obviates the need for the user to set, or even know, their insulin correction factor.

Meal Announcement Algorithm

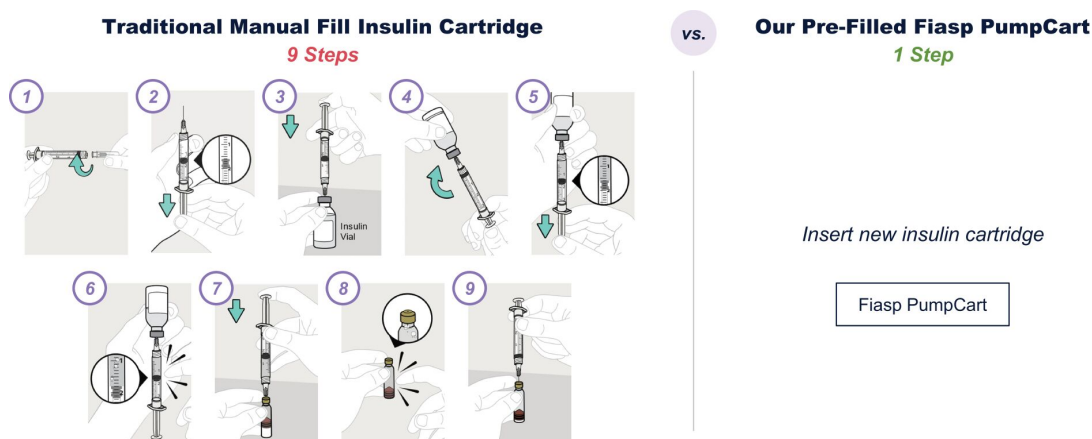
The meal announcement algorithm automatically adapts insulin doses at mealtime without requiring the user to determine the specific level of carbohydrate intake. Instead, the user makes a simple declaration that an upcoming meal will be within historical norms, "the usual for me," or higher or lower than typical. Our adaptive meal dose insulin algorithm obviates the need for the user to set, or even know, their carbohydrate to insulin ratio.

Other advantages of the iLet include pre-filled insulin cartridges, a simplified startup process and a mobile application, as described below.

Pre-filled Insulin Cartridge

Another significant advantage of the iLet is its utilization of prefilled faster insulin aspart (Fiasp) cartridges that allow users to quickly swap out expired cartridges with new ones without the multiple cumbersome steps required of users of the self-filling insulin reservoirs used by other pump systems. This eliminates the burden of requiring users to handle an insulin vial and use a syringe with a needle to fill a pump cartridge or reservoir. We believe prefilled cartridges present convenience advantages and lower training requirements as compared to self-filling reservoirs; they may also reduce user error because of the fewer steps involved. To provide flexibility, the iLet also provides users with the option to fill ready-to-fill cartridges with their choice of insulin aspart (Novolog) or insulin lispro (Humalog). Both are rapid-acting forms of insulin that begin working within 20 minutes of delivery. The iLet's algorithms automatically adjust to the type of insulin being delivered without requiring any input by the user.

Figure 5. Comparison Between a Manual Fill Insulin Cartridge and Our Pre-Filled Insulin Cartridge



Simplified Startup Process

In contrast to existing technologies, the iLet features a simple user interface that only requires the input of a user's body weight to initialize dosing. Should a user's body weight increase or decrease by more than 15%, changing the device input can be done easily.

The iLet Mobile Application

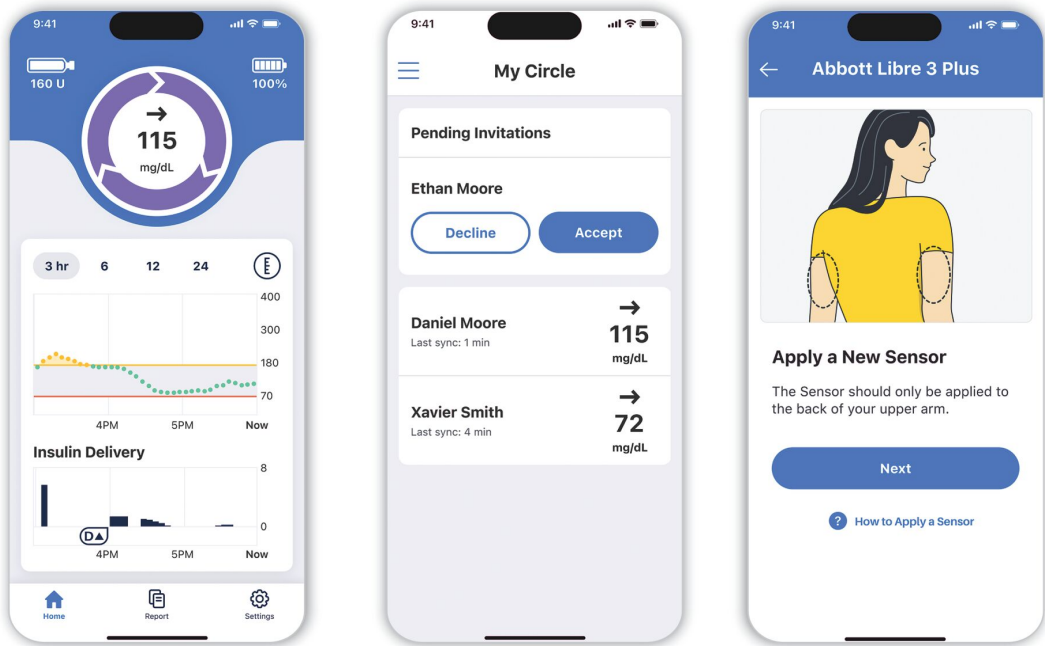
The iLet mobile application's features include:

- an easy-to-use interface;
- easy-to-understand reports for the user and physician;
- firmware over-the-air upgrades;
- compatibility with the iOS platform and the Android platform; and
- automatic data uploads to the cloud.

The mobile application receives information from the iLet and displays that information discreetly to the user. This user-friendly, intuitive mobile application provides real-time glucose readings, trends, and graphs. It also allows for cloud-based storage.

The iLet's share/follow feature allows data to be shared in real time with a trusted "Bionic Circle" of friends and family members. This feature can be particularly helpful in the pediatric setting, where PWD and their parents are learning the nuances of T1D.

Figure 6. The iLet Mobile Application’s Share/Follow Feature



The Commercial Opportunity for the iLet Bionic Pancreas to Address the Unmet Need

Despite the inherent benefits that pump technology provides, the management of insulin-dependent diabetes remains difficult. Smart pump technologies have had little success in alleviating the heavy burden on PWD as they still generally require perpetual monitoring and disciplined intervention. We believe this burden is responsible for limiting the number of users who have transitioned to pump use to roughly half the number of users that have adopted CGM. This remaining burden represents a significant unmet need that the iLet can address. Therefore, we believe the availability of the iLet may substantially increase the number of PWD who would consider pump use. In fact, approximately 51% of the iLet’s adoption through December 31, 2023 came from PWD who were previously utilizing MDI. We believe that the iLet represents one of the first significant advances in insulin delivery technology since the commercial availability of hybrid closed-loop systems in 2017 and offers users a substantially enhanced experience relative to all insulin delivery methods because it automates the determination of all insulin doses and provides the greatest flexibility in CGM and insulin choice. This allows the iLet to remove a substantial daily burden from users while offering improved glycemic control.

Figure 7. The Current Commercial Landscape for the iLet

	iLet Bionic Pancreas	Tubeless Hybrid Closed-Loop System	Tubed Hybrid Closed-Loop System	Insulin Pens
	Beta Bionics	Insulet	Medtronic and Tandem	Multiple
Initialized with only body weight	✓	✗	✗	✗
Algorithm(s) determine 100% of insulin doses	✓	✗	✗	✗
No carb counting	✓	✗	✗	✗
Pay-as-you-go pharmacy reimbursement	✓	✓	✗	✗
Patch form factor	✗	✓	✗	✗
Prefilled cartridges	✓	✗	✗	✗

The commercial opportunity for the iLet in T1D is substantial. The T1D total addressable market for insulin pumps in the United States is estimated to be approximately \$6 billion and is forecasted to grow at approximately 2% per year (in line with overall population growth). There are two distinct subpopulations whose needs could be addressed by a product of iLet’s profile:

Existing Pump Users: Approximately One-Third of the total T1D population, \$2 billion total addressable market

The value of the existing pump market in the United States was estimated to be approximately \$2 billion in 2023, with a projected compound annual growth rate (CAGR) of 11% through 2027. The market is concentrated primarily among three leading competitors—Medtronic, Tandem, Insulet Corporation (Insulet), who collectively hold approximately 96% market share.

Potential New Pump Adopters: Two-thirds of the total T1D population, \$4 billion total addressable market

Approximately two-thirds of people with T1D in the United States do not currently utilize a pump for insulin treatments and instead use MDI via either a syringe or an insulin pen. PWD who use MDI encounter similar challenges as those who use hybrid closed-loop systems, including the need to count carbohydrates and calculate correction boluses. Furthermore, insulin pens lack the discretion and convenience of pumps. This U.S. patient population, though declining at an approximate 9% CAGR, would be valued at \$4 billion if fully converted to pumps.

Figure 8. A Comparison Between the iLet and MDI Therapy

iLet Bionic Pancreas	Prefilled Insulin Syringes and Insulin Pens
✓ Simplest to operate ✓ Algorithms learn users’ unique physiology ✓ No settings ✓ No carb counting	✗ Inconvenient and cumbersome process; need to carry insulin syringes and pens and overtly deliver boluses prior to meals • Daily: administer 4-5 shots per day including ~1-2x of basal insulin ✗ Carb counting / delivering boluses ✗ Adjust basal insulin rates ✗ Calculate insulin correction factors ✗ Extend bolus for high fat meals

In the past, people with T1D have shown willingness to quickly adopt new technologies when the value proposition was far superior to previously available options. We believe the iLet represents such a breakthrough, and its superiority could catalyze an adoption cycle similar to the one observed with CGMs in recent years. In that product space, the innovation of removing manual calibration materially accelerated adoption by improving both user experience and outcomes. Similar to insulin pumps, CGMs struggled for decades to gain a majority

share. The first real-time CGM received FDA approval in 2005, but it was not until 2018, with the release of the DexCom G6, the first CGM that did not require fingerstick calibrations, that the CGM value proposition became compelling to a majority of people with T1D. Since then, CGMs have been adopted by an estimated 70% of people with T1D in the United States. We believe a similar potential exists for the iLet to dramatically expand the reach of insulin delivery technologies in the marketplace.

iLet Development History

The iLet is the culmination of over 20 years of research, including extensive pre-clinical and clinical trial work. To date, the iLet and its predecessor bionic pancreas devices have been evaluated in 21 pre-pivotal clinical trials and one 440-participant pivotal trial. In total, over 800 individuals participated across all 22 trials. Results from these trials have been published in over 15 peer-reviewed manuscripts. Collectively, these trials demonstrated both strong efficacy and safety data for the iLet and, over time, informed the refinement and development of the iLet's algorithms. The pivotal trial results have been supported by our real-world data, which we have been gathering since first commercializing the iLet in May 2023. The iLet algorithms are the most thoroughly studied and tested of all dosing-decision technologies for AID systems. Efforts to emulate these algorithms would require years of clinical testing, iteration, and retesting, along with extensive regulatory review.

Pre-pivotal clinical trials testing the bionic pancreas algorithms and the iLet Bionic Pancreas System

The pre-pivotal clinical trials testing the bionic pancreas algorithms began in 2008 and continued through 2019, the year before the test-run period of the pivotal BPPT began in the fall of 2020. The 22 pre-pivotal trials were completed over this 12-year period. Twenty of these trials involved subcutaneous insulin infusion alone or subcutaneous insulin and glucagon infusion, and 16 of those 20 trials studied people with T1D. During the first four years (2008–2012), three of those 16 T1D trials were conducted in the inpatient setting at the Translational and Clinical Research Centers (formerly the Mallinckrodt General Clinical Research Center) at the Massachusetts General Hospital (MGH), with the control algorithms running on a laptop computer. Eleven of the remaining 13 T1D trials were conducted between 2013 and 2019 in the outpatient setting in either a hotel, summer camp, or home-use environment. In seven of these 11 outpatient trials, the control algorithms ran on an iPhone that received real-time data from a CGM and delivered insulin and/or glucagon through one or two Tandem t:slim insulin pumps that were actuated via Bluetooth with doses commanded by the control algorithms running on the iPhone. In 2018 and 2019, the remaining four of the 11 outpatient trials were conducted with the iLet in adults and children with T1D.

An additional four pre-pivotal trials, which are not described in the table below, were conducted with the iPhone or iLet versions of the bionic pancreas in people with congenital hyperinsulinism, cystic fibrosis related diabetes, T2D, and people who had received bariatric surgery and were at risk of hypoglycemia. Also not described below are two of the T1D trials (one in the in-patient setting with the iPhone system and one in the home-use setting with the iLet) that were conducted with a previous bihormonal configuration of the bionic pancreas, using dasiglucagon (ZEGALOGUE). Descriptions of the remaining 13 T1D trials are included in the table below. In all of the more than 20 pre-pivotal trials that were conducted to test the algorithms over a 12-year period, or in any of the other trials that are not included in Figure 9 below, there were no severe hypoglycemic events or DKA events associated with the bionic pancreas algorithms.

Figure 9. Summary of the iLet Bionic Pancreas Pre-Pivotal Clinical Trials in Adults and Children with T1D

Year	Name of Study	System	Setting	Design			Evolution of Bionic Pancreas and Algorithm Innovations
				Cohort	Method	Duration / Participant	
2008-2009	First Inpatient Study	Laptop system (bihormonal)	Inpatient	11 adults with T1D	Single-arm intervention	27 hours	• First ever Investigational Device Exemption (IDE) approved by the FDA of an academically derived closed-loop BG control system • First ever human trial of a bihormonal closed loop BG control system • Allowed for testing, refining and validating the pharmacokinetic model for insulin absorption used by corrections algorithm (static basal insulin algorithm) Reference: El-Khatib et al. (2010) <i>Science Translational Medicine</i>, 2:27ra27
2010	Second Inpatient Study	Laptop system (bihormonal)	Inpatient	6 adults with T1D	Single-arm intervention	51 hours with exercise	• First ever CGM driven control of the bihormonal BG control system with static (non-adaptive) meal announcements • First tested autonomous modulation of insulin basal rate by the bionic pancreas based on CGM input Reference: Russell et al. (2012) <i>Diabetes Care</i>, 35:2148-2155
2012	Third Inpatient Study	Laptop system (bihormonal)	Inpatient	12 adults with T1D, 12 teens with T1D	Randomized controlled trial with two intervention arms (with and without meal-priming boluses) and no control arm	51 hours with exercise	• First test of the adaptive meal announcement algorithm • Added lifelong learning capabilities of the insulin corrections algorithm • Added an adaptive PD algorithm for basal insulin delivery • Included multiple time-scale adaption for both algorithms (corrections and basal insulin) Reference: El-Khatib et al. (2014) <i>Journal of Clinical Endocrinology & Metabolism</i>, 99:1701-1711

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Year	Name of Study	System	Setting	Design		Duration / Participant	Evolution of Bionic Pancreas and Algorithm Innovations
				Cohort	Method		
2013	<i>The Beacon Hill Study</i>	iPhone bionic pancreas (bihormonal)	Outpatient (hotel setting)	20 adults with T1D	Two-arm, random-order cross-over	5 days	- First ever outpatient trial on a mobile platform of a closed-loop BG control system - Further refinement was made of the multiple time-scale adaptation and lifelong-learning capabilities of the insulin algorithms <i>Reference: Russell et al. (2014) New England Journal of Medicine, 371:313-325</i>
2013	<i>The 2013 Summer Camp Study</i>	iPhone bionic pancreas (bihormonal)	Outpatient (sleep-away camp setting)	32 children with T1D (12-21 years old)	Two-arm, random-order cross-over	5 days	- First outpatient study of the iPhone bionic pancreas in adolescents with T1D - Further refinement was made of the multiple time-scale adaptation and lifelong-learning capabilities of the insulin algorithms <i>Reference: Russell et al. (2014) New England Journal of Medicine, 371:313-325</i>
2014	<i>The 2014 Summer Camp Study</i>	iPhone bionic pancreas (bihormonal)	Outpatient (sleep-away camp setting)	19 children with T1D (6-11 years old)	Two-arm, random-order cross-over	5 days	- First outpatient study of the iPhone bionic pancreas in pre-adolescents with T1D - Further refinement was made of the multiple time-scale adaptation and lifelong-learning capabilities of the insulin algorithms <i>Reference: Russell et al. (2016) The Lancet Diabetes and Endocrinology, 4:233-243</i>
2014-2015	<i>The Multi-Center Study</i>	iPhone bionic pancreas (bihormonal)	Outpatient (home-use setting)	39 adults with T1D	Two-arm, random-order cross-over	11 days	First home-use study and first multi-center study of the iPhone bionic pancreas with near-final algorithm technology <i>Reference: El-Khatib et al. 2017 The Lancet, 389:369-380</i>
2015-2016	<i>The Stanford Insulin-Only Study</i>	iPhone bionic pancreas (insulin-only)	Outpatient (home-use setting)	13 adults with T1D	Three-arm, non-randomized	7 days	First home-use study of the insulin-only configuration of the iPhone bionic pancreas including preliminary testing of both static and dynamic glucose targets <i>Reference: Ekhlaspour et al. (2019) Journal Diabetes Science & Technology, 13:1001-1007</i>

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Year	Name of Study	System	Setting	Design		Duration / Participant	Evolution of Bionic Pancreas and Algorithm Innovations
				Cohort	Method		
2015-2016	<i>The MGH Set-Point Study</i>	iPhone bionic pancreas (bihormonal and insulin-only)	Outpatient (home-use setting)	20 adults with T1D	Multi-arm, random-order cross-over	3 days	- Comprehensive testing across multiple glucose targets for both the insulin-only and bihormonal configurations of the iPhone bionic pancreas - Determined the optimal ranges of safe and effective glucose targets for both the insulin-only and bihormonal configurations <i>Reference: Balliro et al. (2017) 77th Scientific Sessions of the American Diabetes Association, 1062-P</i>
2017	<i>The MGH Monitoring Study</i>	iPhone bionic pancreas (bihormonal and insulin-only)	Outpatient (home-use setting)	23 adults with T1D	Six-arm, random-order cross-over	5 days	- First test of the insulin-only and bihormonal configurations of the iPhone bionic pancreas without remote telemetric monitoring for hypoglycemia - Determined that remote telemetric monitoring was not required in final algorithm technology for both configurations <i>Reference: Sherwood et al. (2018) 78th Scientific Sessions of the American Diabetes Association, 299-OR</i>
2018	<i>The Insulin-Only Bridging Study</i>	iLet Bionic Pancreas (insulin-only)	Outpatient (home-use setting)	34 adults with T1D	Three-arm, random-order cross-over	7 days	- First human trial in adults with T1D of the insulin-only configuration of the first-ever, purpose-built, fully integrated insulin-only iLet Bionic Pancreas (Gen 3 iLet) in the home-use setting - First human trial to test Fiasp in the bionic pancreas in adults with T1D <i>Reference: Jafri et al. (2019) 79th Scientific Sessions of the American Diabetes Association, 77-OR</i>
2018	<i>The Day-Camp Transitional Study</i>	iLet Bionic Pancreas (insulin-only)	Outpatient (home-use setting overnight / camp setting during the daytime)	20 children with T1D (6-17 years old)	Two-arm, random-order cross-over	5 days	First human trial in children with T1D of the insulin-only configuration of the first-ever, purpose-built, fully integrated insulin-only iLet Bionic Pancreas (Gen 3 iLet) in the home-use setting <i>Reference: Ekhlaspour et al. (2019) 79th Scientific Sessions of the American Diabetes Association, 1063-P</i>

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Year	Name of Study	System	Setting	Design		Duration / Participant	Evolution of Bionic Pancreas and Algorithm Innovations
				Cohort	Method		
2018	<i>The Fiasp Tmax Study</i>	iLet Bionic Pancreas (insulin-only)	Outpatient & Inpatient settings	24 adults with T1D	Two-arm, random-order cross-over in three cohorts	2 days inpatient followed by 5 days outpatient (home-use setting)	- First trial to test non-default tmax values (insulin-absorption time assumed by corrections algorithm) with Fiasp in the iLet - No changes to the algorithms resulted from the trial, but a safe range of tmax values for Fiasp in the iLet were determined that could produce even better glycemic control than can be achieved with the default setting <i>Russell et al. (2021) Diabetes Therapy, 12:2019-2033</i>

All of the clinical trials listed in Figure 9 were investigator initiated. The inpatient trials were all reviewed by the institutional review boards at both Boston University and MGH and were conducted under investigational device exemptions approved by the FDA. Funding for the inpatient trials came from the National Institutes of Health (NIH), the Helmsley Charitable Trust, and the Juvenile Diabetes Research Foundation (JDRF). The investigational devices were provided by Boston University.

The outpatient trials were all reviewed by the institutional review boards at either MGH or Stanford University, and were conducted under investigational device exemptions approved by the FDA. Funding for the outpatient trials came from the NIH and the Helmsley Charitable Trust. The investigational devices were provided by Boston University or Beta Bionics.

The iLet Bionic Pancreas Pivotal Trial (BPPT) testing the iLet in adults and children with T1D

Background

The BPPT was conducted in 2021 as a parallel-group Randomized Controlled Trial (RCT) to evaluate the efficacy and safety of the iLet in a cohort that was designed to approximate the demographics of the U.S. T1D population with respect to race and ethnicity, socioeconomics, baseline glycemic distribution, educational attainment, and annualized household income. Participants were not excluded for very high HbA1c, history of hypoglycemia unawareness, or recent episodes of severe hypoglycemia or DKA.

Unlike most other AID pivotal trials, the BPPT was an RCT, in which those who randomized to the control arm remained on their usual method of diabetes management, with the addition of CGM if they were not already using a CGM. Approximately one-third of the cohort used MDI at baseline, approximately one-third used a hybrid closed-loop system, and approximately one-third were on insulin pump therapy without automation. We believe the BPPT was the only AID pivotal trial that included AID systems as part of the comparator arm. The use of a control arm was critical in determining the level of improvement in glycemic control that was directly attributable to the iLet rather than other aspects of the clinical trial. In contrast, single arm safety trials, such as the pivotal trials of other AID systems, cannot isolate the effects of the system from other trial-related factors, such as more frequent HCP visits and insulin dosing parameter adjustments, that are common in clinical practice. The BPPT was also unique among AID pivotal trials in that users of any FDA-cleared AID device could enroll in the BPPT and still continue to use the AID if they were randomized to the control arm. This aspect of the trial was designed to assess the potential for the iLet to impact glycemic control in the population of people with T1D at large, where other AID systems were already in use.

The BPPT was conducted at 16 centers in the United States, and it enrolled 440 adults and children (≥ 6 years old) with T1D. Prior to randomization, baseline CGM data and total daily insulin were collected with the

DexCom G6 over a two-week evaluation period on each participant's own therapy. Participants ≥ 18 years old (N=275) were randomly assigned in a 2:2:1 ratio to the iLet with insulin aspart or insulin lispro (Humalog, iLet-A/L group, N=107), the iLet with fast-acting insulin aspart (Fiasp, iLet-F group, N=114), or standard-of-care insulin delivery plus use of an unblinded DexCom G6 CGM (SC group, N=54). Participants 6-17 years old (N=165) were randomly assigned in a 2:1 ratio to the iLet with insulin aspart or insulin lispro (iLet-A/L group, N=112) or standard-of-care insulin delivery plus use of an unblinded DexCom G6 CGM (SC group, N=53).

We believe the BPPT cohort is the most diverse group that has participated in a pivotal trial for an AID system to date. The participating individuals self-identified as 74% White non-Hispanic, 10% Black non-Hispanic, 10% Hispanic or Latino, and 6% other or more than one race. At screening, 31% of participants used a hybrid closed-loop system, 4% used a system with predictive low glucose suspension, 31% used insulin pumps without automation, and 34% used MDI.

The primary outcome of the BPPT was the glycated hemoglobin at 13 weeks. The key secondary outcome was the percentage of time that the CGM glucose level was less than 54 mg/dL, the threshold below which cognitive impairment can occur, especially if the exposure is prolonged. Another secondary outcome was the percentage of time that the individual spent in time in range (TIR), which is the amount of time a PWD spends in the target BG range (70–180 mg/dL), based on ADA guidelines. Additional outcomes included the percentage of time that the CGM glucose level was less than 70 mg/dL, the threshold for less concerning hypoglycemia, and percentage of time above 180 mg/dL and 250 mg/dL.

Statistical analyses were performed on an intention-to-treat basis. Continuous outcomes were compared between groups using linear mixed effects regression models and binary outcomes with logistic regression models, adjusting for the baseline value of the metric, age, and clinical center (random effect). Safety outcomes included the frequency of severe hypoglycemia, DKA, and other serious adverse events.

Results in the Primary Cohort

In the primary analysis (Figure 10) comparing the iLet using insulin aspart or lispro (iLet-A/L) with the SC in participants of all ages, the primary outcome, mean glycated hemoglobin at 13 weeks, decreased from 7.9% at baseline to 7.3% in the iLet group at week 13 and did not change (7.7% to 7.7%) in the SC group. The mean adjusted group difference in glycated hemoglobin level at 13 weeks for iLet versus SC was -0.5 percentage points ($P<0.001$). In the key secondary analysis, the percentage of time the CGM level was <54 mg/dL was non-inferior in the iLet group compared with the SC group ($P<0.001$). The median values at baseline and over 13 weeks were 0.21% and 0.32% in the iLet group and 0.20% and 0.24% in the SC groups, respectively; the 13-week mean adjusted group difference was 0.00%, corresponding to zero minutes per day. Therefore, the iLet reduced the glycated hemoglobin level by 0.5% without increasing time <54 mg/dL at all.

The mean adjusted group difference for iLet versus SC in mean CGM level at 13 weeks was -16 mg/dL ($P<0.001$), consistent with the change in glycated hemoglobin. For percentage of TIR of 70-180 mg/dL, the difference was +11%, corresponding to 2.6 hours per day of increased TIR ($P<0.001$). The increase in TIR occurred, on average, within 48 hours of initiating the iLet using only the participants' bodyweight. The percentage of time the CGM level was <70 mg/dL was not different between the groups ($P=0.51$).

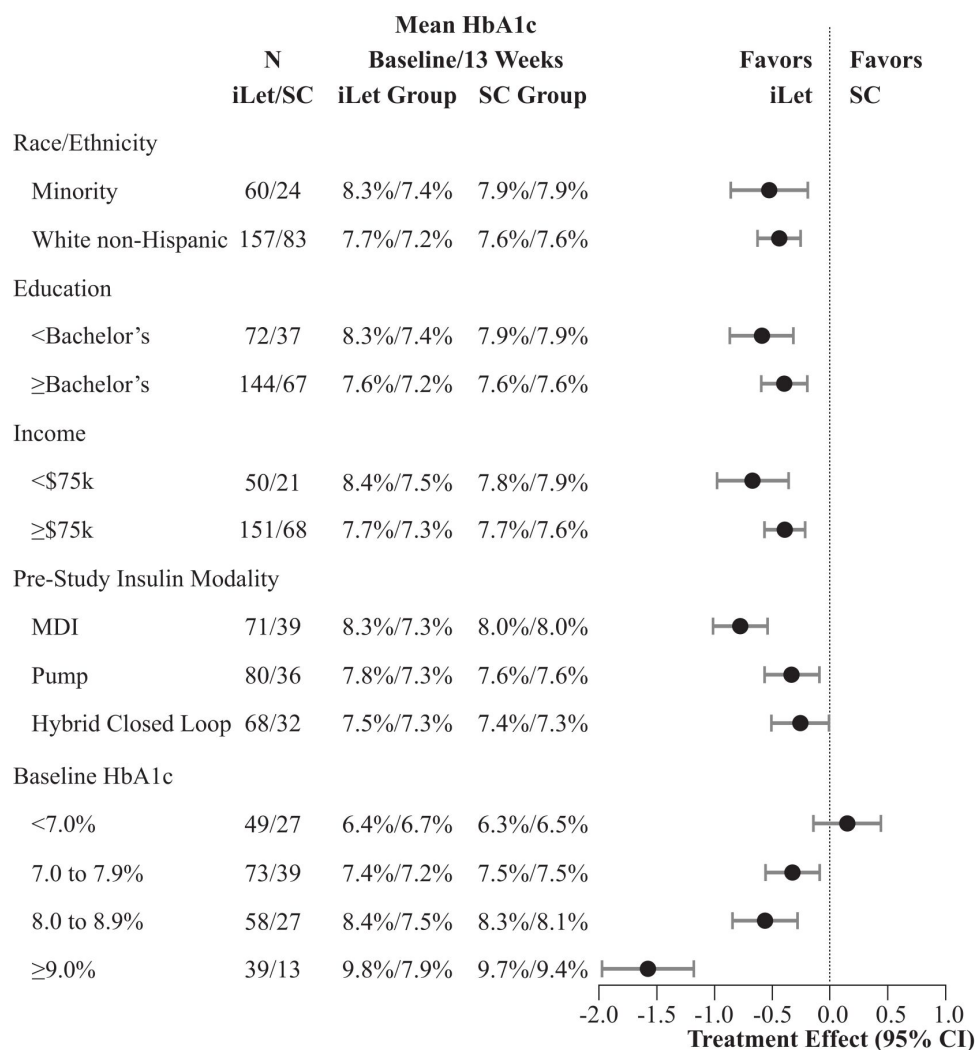
Figure 10. Primary and Secondary Efficacy Outcomes in the Primary Analysis (All Ages, iLet-A/L vs. SC)

	Baseline		Follow-up (Over or at 13 Weeks)		Adjusted Difference iLet minus SC ^a (95% CI)	P-value
	iLet Group (N=219)	SC Group (N=107)	iLet Group (N=219)	SC Group (N=107)		
Primary Outcome						
Glycated Hemoglobin at 13 weeks % mean (SD)	7.9 (1.2)	7.7 (1.1)	7.3 (0.7)	7.7 (1.0)	-0.5 (-0.6, -0.3)	<0.001
Key Secondary Outcome						
Percent Time <54 mg/dL median (IQR)	0.21% (0.02%, 0.57%)	0.20% (0.00%, 0.44%)	0.33% (0.16%, 0.60%)	0.24% (0.13%, 0.63%)	0.00% (-0.06%, 0.04%)	<0.001 ^b
Other Secondary Outcomes in Pre-specified Order						
Mean Glucose—mg/dL mean (SD)	187 (40)	190 (42)	164 (15)	181 (32)	-16 (-19, -12)	<0.001
Percent Time 70-180 mg/dL mean (SD)	51% (19%)	51% (20%)	65% (9%)	54% (17%)	11% (9%, 13%)	<0.001
Percent Time >180 mg/dL mean (SD)	46% (20%)	47% (21%)	33% (9%)	44% (18%)	-10% (-12%, -8%)	<0.001
Percent Time >250 mg/dL median (IQR)	16.0% (7.0%, 27.3%)	17.8% (6.0%, 33.5%)	8.5% (5.3%, 13.2%)	14.9% (6.3%, 25.3%)	-5.0% (-6.6%, -3.6%)	<0.001
Standard Deviation—mg/dL mean (SD)	67 (16)	68 (18)	60 (11)	67 (16)	-7 (-8, -5)	<0.001
Percent Time <70 mg/dL median (IQR)	1.5% (0.5%, 2.8%)	1.4% (0.4%, 2.9%)	1.8% (1.1%, 2.9%)	1.8% (0.8%, 3.1%)	-0.1% (-0.3%, 0.2%)	0.51
Percent Time <54 mg/dL median (IQR) ^c	0.21% (0.02%, 0.57%)	0.20% (0.00%, 0.44%)	0.33% (0.16%, 0.60%)	0.24% (0.13%, 0.63%)	0.00% (-0.06%, 0.04%)	NA
Coefficient of Variation (%) mean (SD)	36% (6%)	36% (6%)	36% (5%)	37% (5%)	-0.8% (-1.6%, 0.0%)	NA

SD = Standard Deviation; IQR = Interquartile Range

A post-hoc analysis of participants of all ages in the iLet-A/L versus SC groups was performed to assess outcomes stratified by participant socioeconomic characteristics. The treatment effect of the iLet on glycated hemoglobin levels was similar by racial/ethnic group, educational attainment, and income category, and was nominally greater in racial/ethnic minorities and in those with lower educational attainment and income. The mean adjusted group difference was larger for participants using MDI (-0.8%) than for those who were using insulin pumps (-0.3%) or hybrid closed-loop AID systems (-0.3%) at enrollment. Of note, the treatment effect was statistically significant for iLet as compared to other AID systems. Higher baseline glycated hemoglobin levels were associated with larger mean adjusted group differences when using the iLet (e.g., -1.6% for >9% at baseline). For individuals with baseline HbA1c <7%, there was no statistically significant change in the HbA1c, indicating that the iLet was able to maintain the pre-trial level of glycemic control in these individuals despite the reduced setup and lower ongoing input requirements of the iLet.

Figure 11. Glycated Hemoglobin Levels, in the Primary Analysis (All Ages, iLet-A/L vs. SC), According to Subgroups at Baseline

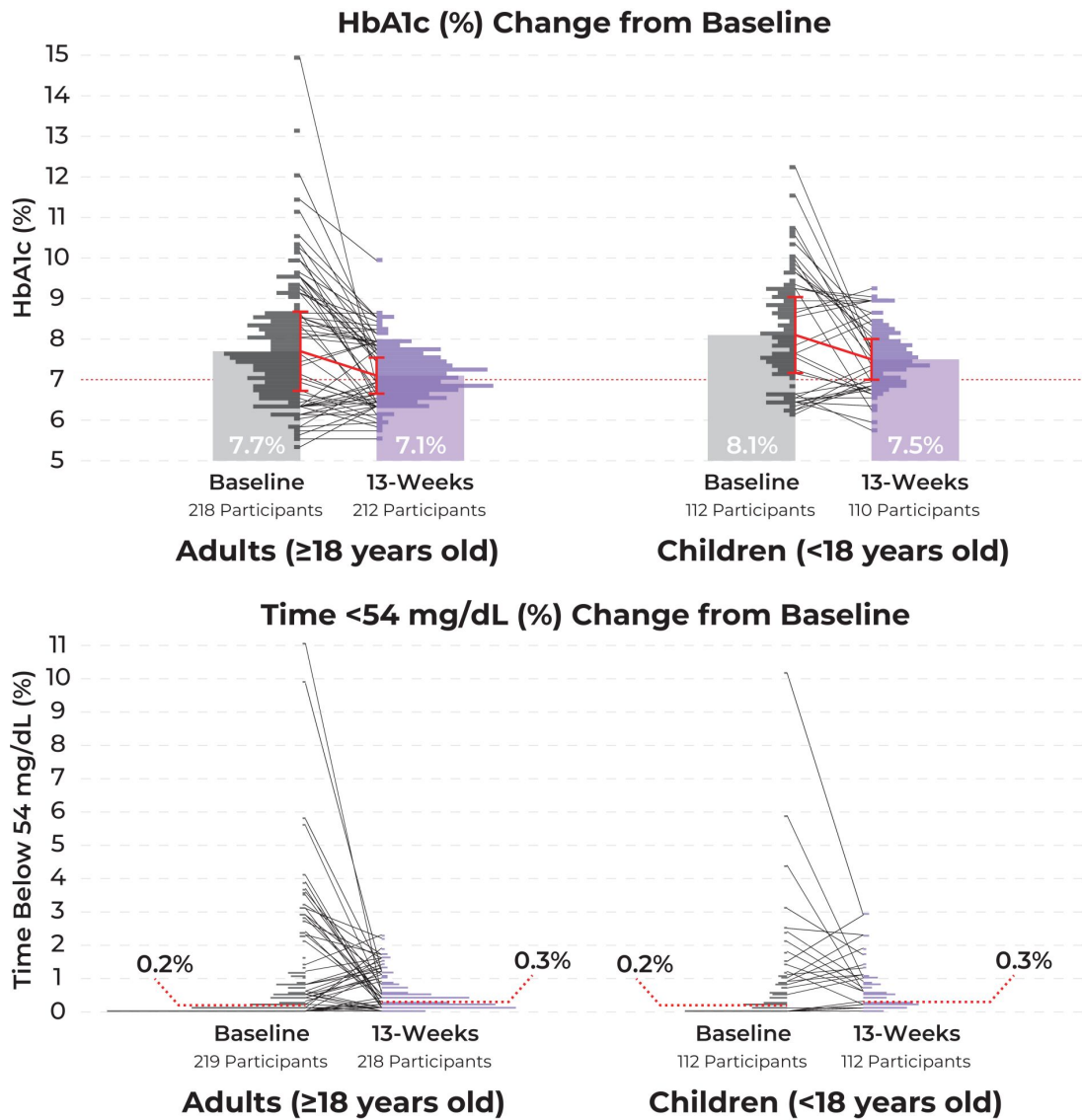


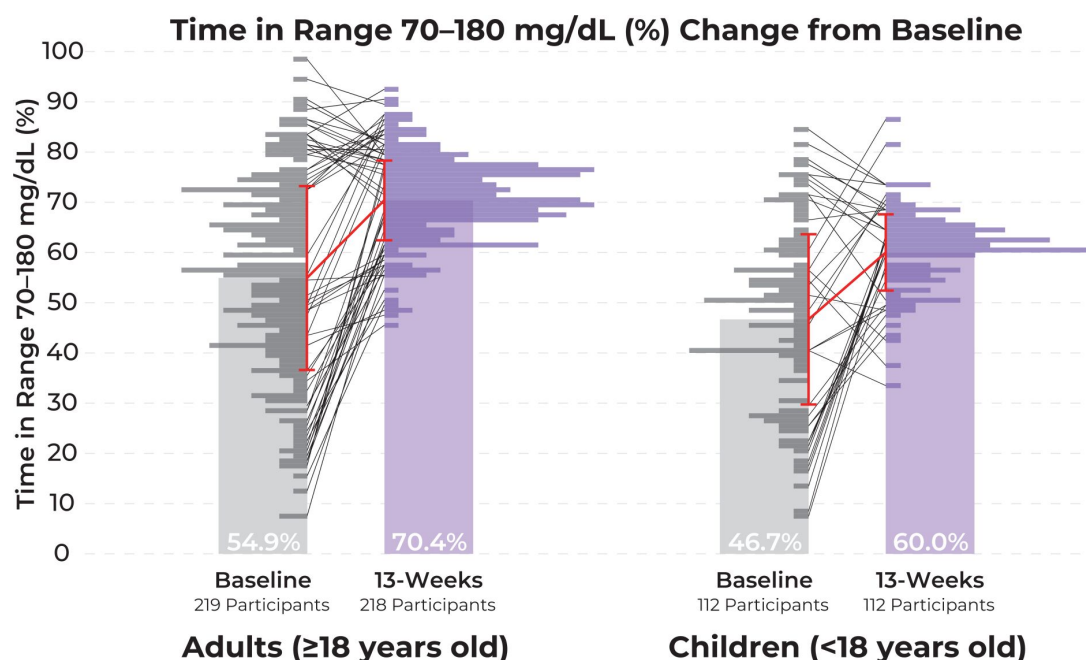
Results in Secondary Cohorts

Secondary analyses were performed separately in adults and in children randomized to either iLet-A/L or SC. These results were consistent with those from the primary cohort analyses, which combined both age groups. The mean adjusted group difference in glycated hemoglobin level at 13 weeks for iLet versus SC was -0.5 percentage points ($P < 0.001$) for both adults and for children. In the key secondary analysis, there was no significant difference in the percentage of time the CGM level was <54 mg/dL between the iLet group and the SC group in both adults and children. Over 13 weeks, the mean CGM glucose was reduced for iLet compared with SC by 16 mg/dL for adults and by 15 mg/dL for children (both $P < 0.001$). The mean TIR 70-180 mg/dL was greater for iLet compared with SC by 11% (2.6 hours per day) for adults and by 10% (2.4 hours per day) for children (both $P < 0.001$). In both cohorts, the increase in TIR occurred, on average, within 48 hours of initiating the iLet using only the participants' bodyweight.

Secondary analyses were performed separately in adults randomized to the iLet with faster insulin aspart (Fiasp, iLet-F group). The mean adjusted group difference in glycated hemoglobin level at 13 weeks between the iLet-F and SC groups was -0.5 percentage points ($P<0.001$). There was no significant difference in the time <54 mg/dL or time <70 mg/dL over 13 weeks in the iLet-F group compared with the SC or the iLet-A/L groups. Mean CGM glucose was decreased by 18 mg/dL on average in the iLet-F group compared with the SC group ($P<0.001$). TIR was increased by 14% (3.4 hours per day) on average in the iLet-F group compared with the SC group ($P<0.001$). The only statistically significant difference between the outcomes between the iLet-F and iLet-A/L groups was a TIR that was greater by 29 minutes per day than in the iLet-A/L group ($P=0.005$). The increase in TIR occurred, on average, within 48 hours of initiating the iLet using only the participants' bodyweight.

Figure 12. HbA1c, Time <54 mg/dL and Time in Range 70-180 mg/dL Change from Baseline





Glycated hemoglobin levels and time with glucose <54 mg/dL in the iLet groups for all participants (iLet-A/L, iLet-F, and SC) by age group at baseline. Baseline and 13-week values are connected by lines for the top and bottom 10% of values at either baseline or over 13 weeks.

Figure 12 shows the baseline and 13-week HbA1c and time <54 mg/dL values for all adults and all children in the BPPT. In addition to the reduction in mean HbA1c, the variability in the 13-week HbA1c was much smaller than the variability in the baseline HbA1c. Although there was no overall difference in the amount of time <54 mg/dL between the iLet groups and the SC groups in either adults or children, Figure 12 shows that individuals who had large amounts of time <54 mg/dL at baseline (e.g., >2% time <54 mg/dL) experienced reductions in hypoglycemia on the iLet.

Results of the patient-reported outcomes analysis on the BPPT revealed that in all age groups, the majority of participants would recommend using the iLet, including those with previous experience using AID. Similarly, all respondent groups (adults, teenagers, children, and caregivers) endorsed significantly greater benefits versus burdens, and most participants (74%-81%, depending on the group) reported strongly recommending the iLet. Adult participants reported statistically significant decreases in fear of hypoglycemia and in diabetes-specific emotional distress, as well as improvements in their perceived well-being. Children and teenagers also reported high acceptability and reduced burden, but less clear improvements in psychosocial outcomes, perhaps because they reported low levels of fear and distress and high levels of perceived well-being at baseline. Analysis of focus group material found that participants' overall experience was positive, with decreased burden and improved freedom and flexibility.

Safety Results

In the primary analysis (adults and children randomized to either iLet-A/L or SC) a total of 244 adverse events were reported among 126 patients in the iLet-A/L group and 10 adverse events were reported in eight patients in the SC group. There were 214 episodes of hyperglycemia with or without ketosis reported in the iLet-A/L group and two reported in the SC group. Nearly all of the events in the iLet-A/L group were adjudicated by the medical monitor as due to infusion set failure. Participants in the iLet-A/L group were required to notify trial staff in the event of hyperglycemia, whereas those in the SC group followed their usual practices and were

instructed to contact their diabetes HCP in such events. Infusion set failures were the only reportable adverse events in the iLet-A/L group. These factors are thought to account for the difference in reported adverse events and hyperglycemia episodes between the two groups. Consistent with this, there were fewer episodes of prolonged hyperglycemia (defined as CGM glucose >300 mg/dL for at least 90 minutes during a 120-minute period) and less time >180 mg/dL and >250 mg/dL with the iLet than SC. There were no episodes of DKA in either group. In the secondary analysis comparing adults using the iLet with Fiasp against those using the iLet with aspart of lispro, two participants in the iLet-F group each experienced one DKA event, both confirmed to have been caused by an infusion set failures.

In the primary analysis (adults and children randomized to either iLet-A/L or SC), the incidence rates for severe hypoglycemia were 17.7 and 10.8 events per 100 person-years, respectively ($P=0.39$). In the secondary analysis (adults randomized to iLet-F or SC) the incidence rates were 10.2 versus 14.2 events per 100 patient-years ($P=0.83$). Therefore, there were no significant differences in the rates of severe hypoglycemia between any of the iLet or SC groups.

Conclusion

Use of the iLet was associated with lower glycated hemoglobin, lower mean glucose, and increased TIR without an increase in CGM-measured hypoglycemia or the rates of severe hypoglycemia events relative to SC. Patients in the iLet groups had a lower glycated hemoglobin by 0.5% overall and in both the pediatric and adult subgroups using the iLet with insulin lispro or aspart and in adults using the iLet with Fiasp. The largest improvements in glycated hemoglobin were in comparison to MDI, but there was a significant reduction in glycated hemoglobin even when compared to the use of other AID systems. The amount of time with glucose <54 mg/dL and the rates of severe hypoglycemia events were not statistically or significantly different between the iLet and SC groups. The TIR was increased by 2.4 to 3.4 hours per day in the iLet versus the SC, and, on average, this increase occurred within 48 hours of starting use of the iLet. Study participants using the iLet reported a high number of benefits and a low number of perceived burdens, and adults using the iLet reported reduced fear of hypoglycemia and diabetes distress. The majority of participants would recommend the iLet, regardless of what method of glucose management they used before. The results of this trial show that good glycemic control can be achieved by the iLet, with improvements compared to SC that are statistically and clinically significant, with only qualitative meal announcements and without a pre-specified insulin regimen, carbohydrate counting, user-initiated correction doses, or any titration of insulin by the user or HCP.

Comparison between iLet outcomes in the commercial setting and the BPPT

Background

The BPPT was designed to enroll a clinical trial cohort that was as representative as possible of the demographics of people with T1D in the United States with respect to race and ethnicity, socioeconomic, baseline glycemic distribution, educational attainment, and annualized household income. It was hypothesized that the results based on such a cohort would be scalable to the commercial setting. To test this hypothesis, we analyzed the impact of the commercial iLet on glycemic control during the first year after FDA clearance and compared the results of that analysis to the results of the BPPT.

Analysis

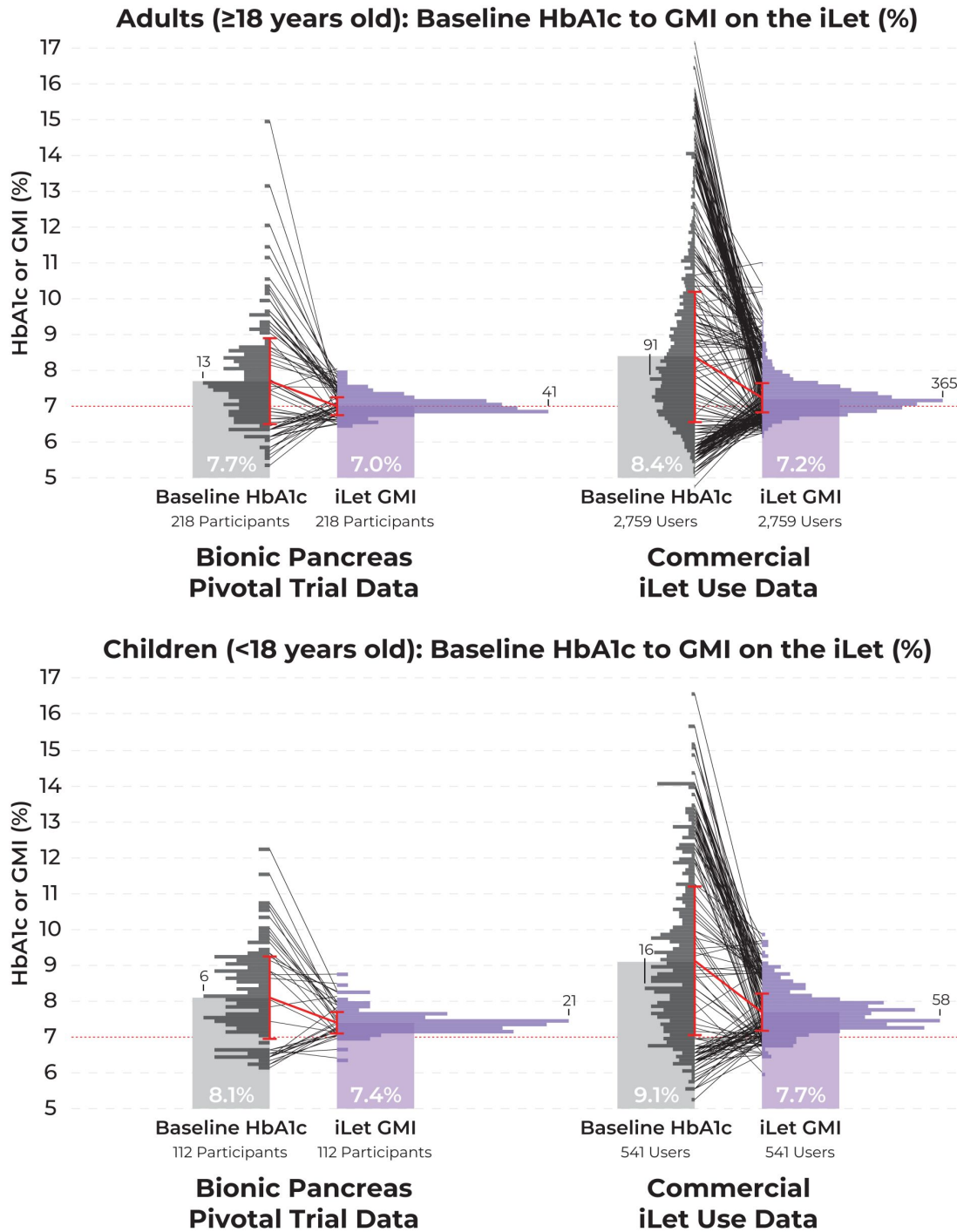
iLet CGM data were captured (i) during BPPT¹⁻⁴ between January 2021 and October 2021, and (ii) from 5,190 commercial iLet users in the first year after FDA clearance of the iLet on May 19, 2023. Of those 5,190 commercial iLet users, 3,675 had at least three weeks' worth of iLet data in the Beta Bionics cloud. Of those 3,675 users, 3,300 had baseline HbA1c values that were compared with GMI values, which were calculated using all available iLet CGM data from among those 3,300 users.

Results

Data from 2,759 adults (≥ 18 years) and 541 children (< 18 years) were included in the analysis of commercial iLet users and compared with data from the 218 adults and 112 children who randomized to the iLet in the BPPT.

The upper left and upper right panels of Figure 13 below show the change from baseline HbA1c for, respectively, 218 adult participants in the BPPT and 2,759 iLet adult users in the post-market setting to the mean GMI after (i) 90 days of iLet usage for each participant in the BPPT and (ii) at least 21 days' worth of iLet usage for each user in the post-market setting. Histograms showing the distributions of HbA1c and GMI for these two populations are shown superimposed on the bar graphs. The highest and lowest baseline HbA1c values are connected with lines to their corresponding GMI values on the iLet, and the highest and lowest GMI values on the iLet are connected with lines to their corresponding baseline HbA1c values. The corresponding results are shown in the bottom two panels of Figure 13 for children < 18 years old.

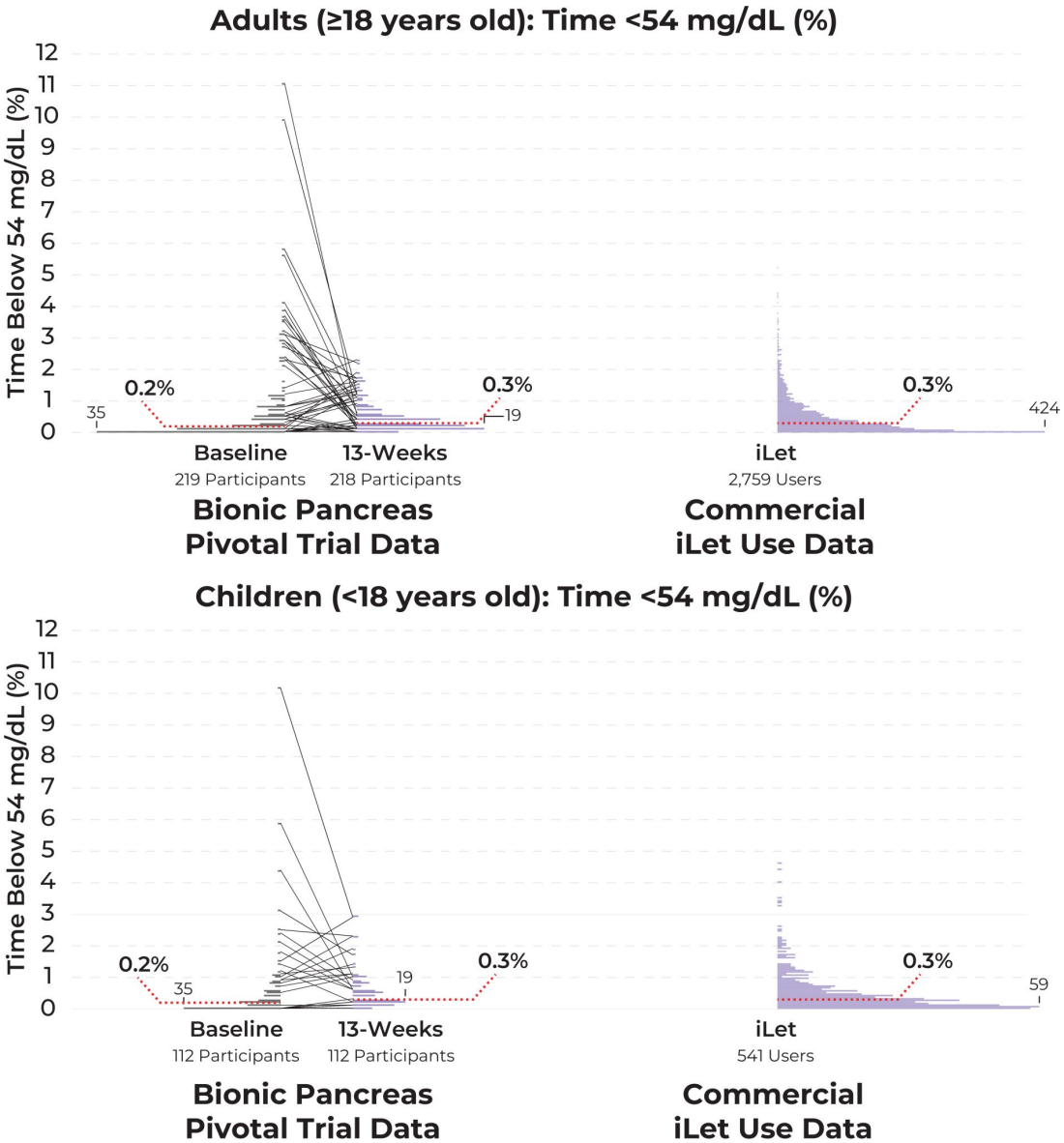
Figure 13. Baseline HbA1c to GMI on the iLet



HbA1c at baseline and iLet GMI at follow up are shown for adults and children in the BPPT (left panels) and in the commercial setting (right panels).

Figure 14 shows the change in the percentage of time spent with CGM glucose <54 mg/dL during the two-week baseline period to the 13-week period on the iLet in the BPPT in adults (left panel) and children (right panel).

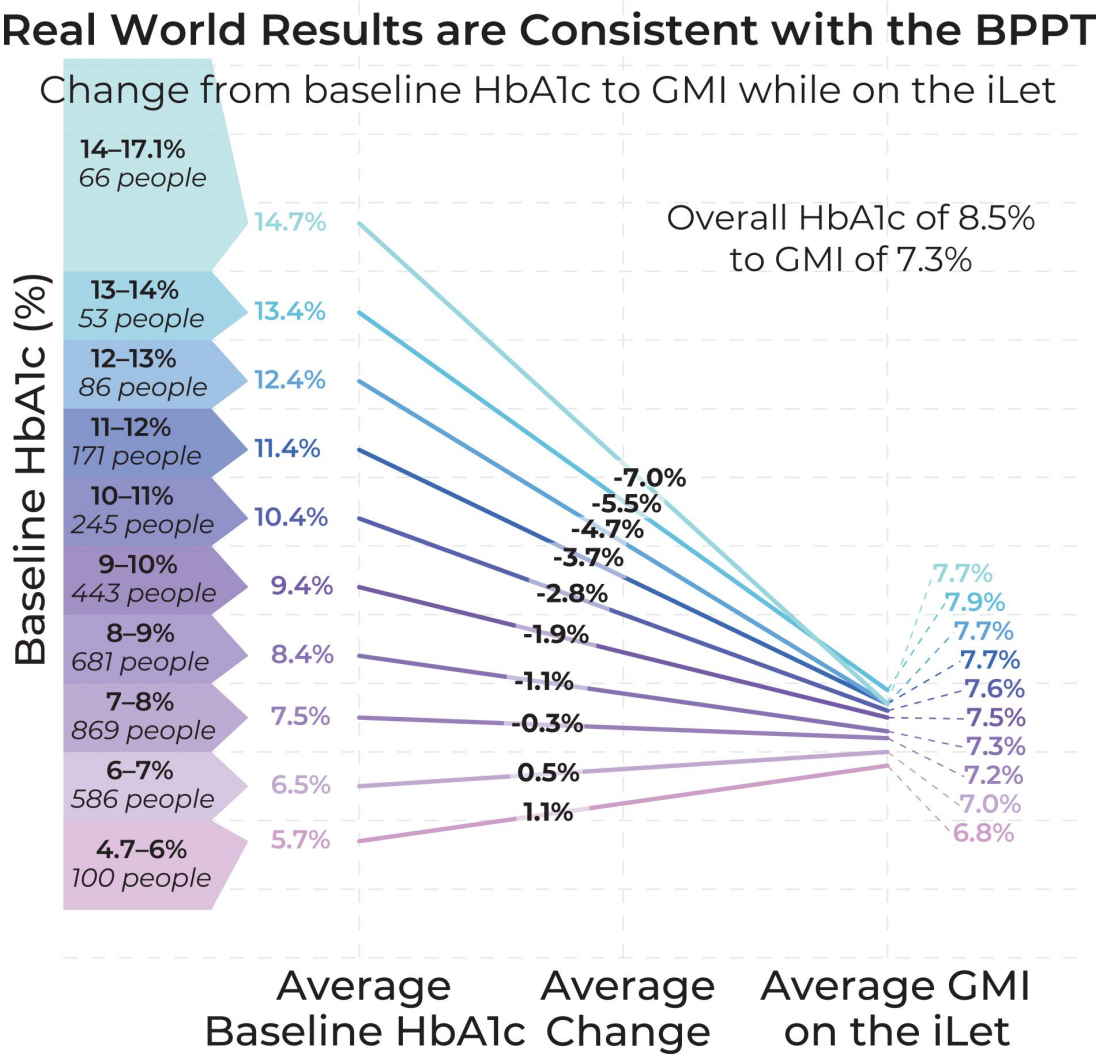
Figure 14. Percentage of Time Spent with CGM Glucose <54 mg/dL at Baseline and Over 13 Weeks on the iLet



Percentage of time spent with CGM glucose <54 mg/dL at baseline and over 13 weeks on the iLet are shown for adults (left panel) and children (right panel) in the BPPT.

An alternative visualization demonstrating the efficacy of the iLet in the commercial setting, in which each of the 3,300 users (adults and children combined) are binned into one of 10 bins according to their baseline HbA1c, as shown below.

Figure 15. Real-World Results Are Consistent with the BPPT



Conclusion

The baseline HbA1c values of commercial iLet users were higher and the decreases from baseline HbA1c to iLet GMI values were larger than among participants in the BPPT. The time spent <54 mg/dL were comparable in both the BPPT and commercial settings.

iLet device outcomes are independent of the frequency of user interaction

Background

Unlike any other commercially available glucose-monitoring device or insulin-delivery system used in diabetes management, the quality of glycemic control achieved by the iLet is virtually independent of the frequency of user interaction, as measured by the swipe-to-unlock frequency of the iLet lock screen. Beyond observing current device status, users are required to swipe to unlock the iLet lock screen before engaging with their therapy, and as such, the swipe-to-unlock gesture is the best single proxy for user interaction with the iLet. In large population trials, each with thousands or tens-of-thousands of participants, it has been observed that a higher frequency of glucose monitoring was strongly associated with a lower HbA1c level, and a higher frequency of user-initiated correction boluses from a sensor-augmented insulin pen or a hybrid closed-loop system correlated strongly with improvements in TIR (although hypoglycemia worsened as the number of user-initiated correction boluses increased).

Because the iLet determines and delivers 100% of all insulin doses and therefore does not require the user to make any quantitative assessment, we hypothesized that glycemic and CGM outcomes achieved by the iLet might be independent of the frequency of user interaction with the device. We tested this by capturing the swipe-to-unlock frequency from 324 participants in the BPPT over the 13-week intervention period as well as from 3,295 iLet users in the commercial setting who had baseline HbA1c data available, uploaded at least three weeks’ worth of CGM data to the Beta Bionics cloud, and had device-interaction data available. These data were analyzed using linear regression to assess if correlations existed between user interaction with the iLet (as measured by the swipe-to-unlock frequency) and CGM outcomes.

Analysis and Results

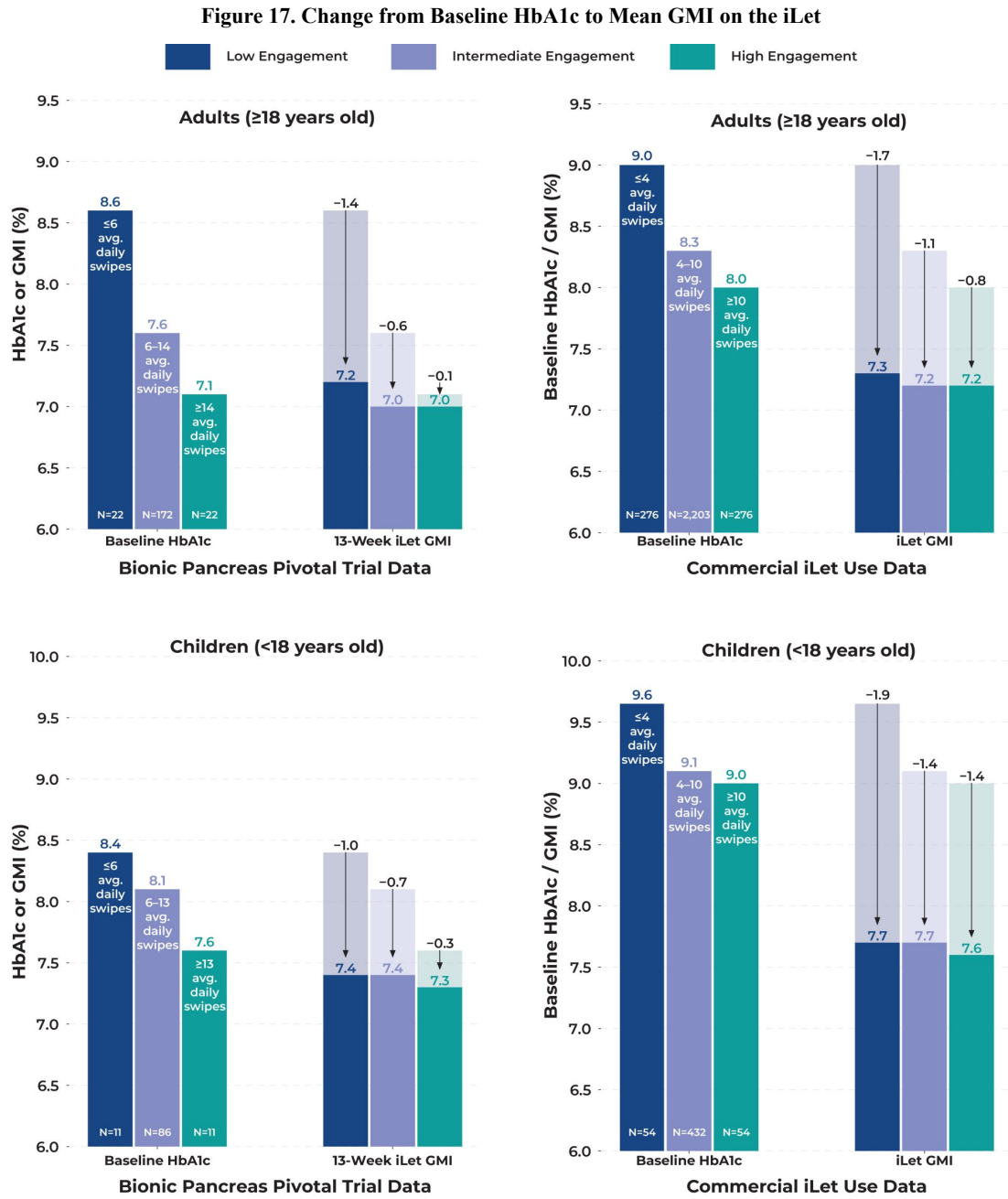
Correlations were quantified with the R^2 correlation coefficient, which is an indicator for how strongly correlated two metrics are (such as between average number of swipes to unlock and GMI). An R^2 correlation coefficient of “1” represents a perfect one-to-one correlation and an R^2 correlation coefficient of “0” represents no correlation. In both the BPPT and the commercial settings, the R^2 correlation coefficients associated with the linear regression analysis between the average GMI on iLet therapy and the average daily number of swipes to unlock the screen were <0.01 across both adults and children (see Figure 16 below). In addition to GMI, CGM-measured hypoglycemia on the iLet appeared to be nearly independent of the average daily swipes to unlock the iLet (see Figure 16).

Figure 16. R^2 Correlation Coefficients Between Average Daily Swipes to Unlock the iLet and CGM Outcomes

Correlation Coefficients	Bionic Pancreas Pivotal Trial Data		Commercial iLet Use Data	
	Adults (≥18 yrs old)	Children (<18 yrs old)	Adults (≥18 yrs old)	Children (<18 yrs old)
GMI (%) <i>mean±SD</i>	$R^2 < 0.01$ <i>(7.0±0.3%)</i>	$R^2 < 0.01$ <i>(7.4±0.3%)</i>	$R^2 < 0.01$ <i>(7.2±0.4%)</i>	$R^2 < 0.01$ <i>(7.7±0.6%)</i>
Time <54 mg/dL (%) <i>median (IQR)</i>	$R^2 < 0.01$ <i>0.3% (0.1, 0.5)</i>	$R^2 < 0.01$ <i>0.3% (0.2, 0.6)</i>	$R^2 < 0.01$ <i>0.3% (0.1, 0.6)</i>	$R^2 < 0.01$ <i>0.3% (0.1, 0.6)</i>

R^2 correlation coefficients between average daily swipes to unlock the iLet and each of GMI and time spent with CGM level <54 mg/dL are shown for adults (≥18 years old) and children (<18 years old) from the iLet BPPT and from iLet usage in the commercial setting. The mean GMI and the median time spent with CGM levels <54 mg/dL on iLet therapy for the BPPT participants and iLet users in the commercial setting are shown in italics under the correlation coefficients.

The bar chart in Figure 17 below also shows that, regardless of engagement level, adults and children in both the commercial and BPPT setting achieved similar GMI levels relative to disparate levels of baseline HbA1c.



Change from baseline HbA1c to mean GMI on the iLet for 216 adults (≥18 years old) in the BPPT (top left), 108 children (<18 years old) in the BPPT (bottom left), 2,755 adults in the commercial setting (top right), and 540 children in the commercial setting (bottom right). Low engagement (lowest decile) users are shown in blue, intermediate engagement users in purple, and high engagement (highest decile) users are shown in green.

Conclusion

The quality of glycemic control achieved by the iLet, measured in terms of GMI, TIR, or hypoglycemia, is virtually independent of the frequency of user interaction. The users who were least engaged during iLet usage had the highest HbA1c on average before starting iLet therapy, and those who were most engaged during iLet usage had the lowest baseline HbA1c on average before starting iLet therapy. Therefore, we believe that those who were least engaged on iLet therapy were similarly disengaged with their baseline method of diabetes management. We believe this behavior speaks to the iLet's ability to eliminate nearly all disparities in glycemic control that arise from user engagement with diabetes management. So, in addition to the iLet being nearly agnostic to insulin modality, socioeconomic, racial, and ethnic demographics, it also appears to be similarly agnostic to user interaction.

Commercial Strategy

To fully realize the opportunity presented by the iLet, we have developed an integrated commercial and overall corporate strategy to drive adoption across the T1D population, establish and maintain customer loyalty through customer service and education programs, maximize profitability through a disciplined, capital-efficient approach to cost management and reinvestment, and maintain our long-term competitive position with continuous innovation.

We are promoting sales of the iLet through our internal sales organization, initially focusing direct sales efforts on high-volume endocrinology practices located within geographic territories defined by the sites of our pivotal clinical trial. We optimize these efforts with an internal customer support team and supplement them with strategic marketing initiatives. We believe that initially focusing on endocrinologists will facilitate their experience with the iLet and encourage them to become advocates for our solution.

We also intend, over time, to target the larger, but more dispersed, PCP market. These generalist physicians treat approximately 50% of the T1D population in the United States but do so among a broader PWD base. We believe iLet's aforementioned core value proposition of marrying effective glycemic control with the simplicity of use that is brought about by adaptive closed-loop algorithm insulin dose determination may resonate particularly well among PCP who do not possess the subspecialty-level of expertise, the resources, or the clinical bandwidth that is needed to initiate insulin-pump therapy or hybrid closed-loop therapy or for the continual demand those systems place on clinical practices in follow-on care.

The key elements of our commercialization strategy are:

- **Identify:** We have developed a target customer profile of those PWD whose glycemic control is either equivalent to or worse than guideline levels who would prefer a more hands-off approach to their daily disease management.
- **Attract:** We have 43 field sales teams divided into geographic territories that will engage in direct physician marketing and education campaigns to raise awareness of the iLet among PWD and high-prescribing caregivers.
- **Fulfill:** We have a system to integrate lead capture, ordering, manufacturing, distribution, and returns for iLet, streamlining these processes for both PWD and caregivers.
- **Educate:** We offer comprehensive education and training programs to both PWD and HCPs to ensure that all iLet users are trained by a certified trainer and have the resources needed to answer any questions they may have about the device or its user experience.
- **Support:** We offer comprehensive, 24/7 technical support to assist both PWD and HCPs during device initialization and throughout its lifetime, with a goal of answering 90% of calls within the first 30 seconds of receiving them.

- **Retain:** We utilize both direct and social media communication strategies to build the iLet community of users, caregivers, and KOLs and use feedback from this community to continuously upgrade both current and future device generations.

Multi-Channel Coverage and Reimbursement Strategy

To maximize access to the iLet within the T1D population and flexibility for PWD in choosing their device, advantageous coverage, and reimbursement terms, we are pursuing a multi-channel coverage and reimbursement strategy. We are working with payors to establish coverage and reimbursement under both the DME and PBP channels as we believe that this strategy increases access and optimizes the potential for better medical outcomes for PWD through the adoption of the iLet.

The majority of durable insulin pumps have traditionally been reimbursed by both private and government payors through the DME channel. The iLet currently enjoys DME reimbursement with third-party payors covering a portion of the current T1D population.

Third-party payors that cover the iLet through the DME channel typically require a large, upfront payment (in the thousands of dollars). Under the DME channel, the PWD's medical insurance will not provide reimbursement for an additional durable pump until the four year warranty period of the device has expired. This channel ensures the broad availability of pumps but places potentially significant financial constraints on PWD's ability to access the improved outcomes provided by innovative technology. For PWD of certain socioeconomic backgrounds, the size of the upfront payment is often beyond their means, and, for most PWD, the typical four-year commitment may deter them from immediately adopting any innovative device that emerges within four years of their prior selection. However, this model does mean that each year, a large number of existing, commercially insured pump users may obtain coverage for a new insulin pump upon the expiration of their warranty period, which allows us to present these existing pump users with the opportunity to switch to the iLet.

As an alternative to covering insulin pumps through the DME channel, certain payors allow their members to access insulin pump technology under their PBP coverage. This structure, which follows a "pay as you go" model, eliminates the need for a large upfront payment and removes time-based constraints on accessing new technologies or switching pumps. However, the PBP channel does require higher payments by the insurance carrier for the purchase of single-use products required to use the iLet over the expected life of the iLet, which we generally expect to be four years. Payors have demonstrated a willingness to absorb these potentially higher costs on behalf of their T1D members to subsidize higher pump utilization, which can improve overall disease management, reduce long-term morbidity and mortality, and decrease total lifetime costs per member.

Figure 18. Benefits of Pharmacy Pay-As-You-Go



We are pursuing our multi-channel coverage and reimbursement strategy by negotiating with pharmacy benefit managers (PBMs) and payors to expand PBP coverage and reimbursement for the iLet from their provider. We believe that as PWD experience the quality of life and disease management benefits of iLet, they will have a sufficiently high probability of long-duration utilization to offset the potential risk of short-term discontinuation associated with this model. Over time, we expect sales through the PBP channel will have a more favorable economic impact on our financial results over the lifetime of the iLet. We have contracts with PBMs covering a portion of people with T1D in the United States.

Streamlined and Efficient Manufacturing and Quality Control

Both the iLet and our ready-to-fill insulin cartridges are assembled from readily available standardized components that require minimal customization and are centrally manufactured at our facilities in Irvine, California. Any potential future upgrades to the iLet’s functionality, we believe, will be enabled by innovative refinements to our proprietary algorithms without the need for fundamental alterations to the iLet’s form factor, components, or manufacturing processes. We believe our utilization of a standardized bill of materials provides us with insulation from component shortages and is designed to enable us to efficiently scale our production levels to accommodate our material anticipated increases in iLet demand.

Our standards-based model also provides us with numerous benefits to our per-unit cost structure, which may allow us to achieve higher gross margins than have been previously attained at launch by other insulin pumps within our industry. Among these benefits are the ability to achieve competitive pricing by actively sourcing from multiple vendors, the avoidance of costly alterations or customizations to either the iLet or to our manufacturing facilities, and full utilization of the depreciable life span of our manufacturing equipment. By assembling and testing our subassemblies and products in-house, we believe we can also maintain high quality control, ensure compliance with applicable regulatory standards and our internal specifications, and limit outside access to our proprietary technology.

We occupy and set up production at our leased Hughes building located in Irvine, California. This 50,000 square foot facility includes 11,500 square feet of warehouse and production space. The iLet is assembled via manual and semi-automated equipment, while cartridge production and packaging utilize industry standard automation. We anticipate that our current annual manufacturing capacity at the Hughes building is sufficient to fulfill our internally projected demand for at least the next 12 months.

We are subject to and maintain compliance with ISO manufacturing standards, including ISO 13485 certification, current good manufacturing practices (cGMP), and the relevant Quality System Regulation requirements. Our manufacturing operations are led by a team whose members have extensive experience in the commercial manufacture of medical devices, including other technological advances in diabetes treatment.

Product Development Pipeline and Future Initiatives

Patch Pump

We are developing an insulin pump that is designed to adhere directly to the skin and administer insulin without the need for tubing, commonly known in the diabetes industry as a “patch pump.” Our patch pump features a two-component design: a durable part that contains the electronics and motor and a disposable part that includes the insulin reservoir, adhesive, insertion device, and cannula. This design is intended to enable efficient manufacturing and provide a convenient pump-change experience. Our patch pump is intended to unlock a new pool of PWD who are looking to receive the many benefits of the iLet, but prefer the patch pump form factor.

Bihormonal iLet

The iLet is designed and configured to potentially administer both insulin and glucagon, the hormone responsible for maintaining minimum BG levels, with adaptive closed-loop algorithms where all doses of both hormones are autonomously determined. We believe this bihormonal capability could offer a meaningful additional benefit to PWD, as it would allow the active raising of glycemic levels when they fall too low, in addition to the iLet’s existing capability of actively lowering glycemic levels when they elevate too high. Currently, there are no commercially available automated devices to raise BG when it is too low, and many people living with T1D live with an ever-present fear of hypoglycemia.

Hypoglycemia, if untreated, can lead to a range of acute medical complications, including tissue and organ damage, seizures, and coma, and death, and hypoglycemic episodes are responsible for over half of all emergency room visits by PWD each year, despite their relatively low frequency. Approximately one-third of people living with T1D can also be classified as “hypo unaware,” a condition that prevents them from sensing a pending hypoglycemic event and puts them at increased risk for suffering a severe hypoglycemic episode without warning. Due to these primary risks and other secondary risks, such as losing consciousness while driving an automobile, many people living with T1D tend to live with perpetual fear of a severe hypoglycemic episode. These fears can reduce quality of life, as they may lead to a restriction of otherwise necessary and beneficial activities like exercise in order to avoid the risk of a catastrophic hypoglycemic episode.

In six pre-pivotal outpatient clinical trials conducted from 2012 to 2017, we observed participants utilizing our bihormonal configuration to achieve reduced hypoglycemia and increased TIR relative to both standard-of-care treatment and our insulin-only bionic pancreas configuration. We expect to initiate pivotal clinical trials and seek FDA device clearance for our bihormonal configuration and, if successful, seek FDA marketing authorization for this configuration, as well as FDA approval for a pump-compatible formulation of glucagon for chronic usage. Glucagon is currently only approved in an acute formulation for rescue from acute hypoglycemia, so approval of a new drug application will be required in addition to FDA clearance for the bihormonal configuration of the iLet as a device.

To realize the full commercial potential of this opportunity, we have signed an exclusive collaboration and license agreement with Xeris to develop and commercialize a pump-compatible glucagon formulation utilizing Xeris’ XeriSol technology for use in our proprietary bihormonal pump and pump systems. Under the commercial terms of the and collaboration and license agreement, we will receive all revenue from any sales of the system and glucagon, and pay Xeris a tiered, low double-digit royalty on glucagon sales.

Type 2 Diabetes

We intend to pursue expanded use of the iLet to treat people with insulin-dependent T2D, as we believe the size and composition of this population make it a compelling opportunity. While there are certain differences in how T2D is treated relative to T1D, these differences primarily relate to the amount and rate of insulin delivered. Among the T2D population, approximately 1.8 million require intensive insulin therapy, but fewer than 10% have adopted pump technology to date. We believe these PWD, who span socioeconomic and educational levels, and their HCPs, 90% of whom are PCP, may find the iLet's combination of simplicity and efficacy particularly appealing, if authorized for marketing for this use.

Competition

The medical device industry is intensely competitive, subject to rapid change, and highly sensitive to the introduction of new products, treatment techniques or technologies, and other market activities of industry participants. We compete with a number of companies that manufacture and sell insulin pumps, such as Medtronic, Tandem, and Insulet. We also compete with a number of companies that manufacture prefilled insulin syringes and insulin pens, such as Abbott, Eli Lilly, Medtronic, and Novo Nordisk A/S. Moreover, we face competition from a number of companies, medical researchers and pharmaceutical companies that offer or are pursuing competing delivery devices, technologies and procedures, such as inhalable insulin products, as well as companies with approved therapeutics or in-development therapeutic candidates impacting diabetes.

Many of our competitors are either publicly-traded companies or divisions or subsidiaries of publicly-traded companies that have several competitive advantages over us, including greater market share and name recognition, greater financial and human resources for sales and marketing and product development, more well-established relationships with HCPs, customers and third-party payors, greater experience, additional lines of products with the ability to offer rebates or bundle products, and larger and more established distribution networks. In some instances, our competitors also offer products that include features that we do not currently offer. For example, Insulet offers a product with a patch form factor.

Mergers and acquisitions in the medical device industry may result in even greater resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, either alone or through collaborative arrangements with large and established companies. Key competitive factors affecting our success are likely to be health efficacy, safety, ease of use (including complexity and disease management burden), price, reimbursement, user retention, and ability to continue to effectively innovate.

Intellectual Property

Our success depends in substantial part on our ability to obtain, defend and enforce patents, maintain trade secrets and operate our business without infringing the proprietary rights of others, both in the United States and abroad. We rely on a combination of patents, trademarks, trade secrets, and confidentiality and invention assignment agreements to protect our intellectual property rights. We license from third parties certain patent rights and proprietary know-how that we believe to be necessary or useful to our business.

We also rely upon trade-secret protection for certain confidential and proprietary information and take active measures to control access to that information. There is also substantial proprietary know-how surrounding the iLet development and manufacturing processes that remains a trade secret, which we protect by maintaining and implementing appropriate policies and procedures for ensuring secrecy and confidentiality.

Our U.S. and foreign patents and patent applications generally relate to alternate controller enabled (ACE) insulin and bihormonal pumps, software and algorithms for modular blood glucose control systems, graphical user interfaces (GUIs) including animations and transitional GUI screens, and/or communication

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interfacing including disposables and wearables for connecting pumps to infusion sets. As of August 20, 2024, our owned and licensed patent estate contains approximately fifty-nine (59) issued U.S. patents, twenty-seven (27) pending U.S. nonprovisional patent applications, two (2) pending PCT patent applications, sixty-eight (68) issued foreign patents, and fifty-nine (59) pending foreign patent applications. The sixty-eight (68) issued foreign patents include one or more issued patents in jurisdictions such as Australia, Canada, China, France, Germany, Great Britain, Italy, Japan, and Spain. The fifty-nine (59) pending foreign patent applications include one or more pending applications in jurisdictions such as Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, Russia, and Saudi Arabia. Assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable, our owned or licensed issued U.S. patents expire between 2026 and 2040.

As set forth in tabular form below, of the 59 total U.S. issued patents in our patent estate, 20 contain one or more claims that cover the currently commercial iLet BIONIC PANCREAS system.

Jurisdiction	Patent Number	Expiration	Ownership	Type of Patent
U.S.	11,633,535	7/15/40	BETA BIONICS	Utility
U.S.	11,571,507	7/15/40	BETA BIONICS	Utility
U.S.	11,278,661	3/10/40	BETA BIONICS	Utility
U.S.	11,135,365	7/15/40	BETA BIONICS	Utility
U.S.	11,135,364	7/15/40	BETA BIONICS	Utility
U.S.	11,135,363	7/15/40	BETA BIONICS	Utility
U.S.	11,103,638	7/15/40	BETA BIONICS	Utility
U.S.	D981,439	3/14/2038	BETA BIONICS	Design
U.S.	D980,859	3/21/2038	BETA BIONICS	Design
U.S.	D980,858	3/14/2038	BETA BIONICS	Design
U.S.	D980,857	3/14/2038	BETA BIONICS	Design
U.S.	D1,032,264	6/25/2039	BETA BIONICS	Design
U.S.	D1,031,975	6/18/2039	BETA BIONICS	Design
U.S.	D1,022,185	4/9/2039	BETA BIONICS	Design
U.S.	US RE50075	1/17/36	Licensed	Utility
U.S.	US RE50085	8/8/33	Licensed	Utility
U.S.	9,833,570	12/25/34	Licensed	Utility
U.S.	8,273,052	7/10/26	Licensed	Utility
U.S.	7,806,854	6/18/26	Licensed	Utility
U.S.	11,135,366	7/15/40	BETA BIONICS	Utility

Depending on circumstances, we intend to file and prosecute patent applications for our technology in jurisdictions where we believe that patent protection is available and commercially important. Generally, for investigational devices that we believe are appropriate for patent protection, we will attempt to obtain patents in the United States, as well as key markets in Europe. However, depending on circumstances, we may not apply for patents in all or any of those jurisdictions, or we may pursue patent protection elsewhere. We plan to enforce our issued patents and our rights to proprietary information and technology as circumstances permit. We review third-party patents and patent applications in our fields of endeavor, both to shape our own patent strategy and to identify useful licensing opportunities.

Notwithstanding the foregoing, the patent positions of medical device companies, including our company, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or that any existing or future patent will not be circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. Generally, patent applications can be maintained in secrecy for at least 18

months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent the subject matter covered by each of our pending U.S. patent applications or that we were the first to file either U.S. or non-U.S. patent applications for such subject matter.

If a third party files a patent application relating to an invention claimed in our patent application, we may be required to participate in an interference or derivation proceeding declared by the U.S. Patent and Trademark Office to determine who is entitled to the patent rights. Such a proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court.

Third parties may claim that our products infringe their patents and other intellectual property rights. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product designs, license rights in order to continue manufacturing and selling our products or pay substantial damages. Third party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management's time and effort. Such claims could also cause our customers or potential customers to defer or limit their purchase or use of the affected products until resolution of the claim.

In addition to patents, we rely on trademarks, trade secrets, and know-how relating to our proprietary technology and programs, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position and protect our product brands. As of August 20, 2024, our trademark portfolio consists of fifteen (15) registered trademarks and nine (9) pending trademark applications. For example, our registered trademarks include: house marks (BETA BIONICS, stylized), product marks (iLet® bionic pancreas system) and tag-lines (DIABETES WITHOUT NUMBERS).

We rely on trade secret protection for certain unpatented aspects of other proprietary technology. There can be no assurance that others will not independently develop or otherwise acquire substantially equivalent proprietary information or techniques, that others will not gain access to our proprietary technology or disclose such technology, or that we can meaningfully protect our trade secrets. We have a policy of requiring key employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. Our confidentiality agreements also require our employees to assign to us all rights to any inventions made or conceived during their employment with us. We also require our consultants to assign to us any inventions made during the course of their engagement by us. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of confidential information or inventions.

The laws of foreign countries generally do not protect our proprietary rights to the same extent as do the laws of the United States. In addition, we may experience more difficulty enforcing our proprietary rights in certain foreign jurisdictions. We work with subject matter experts internationally, and our licensing partners to best manage foreign intellectual property matters, with their advice and consent to assure that our business and proprietary data strategies are co-extensive and consistent.

For more information regarding risks related to intellectual property, please see “*Risk Factors—Risks Related to Our Intellectual Property.*”

License and Collaboration Agreements

Device License Agreement with Boston University

In December 2015, we and BU, entered into a device license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the Device License Agreement). Under the

Device License Agreement, we received a royalty-bearing license (with the right to sublicense) under certain of BU's patent rights related to a system and individual components thereof for delivering multiple medicaments to a patient without medicament mis-channeling to make, use, sell, and import products, and practice processes covered by the licensed patent rights (collectively, the Licensed Products and Licensed Processes). The rights granted to us by BU under the Device License Agreement are exclusive, subject to certain reserved rights, including BU's right to practice and/or use the licensed patent rights for non-profit purposes such as sponsored research and collaborations, government rights and other third party rights. Furthermore, at BU's request, we will be required to negotiate a sublicense in good faith with a third party if we are unable or unwilling to use the patent rights licensed to us under the Device License Agreement to address the unmet needs of neglected people or geographic areas that such party is willing and able to address. The exclusivity may be terminated by BU if we fail to meet a specified percentage of the applicable minimum royalty amount for a given calendar year. The minimum royalty amount is a non-material amount.

Pursuant to the Device License Agreement, we agreed to use commercially reasonable efforts to market Licensed Products in the United States and elsewhere in the world. Additionally, we are obligated to meet certain diligence milestones under the Device License Agreement. We have satisfied all the milestones set forth under the Device License Agreement required to be achieved to date, with specified regulatory milestones remaining to be achieved in connection with our development of the Licensed Products and Licensed Processes.

In consideration for the licensed patent rights and other rights granted to us under the Device License Agreement, we issued 2,286 shares of our Class B common stock to BU, representing a specified ownership percentage on a fully diluted basis at the time of entering into the Device License Agreement, subject to anti-dilution adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock. We are also required to pay (i) quarterly royalties of a mid-single-digit percentage based on net sales of all Licensed Products and Licensed Processes by us or our affiliates, (ii) quarterly royalties of a low double-digit percentage based on net sales by our sublicensees (in each case (i) and (ii), which royalties are creditable against the minimum royalty amount), and (iii) agreed to make quarterly lump sum payments of a low-double-digit percentage based on certain non-royalty sublicensing revenue received by us from our sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. We also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if we assign the Device License Agreement in connection with the sale of all or substantially all of our assets relating to the licensed patent rights, we will be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment.

The Device License Agreement remains in effect for the Licensed Products and Licensed Processes on a country-by-country basis until the expiration, invalidation or termination of the last to expire, terminate, or invalidated licensed patent right, unless earlier terminated by BU. BU may terminate the Device License Agreement (i) for our uncured material breach, including our failure to meet any diligence milestone by the specified achievement date or our failure to make a payment due pursuant to the Device License Agreement, (ii) our breach of certain representations and warranties, (iii) upon our challenge of the validity of the licensed patent rights, or (iv) upon our bankruptcy or insolvency. BU may also terminate the agreement if it determines we are not diligently pursuing commercialization of the Licensed Products. We may terminate the Device License Agreement upon advance written notice to BU.

Control Algorithm License Agreement with Boston University

In December 2015, we and BU entered into a control algorithm license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the Control Algorithm Agreement). Under the Control Algorithm Agreement, we received a royalty-bearing license (with the right to sublicense) to (i) make, use, sell, and import products, and practice processes, covered by certain of BU's patent rights related to automated control systems for treatment of T1D and similar conditions, involving monitoring and/or delivering insulin, glucagon, and glucose (collectively, the Automated Control System Technology); and (ii) use, reproduce, prepare derivative works, perform, display, and distribute all or any part of the software, source code,

object code and/or related documentation, covered by certain copyright rights, and related to (a) the Automated Control System Technology and (b) the iLet control algorithm. The licenses granted by BU to us pursuant to the Control Algorithm Agreement are exclusive, subject to certain reserved rights including BU, BU's third party licensors' and other not-for profit institutions' rights to practice and/or use the patent rights for non-profit purposes such as sponsored research and collaborations and to permit other academic, government and not-for-profit institutions to make use of the same for educational purposes. Furthermore, at BU's request, we will be required to negotiate a sublicense in good faith with a third party if we are unable or unwilling to use the technology licensed to us under the Control Algorithm Agreement to address the unmet needs of neglected people or geographic areas that such third party is willing to address. The exclusivity may be terminated by BU if we fail to meet a specified percentage of the applicable minimum royalty amount for a given calendar year. The minimum royalty amount is a non-material amount. Additionally, under the Control Algorithm Agreement, we granted a perpetual, non-exclusive, royalty-free license back to BU with respect to the copyrights and patents covering any derivative works of the licensed software for BU's educational and academic purposes and to practice their reserved rights.

Pursuant to the Control Algorithm Agreement, we agreed to use commercially reasonable efforts to market Licensed Products in the United States and elsewhere in the world. Additionally, we are obligated to meet certain diligence milestones under the Control Algorithm Agreement. We have satisfied all the milestones set forth under the agreement required to be achieved to date.

In consideration for the licensed patent rights and other rights granted to us under the Control Algorithm Agreement, we issued 2,247 shares of our Class B common stock to BU, representing a specified ownership percentage on a fully diluted basis at the time of entering into the license agreement, subject to anti-dilution adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock to BU. We are also required to pay BU (i) quarterly royalties of a mid-single-digit percentage based on net sales by us and our affiliates, and royalties of a low double-digit percentage of net sales by sublicensees, in each case (i) and (ii), which royalties are creditable against the minimum royalty amount, and (iii) agreed to make quarterly lump sum payments of a low double-digit percentage of the non-royalty sublicensing revenue received by us from our sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. We also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if we undergo a change of control (as defined in the Control Algorithm Agreement) we will owe BU a one-time change of control payment of \$65,000. We will also be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment if we assign the Control Algorithm License Agreement in connection with the sale of all or substantially all of our assets relating to the licensed patent rights and copyright.

The Control Algorithm Agreement remains in effect (i) with respect to the patent rights for the Licensed Products and Processes, on a country-by-country basis until the expiration, invalidation or termination of the last to expire, terminate, or invalidated patent right, and (ii) with respect to the copyright for the software-based products and processes for thirty (30) years from the effective date of the Control Algorithm Agreement. BU may terminate the Control Algorithm Agreement (i) for our uncured material breach, including our failure to meet a milestone our failure to make a payment due to BU pursuant to the agreement, (ii) our breach of certain representations and warranties, (iii) upon our challenge of the validity of the patent rights, or (iv) upon our bankruptcy or insolvency. BU may also terminate the Control Algorithm Agreement if it determines we are not diligently pursuing commercialization of the Automated Control System. We may terminate the Control Algorithm Agreement for any reason upon advance written notice to BU.

Collaboration and License Agreement with Xeris Pharmaceuticals, Inc.

In May 2024, we and Xeris Pharmaceuticals, Inc. (Xeris), entered into a collaboration and license agreement (Collaboration and License Agreement). Under the Collaboration and License Agreement, we

received a worldwide, exclusive, royalty-bearing, sublicensable license under certain patent rights and know-how related to Xeris' proprietary non-aqueous formulation technology and technology developed during the collaboration (Xeris Technology) to develop and commercialize glucagon products that are reformulated using the Xeris Technology and developed by Xeris under a development plan under the Collaboration and License Agreement for use in a pump product or system for glycemic control (Glucagon Products) in the field of chronic glycemic control in diabetes mellitus, excluding single-dose, one-time use form for treatment of severe hypoglycemia and diagnostic uses (Field). We also received a worldwide, exclusive, sublicensable manufacturing license under the Xeris Technology to manufacture Glucagon Products in the Field following a future manufacturing transfer date to be agreed with Xeris and subject to a separate commercial supply agreement.

We and Xeris will conduct certain development activities for the Glucagon Products in accordance with the mutually agreed development plan. Xeris will be responsible for the cost of completing the activities under the development plan up to a certain development stage, and we will reimburse Xeris for any later-stage or additional work required under the development plan.

We and Xeris each agree not to directly or indirectly develop, commercialize or otherwise exploit any drug product comprising glucagon or a glucagon analogue, other than a Glucagon Product, for use with a pump system in the Field worldwide for the duration of the Collaboration and License Agreement, subject to certain specified exceptions.

Pursuant to the Collaboration and License Agreement, we agreed to use commercially reasonable efforts to develop and seek regulatory approval for a Glucagon Product in certain specified countries.

In consideration for the licenses and other rights granted to us under the Collaboration and License Agreement, we paid Xeris a one-time payment of \$0.5 million and we will pay Xeris a one-time milestone payment of \$3.0 million upon our achievement of a certain development milestone event. In addition, we are required to pay Xeris tiered royalties of low double-digit percentages based on net sales of Glucagon Products by us or our sublicensees, subject to certain customary reductions. Our obligation to pay Xeris royalties will commence, on a Glucagon Product-by-Glucagon Product and country-by-country basis, on the first commercial sale of such Glucagon Product in such country and expire on the later of (i) ten years after the first commercial sale of such Glucagon Product in such applicable country; (ii) expiration of the last valid claim of a specified patent right licensed by Xeris covering such Glucagon Product in such country; and (iii) expiration or termination or regulatory exclusivity for such Glucagon Product in the applicable country (Royalty Term).

The Collaboration and License Agreement will expire on a country-by-country and Glucagon Product-by-Glucagon Product basis upon the expiration of the Royalty Term with respect to such Glucagon Product in such country and will expire in its entirety upon the expiration of all Royalty Terms with respect to all Glucagon Products in all countries within the territory, and our licenses with respect to the Glucagon Products will automatically become fully paid-up, royalty-free, perpetual, and irrevocable. We may terminate the Collaboration and License Agreement in its entirety, or with respect to certain specified regions, on advance notice to Xeris for any or no reason. We or Xeris may terminate the Collaboration and License Agreement if the other party is in material breach of its obligations or if the other party becomes insolvent. Xeris may terminate the Collaboration and License Agreement if we commence any action or challenge regarding the scope, validity or enforceability of any of Xeris' patent rights within the Xeris Technology licensed to us under the Collaboration and License Agreement.

Development and Commercial Agreements

Commercialization Agreement with DexCom, Inc.

In July 2023, we and DexCom, Inc. (DexCom), entered into a commercialization agreement (the Commercialization Agreement). Under the Commercialization Agreement, we and DexCom agreed to

commercialize an AID system that is comprised of our system and DexCom's G6 or G7 iCGM system (the Combined Platform), which we and DexCom developed under a separate development agreement executed in December 2016. We and DexCom will use commercially reasonable efforts to commercialize the Combined Platform in accordance with an agreed commercialization plan, in the territories specified in the commercialization plan. We and DexCom will conduct certain development activities for the Combined Platform in accordance with an agreed development plan.

We granted DexCom a limited license to use certain of our trademarks in connection with commercialization of the Combined Platform under the Commercialization Agreement. DexCom granted us (a) a limited license to use the specifications and communication protocol integrating our system with DexCom's G6 and G7 iCGM devices and (b) a limited license to use certain of DexCom's trademarks, in each case (a) and (b), in connection with the development and commercialization of the Combined System. On termination of the Commercialization Agreement, each party's license will terminate, subject to any wind down period. We and DexCom also granted each other limited licenses to use certain data generated by the other's devices in the Combined System.

Unless earlier terminated, the Commercialization Agreement remains in effect until the five-year anniversary of the effective date, after which it will renew for successive two-year periods. Either party may terminate the Commercialization Agreement on written notice to the other party prior to the expiration of the initial term or any renewal term. We or DexCom may also terminate the Commercialization Agreement (i) in the event of any infringement of a third party's intellectual property rights by the terminating party's system, and the terminating party is unable to modify its system to be non-infringing or upon certain events relating to intellectual property matters, (ii) for the other party's uncured material breach, or (iii) if the other party becomes insolvent. DexCom may terminate the Commercialization Agreement in certain circumstances if we are acquired.

Development and Commercialization Agreement with Abbott Diabetes Care Inc.

In April 2024, we and Abbott Diabetes Care Inc. (Abbott), entered into a development and commercialization agreement (Development and Commercialization Agreement). Under the Development and Commercialization Agreement, we and Abbott agree to develop and commercialize an automated insulin delivery system comprised of our subcutaneous insulin infusion delivery system combined with Abbott's CGM sensor (Libre-Beta System).

Under the Development and Commercialization Agreement, we and Abbott agreed to jointly prepare a development plan setting forth each party's responsibilities in developing the Libre-Beta System in the United States. We are responsible for all development and clinical trials for the Libre-Beta System, and Abbott is responsible for all development for the continuous glucose monitoring system. We and Abbott agreed to jointly develop a regulatory plan for the Libre-Beta System, setting out the regulatory activities to be performed by each party. We and Abbott also agreed to jointly prepare a commercialization plan for the Libre-Beta System to launch the Libre-Beta System in the United States.

Abbott granted us a limited license under Abbott's existing background intellectual property and any intellectual property developed solely by Abbott under the Development and Commercialization Agreement for us to perform our obligations under the Development and Commercialization Agreement. Abbott also granted us a limited license to use Abbott's trademarks for the purpose of developing and marketing the Libre-Beta System.

We granted Abbott a limited license under our existing background intellectual property and any intellectual property developed solely by us under the Development and Commercialization Agreement for Abbott to perform its obligations under the Development and Commercialization Agreement. We also granted Abbott a limited license to use our trademarks for the purpose of developing the Libre-Beta System and marketing the continuous glucose monitoring system for use with the Libre-Beta System.

If the Development and Commercialization Agreement terminates prior to the first commercial sale of a Libre-Beta System, the foregoing licenses will terminate upon termination of the Development and Commercialization Agreement. If the Development and Commercialization Agreement terminates after the first commercial sale of a Libre-Beta System, such licenses will continue for a defined period following such termination in order to provide continued access and support to users of the Libre-Beta System.

The Development and Commercialization Agreement remains in effect for a five-year term, after which it will renew for successive two-year periods. We or Abbott may terminate the Development and Commercialization Agreement on prior written notice to the other party at any time after a defined period following the first commercial sale of the Libre-Beta System in the United States. We or Abbott may also terminate the Development and Commercialization Agreement (i) for the other party's material breach, (ii) upon the other party's bankruptcy or insolvency, or (iii) if the other party is acquired by or merges with any one of certain named competitors. In addition, if the first commercial sale of the Libre-Beta System has not occurred by a specified date, then either party may terminate the Development and Commercialization Agreement on written notice to the other party.

Government Regulation and Product Approval

Our products and operations are subject to extensive regulation by the FDA, and other federal and state authorities in the United States, as well as comparable authorities and bodies in foreign jurisdictions. Our products are subject to regulation as drugs and medical devices in the United States under the federal Food, Drug, and Cosmetic Act (FDCA), as implemented and enforced by the FDA.

FDA Regulation of Medical Devices

The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices to ensure medical devices distributed in the United States are safe and effective for their intended uses and otherwise meet the requirements of the FDCA:

- product design, development and manufacturing;
- pre-clinical and clinical testing, labeling, content and language of instructions for use and storage;
- product safety;
- marketing, sales and distribution;
- pre-market clearance or approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

FDA Pre-Market Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, *de novo* classification, or approval of a pre-market approval (PMA) application from the FDA, unless specifically exempted. Both the 510(k) clearance and PMA processes can be resource intensive, expensive and lengthy, and require payment of significant user fees, unless an exemption is available.

The FDA classifies medical devices into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation (QSR), facility registration and product listing, reporting of adverse medical events and certain device malfunctions (known as medical device reporting (MDR), and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and additional conditions set forth in FDA guidance documents. While most Class I devices are exempt from the 510(k) pre-market notification requirement, manufacturers of most Class II devices are required to submit to the FDA a pre-market notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) pre-market notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices are placed in Class III, requiring approval of a PMA application. Some pre-amendment devices are unclassified but are subject to the FDA's pre-market notification and clearance process in order to be commercially distributed. Novel devices that have not yet been classified are automatically classified as Class III and are subject to the PMA approval process, except that such novel devices that are low to moderate risk may obtain marketing authorization through the *de novo* classification process rather than the PMA process. Our currently commercialized iLet is comprised of hardware and software devices, which are classified as Class II.

The FDA has established three different classification regulations for components of glycemic control systems. These regulations establish the classification (and thus the regulatory path to market), as well as the requirements, such as special controls, to which such components must adhere. These classification regulations govern: (1) the alternate controller enabled insulin infusion pump (ACE) insulin pump; (2) the interoperable automated glycemic controller (iAGC); and (3) the integrated continuous glucose monitor (iCGM), each of which is determined by the FDA to be Class II.

The FDA defines an ACE insulin pump as a device intended for the infusion of insulin into a patient. The ACE pump may include basal and bolus drug delivery at set or variable rates. ACE pumps are designed to reliably and securely communicate with external devices, such as automated insulin dosing systems, to allow drug delivery commands to be received, executed, and confirmed. ACE insulin pumps are intended to be used both alone and in conjunction with digitally connected medical devices for the purpose of insulin delivery.

The FDA defines an iAGC as a device intended to automatically calculate drug doses based on inputs such as glucose and other relevant physiological parameters, and to command the delivery of such drug doses from a connected infusion pump. iAGCs are designed to reliably and securely communicate with digitally connected devices to allow drug delivery commands to be sent, received, executed, and confirmed. iAGCs are intended to be used in conjunction with digitally connected devices for the purpose of maintaining glycemic control.

The FDA defines an iCGM as a system intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.

The iLet bionic pancreas dual chamber pumping platform is cleared by FDA as an ACE insulin pump. Our proprietary automated dosing algorithms embedded within the iLet are cleared by FDA as an iAGC. Our partner's iCGM makes up the third Class II component of our automated glycemic control system.

510(k) Clearance Process

To obtain 510(k) clearance, a manufacturer must submit a pre-market notification to the FDA demonstrating that the proposed device is substantially equivalent to a previously-cleared 510(k) device, a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMA applications, or is a device that has been reclassified from Class III to either Class II or I. In rare cases, Class III devices may be cleared through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months from the date the application is submitted and filed with the FDA, but may take significantly longer, particularly for a novel type of product. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, including clinical data, which may significantly prolong the review process.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. Once a *de novo* application is reviewed and approved, it results in the device having a Class II status and future devices from the company or a competitor may use the company's *de novo*-classified device as a 510(k) predicate.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult and costly for manufacturers to utilize the 510(k) clearance process for their products.

De Novo Classification Process

Devices of a new type that FDA has not previously classified based on risk are automatically classified into Class III, regardless of the level of risk they pose. However, the FDA may authorize such novel devices that are low- to moderate-risk through the *de novo* classification process. A medical device may be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent or a manufacturer may request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 days following receipt of the *de novo* application, although in practice, the FDA's review may take significantly longer.

When FDA grants a request for de novo classification, the device is granted marketing authorization and can serve as a predicate for future devices of that type, through a 510(k) premarket notification.

Pre-market Approval Process

A PMA application must be submitted and approved prior to marketing if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, preclinical, and clinical trials, as well as manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. In addition, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision-making process. Further, the FDA generally will conduct a pre-approval inspection of the manufacturing facility(ies) to evaluate compliance with QSR, which requires manufacturers to implement and follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application typically takes one to three years but could take longer. The review time is often significantly extended as a result of the FDA asking for additional information or clarification of information already provided.

If an FDA evaluation of a PMA application is favorable, the FDA may issue either an approval letter, or approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of a device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facility(ies) is not favorable, the FDA will deny approval of the PMA or issue a not-approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, indications, labeling, device specifications, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMAs.

Exempt Devices

If a manufacturer's device falls into a generic category of Class I or Class II devices that FDA has exempted by regulation, a premarket notification is not required before marketing the device in the United States. Manufacturers of such devices are required to register their establishments and list their devices. Some 510(k)-exempt devices are also exempt from QSR requirements, except for the QSR's complaint handling and recordkeeping requirements.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components, that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the “primary mode of action” of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the device product, the FDA center responsible for premarket review of the device product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a device primary mode of action generally would be reviewed and cleared or approved pursuant to the device review processes under the FDCA. In reviewing the PMA, 510(k), or De Novo request for such a product, however, FDA reviewers in the device center could consult with their counterparts in the drug center to ensure that the drug component of the combination product met applicable requirements regarding safety and effectiveness. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the QSR applicable to medical devices.

Clinical Trials

Clinical trials are almost always required to support a PMA or *de novo* classification and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA’s investigational device exemption (IDE)

regulations, which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a “significant risk” to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA’s regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that FDA may impose with respect to manufacturing.

Investigational devices may only be distributed for use in an investigation and must bear a label with the statement: “CAUTION—Investigational device. Limited by Federal law to investigational use.”

Sponsors of certain clinical trials of medical devices are required to register with clinicaltrials.gov, a public database of clinical trial information, and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product being studied has been approved or cleared. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

Expedited Development and Review Programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for PMA approval, 510(k) clearance and de novo classification.

The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions.

Post-Market Regulation of Medical Devices

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to the following:

- the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- establishment registration, which requires establishments involved in the production and distribution of medical devices, intended for commercial distribution in the United States, to register with the FDA;
- medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with federal law and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

- labeling regulations, which prohibit “misbranded” devices from entering the market, as well as prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The manufacturing processes are required to comply with the applicable portions of the FDA’s QSR that covers the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. In February 2024, the FDA issued the Quality Management System Regulation (QMSR) Final Rule to amend the QSR, incorporating by reference the international standard for medical device quality management systems set by the ISO, ISO 13485:2016. The rule will become effective on February 2, 2026. Until then, manufacturers are required to comply with the QSR.

The FDA has broad post-market and regulatory enforcement powers. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers.

Failure to comply with applicable regulatory requirements may result in enforcement or other adverse action by the FDA, which may include one or more of the following sanctions:

- untitled letters or warning letters;
- customer notifications for repair, replacement or refunds;
- fines, injunctions, consent decrees and civil penalties;
- mandatory recall or seizure;
- administrative detention or bans;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for or denying 510(k) clearance or PMA of new product versions;
- revocation of 510(k) clearance or PMAs previously granted;
- reclassification of a marketed device; and
- criminal prosecution and penalties.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission depending on the type of device and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes.

Furthermore, under the federal U.S. Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice.

FDA Regulation of Drug Products

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending new drug applications (NDAs) warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves nonclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application (IND), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically take many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not issued a clinical hold within this 30-day period, the clinical trial may begin. Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (iii) under protocols detailing the objectives of the trial and the criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by confirmatory evidence.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee unless a waiver applies. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of NDAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the NDA; most applications classified as Priority Review are reviewed within six months of the date the FDA files the NDA. An NDA can be classified for Priority Review when the FDA determines the drug has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information or information intended to clarify information already provided in the NDA submission. Most innovative drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDCA, commonly referred to as a traditional or "full NDA." In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, that established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing approved product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products that would require new clinical data to demonstrate safety or effectiveness. Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate or reduce the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. The FDA may also require companies to perform additional studies or measurements, including nonclinical and clinical studies, to support the change from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). An ETASU can include, but is not limited to, special training or

certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved NDA, including changes in indications, product labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or supplement to an approved NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original NDAs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a drug's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Regulatory Exclusivity and Approval of Follow-on Products

Hatch-Waxman Exclusivity

In addition to enacting Section 505(b)(2) of the FDCA as part of the Hatch-Waxman Amendments to the FDCA, Congress also established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA) to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD).

In order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is “bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if “the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.” Unlike the 505(b)(2) NDA pathway that permits a follow-on applicant to conduct and submit data from additional clinical trials or nonclinical studies in order to support the proposed change(s) to the reference product, the ANDA regulatory pathway does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data.

Upon approval of an ANDA, the FDA indicates whether the generic product is “therapeutically equivalent” to the RLD in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

As part of the NDA review and approval process, applicants are required to list with the FDA each patent that has claims that cover the applicant’s product or method of therapeutic use. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential follow-on competitors in support of approval of an ANDA or 505(b)(2) NDA.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA’s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the follow-on applicant does not challenge the innovator’s listed patents, the FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

An ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivities listed in the Orange Book for the referenced product have expired. The Hatch-Waxman Amendments to the FDCA provided a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity (NCE). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph

IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of data exclusivity if an NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, an applicant submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

A patent claiming a prescription drug for which FDA approval is granted may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The restoration period granted on a patent covering a new FDA-regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for premarket approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. However, the restoration period can be reduced for any time the FDA determines that the applicant did not diligently pursue approval. In addition, patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the marketing approvals. The United States Patent and Trademark Office (USPTO) reviews and approves the application for any patent term extension or restoration in consultation with the FDA. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

Foreign Government Regulation

The regulatory review processes for medical devices and drugs varies from country to country, and many countries also impose product standards, packaging requirements, environmental requirements, labeling requirements and import restrictions on devices. Each country has its own tariff regulations, duties, and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject a company to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, criminal prosecution or other consequences.

Other Healthcare Laws

Our current and future business activities are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims and healthcare professional payment transparency laws and regulations.

The federal Anti-Kickback Statute (AKS) prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation.

Additionally, the civil False Claims Act (FCA) prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U.S. government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of life sciences companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil FCA. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The majority of states also have analogous laws which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers.

HIPAA created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare

benefits, items or services. Like the AKS, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, which impose, among other things, requirements on certain covered HCPs, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act (ACA), and its implementing regulations, also imposed annual reporting requirements on manufacturers of certain devices, drugs and biologics for payments available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; as well as ownership and investment interests held by physicians and their immediate family members.

Finally, there are analogous state and foreign laws and regulations, such as state and foreign laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other HCPs, marketing expenditures or product pricing; state and local laws that require the registration of medical device sales representatives; state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our future operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, administrative civil and criminal penalties, damages, fines, imprisonment, the curtailment or restructuring of our operations, additional reporting and oversight obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

United States Health Reform

The United States and some foreign jurisdictions have enacted or are considering a number of health reform measures to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access.

The implementation of the ACA in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. There have been executive, judicial and congressional challenges, and a number of health reform measures by the Biden administration that have impacted certain aspects of the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other

things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. It is possible that the ACA and the IRA will be subject to additional challenges in the future.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Coverage and Reimbursement

In the United States and markets in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new device acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and devices they will cover and the amount of reimbursement. Coverage may be more limited than the purposes for which the drug or device is approved by the FDA or comparable foreign regulatory authorities. In the United States, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), determines whether and to what extent a new drug or device will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for products exists among third-party payors. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for the iLet, in either configuration for T1D or other indications, the resulting reimbursement payment rates might not be adequate for us to maintain pricing sufficient to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations. It is also possible that CMS and other third-party payors may continue to review and modify the current coverage and reimbursement of diabetes-related products in connection with anticipated changes to the regulatory approval process for insulin pumps and related products, software applications and services. Patients are unlikely to use our devices, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. Because the iLet may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, coverage and reimbursement rates may be inadequate for us to achieve profitability. Moreover, increasing efforts by

governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products. Further, it is possible that some third-party payors will not offer any coverage for iLet or our future products. For instance, it is possible that third-party payors may adopt policies in the future that designate one or more of our competitors as their preferred, in-network provider of insulin pumps and that such policies would discourage or prohibit the payors' members from purchasing our products, which would adversely impact our ability to sell the iLet.

We are pursuing a multi-channel managed care strategy through both traditional DME and PBP channels. If covered, the iLet is typically reimbursed through traditional medical benefit channels. As a medical device company, reimbursement from government and/or commercial third-party healthcare payors, including Medicare and Medicaid, is an important element of our success. Our product is eligible for Medicare coverage as DME under Medicare Part B. Coverage criteria for DME is determined by CMS under national coverage determinations as well as by local Medicare Administrative Contractors under local coverage determinations. Therefore, Medicare reimbursement for the iLet is subject to various coverage conditions. We are also offering the iLet through the PBP channel. However, the commercial opportunity in the PBP channel may be limited unless a substantial portion of the sales price for the iLet is covered by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, federal and state government healthcare agencies, intermediaries, Medicare, Medicaid and other managed care providers. Medicare Part D plan sponsors may provide coverage for iLet under the Medicare Part D prescription drug program, which requires negotiating with third-party payors in order to provide iLet through the PBP channel in the United States. Securing and retaining adequate coverage or reimbursement for the iLet and our future products by third-party payors, and expedient processing approvals by those payors, is necessary for sales and the health of our business, financial condition and operating results.

Data Privacy and Security Laws

In the ordinary course of our business, we may process personal or sensitive data. Accordingly, we are or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the Federal Trade Commission Act, the TCPA, COPPA, the CANSPAM, the CCPA, and Washington's MHMD. Several states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

The CCPA and other similar privacy laws described herein are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collecting, using, and disclosing personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the California Privacy Rights Act of 2020 (CPRA) amended the CCPA effective as of January 1, 2023 by, among other things, giving California residents the ability to limit use of certain sensitive personal data, establishing restrictions on personal data retention, expanding the types of data breaches that are subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the new law.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from directly or indirectly offering, promising, authorizing or making corrupt payments, gifts or transfers to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business. The scope of the FCPA would include interactions with certain healthcare professionals in many countries.

Facilities

Our principal office is located in Irvine, California, where we lease approximately 50,000 square feet of office, laboratory and manufacturing space. We sublease additional corporate offices in San Diego, California that consist of approximately 6,300 square feet of office space. We also lease corporate offices in Concord, Massachusetts that consist of approximately 13,000 square feet of office space. The lease for our office, laboratory and manufacturing space in Irvine, California expires in May 2027, the sublease for our office in San Diego, California expires in March 2027, and the lease for our office in Concord, Massachusetts expires in May 2026. We believe that our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

Employees and Human Capital Resources

As of August 31, 2024, we had 277 full-time employees and three part time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. We have not experienced any work stoppages as a result of labor disputes or strikes. We have built a strong and positive workplace culture and we pride ourselves on maintaining good relationships with our employees. All our employees enjoy a range of benefits including company-matching 401(k) contributions, participation in our incentive stock option incentive program and our payment of health insurance premiums for both the employee and the employee's family.

Environmental Matters

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including flammables, toxics, corrosives and biologics. Our research operations produce hazardous biological and chemical waste products. We seek to comply with applicable laws regarding the handling and disposal of such materials. Given the small volume of such materials used or generated at our facilities, we do not expect our compliance efforts to have a material effect on our capital expenditures, earnings and competitive position. However, we cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages and suspension of our operations.

Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. There are currently no claims or actions pending against us, the ultimate disposition of which we believe could have a material adverse effect on our results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

The following table sets forth certain information for our executive officers and directors as of August 31, 2024:

Name	Age	Position(s)
Executive Officers		
Sean Saint	48	Chief Executive Officer and Director
Stephen Feider	35	Chief Financial Officer
Mike Mensinger	47	Chief Product Officer
Steven Russell, M.D., Ph.D.	56	Chief Medical Officer
Edward Damiano, Ph.D.	59	Executive Chairman
Non-Employee Directors		
Amanda Black	32	Director
Sean Carney	55	Director
James Parker Cassidy	51	Director
Francesco Draetta	39	Director
Westley Dupray	30	Director
Gilad Glick	51	Director
Lennox Ketner	47	Director
Adam Lezack	45	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Sean Saint has served as our Chief Executive Officer and a member of our board of directors since August 2022. Mr. Saint co-founded Luna Diabetes, a private company focused on automated insulin delivery for multiple daily injection users and has served as a member of its board of directors since January 2021. From January 2014 to September 2020, Mr. Saint served as Co-Founder and Chief Executive Officer of Companion Medical, Inc., a medical device company in the diabetes industry, leading the development and launch of the company's InPen, a smart insulin pen for diabetes patients, and the acquisition of the company by Medtronic in 2020. He continued to serve as Vice President of Companion Medical at Medtronic through August 2021. From July 2009 to January 2014, Mr. Saint served as Director of Mechanical Engineering and Advanced Technology at Tandem Diabetes Care, a medical device manufacturer, leading the design and implementation of a pumping mechanism for insulin infusion therapy. From August 2007 to February 2009, Mr. Saint served as Co-Founder and Vice President of Research and Development at Alure Medical, a medical developer, leading the hiring efforts of the engineering and regulatory teams, implementing a clinical trial and receiving 510(k) clearance from the FDA for the company's devices. Prior to that, from October 2003 to August 2007, Mr. Saint worked as Engineering Manager at Dexcom, a public company focused on continuous glucose monitoring systems for diabetes management, managing the development of a short-term transcutaneous sensor and an in-hospital IV-based glucose monitor. Mr. Saint received his B.S. in Mechanical Engineering and minor in Computer Science from California Polytechnic State University – San Luis Obispo. Mr. Saint is also a certified Professional Engineer in California. We believe that Mr. Saint's extensive experience in the diabetes industry qualifies him to serve on our board of directors.

Stephen Feider has served as our Chief Financial Officer since August 2022. Previously, Mr. Feider worked at Medtronic, serving as Diabetes Finance Director from September 2020 to August 2022, and at Companion Medical (acquired by Medtronic), serving as Vice President of Finance from April 2019 to September 2020. Prior to joining Medtronic, Mr. Feider served as Corporate Controller at Marathon Health, a provider of employer population health solutions, from January 2014 to April 2019. From August 2012 to

December 2013, Mr. Feider worked as a Certified Public Accountant at PricewaterhouseCoopers LLP. Mr. Feider received his B.A. and Master's degree in Accountancy from Butler University.

Mike Mensinger has served as our Chief Product Officer since August 2023. Previously, Mr. Mensinger co-founded Companion Medical, Inc. (acquired by Medtronic) and served as Chief Technology Officer from April 2017 to August 2023 and as Vice President, Research and Development from September 2020 to July 2023, where he led the research and development of the company's InPen, a smart insulin pen for diabetes patients. Prior to co-founding Companion Medical, Inc., Mr. Mensinger worked at Dexcom, holding various roles of increasing responsibility, including Engineering Manager from December 2003 to October 2011, Program Manager from September 2011 to March 2012, Senior Mobile and PC Software Development Manager from January 2012 to March 2014 and Director of Software Engineering from March 2014 to April 2017. Mr. Mensinger received his B.S. in Computer and Software Engineering from the University of Delaware.

Steven Russell, M.D., Ph.D. has served as our Chief Medical Officer since November 2022. Dr. Russell has served as Associate Professor of Medicine at Harvard Medical School since April 2012. His research focuses on the development and testing of technologies to improve diabetes management. Dr. Russell has also served as Attending Physician at the Massachusetts General Hospital, focusing on managing diabetes in outpatient and inpatient settings, since July 2006. Dr. Russell was the principal clinical investigator of a collaboration between Massachusetts General Hospital and Boston University to develop a wearable automated blood glucose control system for diabetes patients. Dr. Russell received his B.S. in Biochemistry from Trinity University and his M.D. and Ph.D. in Biological Chemistry from the University of Texas Southwestern Medical School. He completed both his residency in internal medicine and fellowship in endocrinology, diabetes and metabolism at the Massachusetts General Hospital and his postdoctoral fellowship studying insulin and aging at the Joslin Diabetes Center.

Edward Damiano, Ph.D. is our Co-Founder and has served as our Executive Chairman since February 2022. Dr. Damiano was the President and CEO of Beta Bionics from its inception in October 2015 to February 2022. He served as an Associate Professor of Biomedical Engineering at Boston University from September 2004 to August 2015 and as a Professor of Biomedical Engineering at Boston University from September 2015 to June 2023. Prior to that, he was an Assistant Professor of Mechanical Engineering at the University of Illinois at Urbana-Champaign from September 1997 to August 2004. Ever since his son was diagnosed with type 1 diabetes in infancy, he set his sights on designing, developing, and testing a bionic pancreas that integrated autonomous, intelligent systems into a purpose-built, wearable medical device which led to the incorporation of Beta Bionics. Dr. Damiano received his B.S. in Biomedical Engineering from Rensselaer Polytechnic Institute, M.S. in Mechanical Engineering from Washington University in St. Louis, and Ph.D. in Applied Mechanics from Rensselaer Polytechnic Institute. He was a postdoctoral research associate in the Bioengineering Department at the University of Utah in 1994 and a postdoctoral research fellow in the Biomedical Engineering Department at the University of Virginia from 1994 to 1997.

Non-Employee Directors

Amanda Black has served as a member of our board of directors since August 2023. Ms. Black has served as an Investment Director at Farallon Capital Management, a global institutional asset management firm, since January 2024, which she joined in August 2021 as an Investment Analyst. Previously, Ms. Black served as a Private Equity Associate at The Carlyle Group, a private equity firm, as part of its Global Private Equity Healthcare investment team, from July 2017 to June 2019. Ms. Black also served as an Investment Banking Associate from March 2017 to May 2017, an Investment Banking Analyst from July 2015 to February 2017, and an M&A Investment Banking Analyst from July 2014 to June 2015, at Deutsche Bank. Ms. Black received her A.B. in Applied Mathematics from Harvard University and her M.B.A. from Harvard Business School. We believe that Ms. Black's experience working in the finance and healthcare private equity industries qualifies her to serve on our board of directors.

Sean D. Carney has served as a member of our board of directors since February 2020. Mr. Carney has served as a Partner and Head of Global Investment at Hillhouse Investment, a private equity firm, since February 2017, focusing on global leveraged buyouts and carve-outs. Mr. Carney also serves on the boards of several privately held companies, including George Clinical since June 2023 and Versuni since September 2021. From November 1996 to December 2017, Mr. Carney served as a Managing Director at Warburg Pincus LLC, a private equity firm. He has previously served on numerous public and private company boards, including Bausch + Lomb, an eye health products company, Dexcom, and the Wright Medical Group N.V., a global medical device company. Mr. Carney received his A.B. in Economics from Harvard University and his M.B.A. from Harvard Business School. We believe that Mr. Carney's extensive directorship experience and his experience working in the private equity industry qualifies him to serve on our board of directors.

James Parker Cassidy has served as a member of our board of directors since August 2023. Mr. Cassidy has served as a Partner at Sands Capital since August 2021. From April 2020 to June 2021, Mr. Cassidy served as Principal at RA Capital Management, L.P. From November 2015 to April 2020, Mr. Cassidy was Chief Commercial Officer at Farcast Biosciences, a medical diagnostic platform. Prior to that, Mr. Cassidy held roles of increasing responsibility at BD, a global medical technology company, including Director of Product and Business Development from September 2006 to November 2009, Managing Director of Infectious Disease Molecular Diagnostics from November 2009 to February 2011, and Vice President of Continuous Glucose Monitoring from February 2011 to February 2014. Mr. Cassidy currently serves on the boards of directors of several private biotechnology companies, including Nucleix Ltd. since November 2021 and Selux Diagnostics, Inc. since June 2018. He received his B.S. in Mechanical Engineering from Boston University and his M.B.A. from the University of Virginia Darden School of Business. We believe that Mr. Cassidy's leadership experience in commercial operations and extensive directorship experience qualifies him to serve on our board of directors.

Francesco Draetta has served as a member of our board of directors since August 2023. Mr. Draetta has served as Managing Director at Omega Funds, an international investment firm focused on life sciences companies, since January 2024 and focuses on early-stage investments in several of Omega's therapeutic areas of interest and co-leads the firm's fundraising efforts. Previously, Mr. Draetta held roles of increasing responsibility at Omega Funds, including Senior Associate from August 2016 to January 2018, Principal from January 2018 to December 2021 and Partner from December 2021 to January 2024. He was previously part of the investment teams at Brookside Mezzanine Partners and at Commonfund Capital. Mr. Draetta has served on the board of directors of private companies Third Arc Bio, Inc., a biotech company, since December 2021, NRG Therapeutics, a biotech company, since June 2022, and Kestra Medical Technologies, a medical device company, since July 2024. Mr. Draetta also served on the board of directors of CHORD Therapeutics (acquired by Merck), a biotech company, from August 2020 to January 2022. Mr. Draetta was the Chief Financial Officer at Omega Alpha SPAC, a special purpose acquisition company, from November 2020 to January 2023. Mr. Draetta received his B.B.A. in Finance from the Isenberg School of Management at the University of Massachusetts Amherst. Mr. Draetta is a CFA charterholder, a CAIA charterholder, and a Certified FRM. We believe that Mr. Draetta's extensive experience working at investment funds and his leadership experience qualifies him to serve on our board of directors.

Westley Dupray has served as a member of our board of directors since August 2023. Mr. Dupray has served as a Research Analyst at Eventide Asset Management, an asset management firm, since August 2021, focusing on healthcare investments. Prior to that, he worked at SVB Leerink, an investment bank specializing in healthcare and life sciences, serving as Vice President (Equity Research, Life Science Tools and Diagnostics) from February 2021 to July 2021 and as an Equity Research Associate from September 2018 to February 2021. Mr. Dupray has served on the board of directors of private company PreciseDx, Inc. since February 2024. He received his B.S. in Economics-Finance from Bentley University. We believe that Mr. Dupray's extensive experience in life sciences asset management qualifies him to serve on our board of directors.

Gilad Glick has served as a member of our board of directors since May 2022. Mr. Glick has served as the Vice President of Venture Investments (MedTech, JJDC) at Johnson & Johnson since July 2022. From

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December 2021 to July 2022, Mr. Glick served as the President (ZOLL ITAMAR Division) at ZOLL Medical Corporation, a medical technology company. Prior to that, Mr. Glick was the Chief Executive Officer at Itamar Medical, a home equipment medical technology company, from July 2013 to December 2021. Mr. Glick has served on the boards of directors of several private biotechnology companies, including BioBeat Medical since November 2023, UltraSight Medical since January 2023 and eCential Robotics since August 2021. He previously served on the board of directors of Almeda Ventures, an Israeli venture fund, from October 2020 to May 2022. He received his M.B.A. in general strategic management from the Maastricht School of Management. We believe that Mr. Glick's experience working in the medical technology industry qualifies him to serve on our board of directors.

Lennox Ketner has served as a member of our board of directors since August 2023. Ms. Ketner has served as a Partner at Soleus Capital Management, L.P., a life sciences fund, since November 2017. From 2015 to 2017, Ms. Ketner served as Vice President of Paulson & Co., an employee-owned private investment firm. She has served on the board of directors of Q'Apel Medical, a privately held medical device company, since April 2024. Ms. Ketner received her B.A. from Stanford University and her J.D. from the New York University School of Law. We believe that Ms. Ketner's extensive experience in life sciences investing qualifies her to serve on our board of directors.

Adam Lezack has served as a member of our board of directors since December 2023. Mr. Lezack is Co-Founder of Fortis Advisors (acquired by PNC Bank in 2018), a shareholder representative services firm specializing in mergers and acquisitions (M&A), and has served as Managing Director since 2011. Following Fortis Advisors' acquisition by PNC Bank, Mr. Lezack led the build-out and commercialization of the PNC M&A Escrow and Payment Solutions business and served as its Managing Director. Prior to founding Fortis Advisors, Mr. Lezack worked as a Corporate Attorney at DLA Piper from May 2008 to August 2011. Mr. Lezack previously served as a member of the board of directors of the San Diego Chapter of the Juvenile Diabetes Research Foundation (now Breakthrough T1D). He received his B.Com degree from the University of Victoria, his J.D. from the University of Manitoba Faculty of Law and his LL.M. from the University of San Diego School of Law. We believe that Mr. Lezack's entrepreneurial leadership and legal experience qualify him to serve on our board of directors.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Composition of Our Board of Directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of 10 members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and on an ad hoc basis as required. In accordance with the terms of our certificate of incorporation and bylaws, which will become effective immediately prior to and upon the closing of this offering, respectively, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of _____, _____ and _____, whose terms will expire at our first annual meeting of stockholders to be held following this offering;
- Class II, which will consist of _____, _____ and _____, whose terms will expire at our second annual meeting of stockholders to be held following this offering; and
- Class III, which will consist of _____, _____ and _____, whose terms will expire at our third annual meeting of stockholders to be held following this offering.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently ten members. The authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66-2/3% of our voting stock.

Board Leadership Structure

Our board of directors is currently chaired by Edward Damiano, Ph.D., who has authority, among other things, to call and preside over board of directors meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the Executive Chairman has substantial ability to shape the work of the board of directors. We believe that separation of the positions of Executive Chairman and Chief Executive Officer reinforces the independence of the board of directors in its oversight of our business and affairs. In addition, we have a separate chair for each committee of our board of directors. The chair of each committee is expected to report annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

Role of the Board in Risk Oversight

The audit committee of our board of directors is primarily responsible for overseeing our risk management processes on behalf of our board of directors. Going forward, we expect that the audit committee will receive reports from management periodically regarding our assessment of risks. In addition, the audit committee reports regularly to our board of directors, which also considers our risk profile. The audit committee and our board of directors focus on the most significant risks we face and our general risk management strategies. While our board of directors oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee and our board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board of directors' leadership structure, which also emphasizes the independence of our board of directors in its oversight of its business and affairs, supports this approach.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees as it deems necessary or appropriate from time to time. Each committee has adopted a written charter that satisfies the applicable rules and regulations of the Sarbanes-Oxley Act, the SEC and the listing standards of _____, which we will post on our website, www.betabionics.com, upon the closing of this offering.

Audit Committee

Our audit committee consists of _____, _____ and _____. _____ serves as the chair of our audit committee. Our board of directors has determined that each of the members of our audit committee satisfies the and SEC independence requirements. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;

- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and discussing the statements and reports with our independent auditors and management;
- reviewing, with our independent auditors and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and recommending updates to our insider trading policy;
- reviewing and providing oversight of any related-person transactions in accordance with our related-person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial, information security and cybersecurity risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management are implemented;
- reviewing and making recommendations to the full board of directors regarding directors and officers indemnification and insurance matters;
- reviewing on a periodic basis our investment policy and related-person transactions policy; and
- reviewing and evaluating on an annual basis the performance of the audit committee and the audit committee charter.

Our board of directors has determined that _____ qualifies as an “audit committee financial expert” within the meaning of SEC regulations and meets the _____. In making this determination, our board has considered prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Our compensation committee consists of _____, _____ and _____ serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act and satisfies the independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving or, in the case of our chief executive officer's compensation, making recommendations to the full board of directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- overseeing workplace diversity initiatives and progress;
- modifying and overseeing the compensation clawback or similar policies;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- considering questions of possible conflicts of interest of directors as such questions arise;
- reviewing and making recommendations to the full board of directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- reviewing with management and making recommendations to the full board of directors regarding the plans for succession of our chief executive officer and other key executives;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of , and . serves as the chair of our nominating and corporate governance committee. Our board of directors has determined that each of the members of this committee satisfies the independence requirements. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- reviewing and recommending updates to the list of executive officers who are subject to the reporting requirements of Section 16 of the Exchange Act;
- developing a set of corporate governance policies and principles, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- overseeing our environmental, social and governance strategies, targets, policies, performance and reporting; and
- reviewing and assessing on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee Interlocks and Insider Participation

None of our current or former executive officers serve as a member of the compensation committee. None of our officers serve, or have served during the last completed fiscal year, on the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. For a description of transactions between us and members of our compensation committee and affiliates of such members, see the section titled “Certain Relationships and Related Party Transactions.”

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt an amended written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. Following this offering, a current copy of the code will be available on the Corporate Governance section of our website, www.betabionics.com. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment and affiliations, our board of directors has determined that of _____, _____ and _____ do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the applicable listing standards. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares held by each non-employee director and the transactions described in the section titled “Certain Relationships and Related Party Transactions.”

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the year ended December 31, 2024, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- Sean Saint, our President and Chief Executive Officer;
- , our ; and
- , our .

Summary Compensation Table for the Year Ended December 31, 2024

The following table presents all of the compensation awarded to our named executive officers during the year ended December 31, 2024.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Sean Saint	2024	\$	\$	\$	\$	\$
President and Chief Executive Officer	2024					
	2024					

Narrative to Summary Compensation Table

Annual Base Salary

The 2024 annual base salary rates for our named executive officers are set forth in the table below.

Name	2024 Base Salary
Sean Saint	\$

Performance Bonus Opportunity

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is generally based on the extent to which we achieve the corporate goals that our board of directors establishes each year. At the end of the year, our board of directors reviews our performance against each corporate goal and determines the extent to which we achieved each of our corporate goals.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees, including our executive officers. The board of directors or an authorized committee thereof is responsible for approving equity grants.

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Prior to this offering, we have granted stock options pursuant to our 2016 Stock Incentive Plan (2016 Plan) to certain of our executives. Following this offering, we will grant equity awards under the terms of our 2025 Equity Incentive Plan (2025 Plan). The terms of our equity plans are described below under the subsection titled “—Equity Benefit Plans.”

Outstanding Equity Awards as of December 31, 2024

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2024.

Name	Grant Date	Vesting Commencement Date	Option Awards			
			Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price Per Share	Option Expiration Date
Sean Saint					\$	

Employment Arrangements with Our Named Executive Officers

We have employment agreements or offer letters with each of our named executive officers. The material terms of each of these agreements are described below. These agreements provide for base salaries and incentive compensation, and each component reflects the scope of each named executive officer’s anticipated responsibilities and the individual experience they bring to our company. The employment of each of our named executive officers is “at will” and may be terminated at any time.

Sean Saint. We entered into an employment agreement with Mr. Saint in July 2022 and effective August 1, 2022 (Start Date), pursuant to which Mr. Saint was initially hired as a Senior Advisor and, effective August 15, 2022, as the Company’s Chief Executive Officer. Pursuant to his July 2022 agreement, Mr. Saint is entitled to an annual base salary of \$450,000 and an annual discretionary bonus with a target amount equal to 50% of his annual base salary based on the company’s achievement against its objectives. Pursuant to his employment agreement, in July 2022 we granted two options to Mr. Saint, one to purchase 4.5% of our capital stock or 1,476,410 shares of common stock, with an exercise price of \$7.92 per share, which was repriced to \$3.81 per share in March 2023, subject to a four-year vesting schedule, with 25% vesting on the first anniversary of the Start Date and the balance vesting monthly over the remaining 36 months, subject to Mr. Saint’s continued service with us (First Grant). The second option granted to Mr. Saint, in August 2022, provides for the purchase of 0.5% of the capital stock or 164,040 shares of our common stock, also with an exercise price of \$7.92 per share, which was also repriced to \$3.81 per share in March 2023, which vests in 12 equal monthly installments following the four-year anniversary of the Start Date, subject to Mr. Saint’s continued service with us (Second Grant, and together with the First Grant, Initial Options). Pursuant to his employment agreement, in the event that we issue shares of our capital stock to investors in one or more capital raising transactions up to an aggregate of \$75,000,000, Mr. Saint shall receive additional stock options to purchase Class B common stock (Top-Up Options) so that, after taking into account such new capital raising transaction, the capital stock subject to the Initial Options and the Top-Up Options together represent 5.0% of the capital stock of the company on a fully diluted basis as of immediately following each such grant. 90% of each grant of Top-Up Options, if any, shall have the same vesting commencement date as the First Grant and shall have the same vesting schedule as the First Grant, such that 90% of the Top-Up Options, if granted, shall be fully vested on the four-year anniversary of the Start Date, subject to Mr. Saint’s continued service with us on each such vesting date. The remaining 10% of each grant of Top-Up Options, if any, shall have the same vesting commencement date as the Second Grant and shall have the same vesting schedule as the Second Grant, such that 10% of the Top-Up Options, if granted, shall be fully vested on the five-year anniversary of the Start Date, subject to Mr. Saint’s continued service with us on

each such vesting date. Mr. Saint was granted a Top-Up option in September 2023 covering 1,081,746 shares of our common stock. Mr. Saint's eligibility to receive Top-Up Options terminates at the earlier of his receipt of Top-Up options as a result of the Company raising \$75,000,000 in capital raising transactions and immediately prior to the consummation of our initial public offering.

Potential Payments Upon Termination or Change of Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer is entitled to receive amounts earned during his or her term of service, including unpaid salary and unused vacation. In addition, Mr. Saint is entitled to certain severance benefits under his employment agreement, subject to his execution of a release of claims, return of all company property and compliance with post-termination obligations.

Mr. Saint's employment agreement provides that, if his employment is terminated by us without "cause" (other than as a result of death or disability) or Mr. Saint resigns for "good reason" (each, as defined in Mr. Saint's employment agreement), he will be entitled to receive continued payment of his then-current base salary for 12 months, payment for continued group healthcare benefit premiums for up to 12 months, and a lump sum payment equal to his annual bonus, pro-rated for the year of termination, and based on achievement of the performance objectives and payable at the same time as bonus payments are made to other executives of the company. In addition, if the company consummates a change in control and either (a) the Company is not the surviving entity following such change in control or (b) Mr. Saint is terminated without "cause" or resigns for "good reason", he will be entitled to receive a lump sum cash payment equal to (i) 300% of the sum of his then-current base salary plus his then-current target bonus, if the change in control occurs within 12 months of his Start Date, or (ii) 200% of the sum of his then-current base salary plus his then-current target bonus if the change in control occurs more than 12 months after his Start Date. In addition, if the Company consummates a change in control, the vesting and exercisability of all outstanding time-based stock options and other time-based equity awards will accelerate in full effective as of the date of his release agreement with the company.

For the purposes of Mr. Saint's employment agreement, "cause" for termination means (a) Mr. Saint's willful and continued failure to substantially perform reasonable, assigned duties (other than any such failure resulting from incapacity due to physical or mental illness), which failure is not cured, to the extent curable, within thirty (30) days after a written demand for substantial performance is delivered to Mr. Saint by the board of directors; (b) dishonesty to our board of directors with respect to any material matter; (c) misappropriation of funds or property of the company; (d) misconduct by Mr. Saint, regardless of whether in the course of his employment, that would reasonably be expected to result in material injury or reputational harm to the company if he were to continue to be employed in the same position; (e) Mr. Saint's conviction of, or the entry of a pleading of guilty or nolo contendere to, any crime involving moral turpitude, deceit, dishonesty or fraud, or any felony; (f) Mr. Saint's willful engagement in dishonesty, illegal conduct or gross negligence; (g) a material violation of any of the company's harassment, retaliation or discrimination policies or code of conduct; (h) Mr. Saint's unwillingness to consent to an assignment of his employment agreement in connection with any "Change in Control" (defined below) subject to certain exceptions; (i) any material breach by Mr. Saint of his employment agreement or any related agreements with the company; or (j) Mr. Saint's failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the board of directors to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

For the purposes of Mr. Saint's employment agreement, "good reason" means, subject to certain notice and cure rights, (a) any material diminution in the authority, duty or responsibilities of Mr. Saint; (b) a material reduction in salary, except for across-the-board salary reductions based on the company's financial performance similarly affecting all or substantially all senior management employees of the company; or (c) material violation by the company of the terms of Mr. Saint's employment agreement without his consent.

For the purposes of Mr. Saint's employment agreement, "change in control" means (a) the acquisition by any person or entity of more than 50% of our combined voting power, (b) the majority of our board of directors is replaced during any 12-month period by directors whose election is not endorsed by a majority of the members of our board of directors prior to such election; (c) a merger or consolidation in which we are not the surviving corporation (unless the holders of our outstanding voting stock immediately prior to the transaction own, immediately after the transaction, securities representing at least 50% of the voting power of the corporation or other entity surviving such transaction); or (d) a sale of all or substantially all of our assets.

Each of our named executive officers holds stock options that were granted subject to the general terms of our 2016 Plan. A description of the termination and change in control provisions in our 2016 Plan and applicable to the stock options granted to our named executive officers is provided below under "—Equity Benefit Plans" and above "—Outstanding Equity Awards as of December 31, 2024" and "—Equity-Based Incentive Awards."

Other Compensation and Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including medical, dental, vision, short- and long-term disability, health savings and flexible spending accounts, and life and accidental dismemberment insurance plans, in each case on the same basis as all of our other employees. We pay a portion of the premiums for the medical insurance, and the full premiums for dental, life and accidental death and dismemberment insurance, and short- and long-term disability for all our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers. In addition, we provide the opportunity to participate in a 401(k) plan to our employees, including each of our named executive officers, as discussed in the subsection titled "—401(k) Plan" below.

401(k) Plan

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Internal Revenue Code of 1986, as amended (Code) with an annual match of up to 6% of the amount deferred. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Our board of directors may elect to adopt qualified or nonqualified benefit plans in the future, if it determines that doing so is in our best interests.

Equity Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

2016 Stock Incentive Plan

Our board of directors adopted, and our stockholders approved, our 2016 Plan in February 2016. Our 2016 Plan was most recently amended in August 2023. The 2016 Plan will be terminated on the date the 2025

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Plan becomes effective, and thereafter no further stock awards will be granted under the 2016 Plan. However, any outstanding stock awards granted under the 2016 Plan will remain outstanding, subject to the terms of our 2016 Plan and award agreements, until such outstanding options are exercised or until any stock awards terminate or expire by their terms.

Types of Awards. Our 2016 Plan allows for the grant of incentive stock options to employees, including employees of any subsidiary or parent, and grants of non-qualified stock options, restricted stock awards and any other security with the value derived from the value of our shares to our employees, directors and consultants, including employees, directors and consultants of any subsidiary or parent.

Authorized Shares. As of December 31, 2024, we reserved an aggregate of _____ shares of our common stock for the issuance of equity awards under the 2016 Plan. This number is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization. The shares may be authorized but unissued or reacquired shares. As of December 31, 2024, only options have been granted under the 2016 Plan.

Only shares of common stock that have actually been issued under the 2016 Plan in connection with an award shall be counted against the maximum aggregate number of shares of common stock available under the 2016 Plan. Any shares of common stock that are forfeited or canceled, expire, are surrendered, or otherwise become unexercisable before the shares of common stock have been issued under the 2016 Plan shall be deemed not to have been issued for purposes of determining the maximum aggregate number of shares of common stock that may be issued under the 2016 Plan, and such unissued shares of common stock shall become available for future grant under the 2025 Plan. Shares of common stock that have been issued under the 2016 Plan shall not be returned to the 2016 Plan and shall not become available for future issuance under the 2016 Plan.

Administration. Our board of directors or a committee or subcommittee designated by our board of directors administers our 2016 Plan, or the plan administrator. Subject to the provisions of our 2016 Plan, the plan administrator has full authority to, among other things, select recipients of awards, to determine the number of shares or the amount of other consideration subject to each award, to approve forms of award agreements for use under the 2016 Plan, to determine the terms and conditions of awards and to establish additional terms, conditions rules or procedures to accommodate the terms of any corporate transaction, award exchange program, award deferral program or other such program; provided, however, that no award shall be subject to any such additional terms, conditions, rules or procedures that are inconsistent with the provisions of the 2016 Plan. The plan administrator may also amend any outstanding award, provided that no amendment to an award may adversely affect any of the rights of a grantee under any awards previously granted without his or her consent.

Options. The exercise price per share of each stock option is determined by our plan administrator and must equal at least 100% of the fair market value of a share of our common stock on the date of grant. The term of each stock option may not exceed 10 years from the date of grant. In the case of an incentive stock option granted to a grantee who, at the time of grant of such stock option, owns stock representing more than 10% of the voting power of all of our classes of stock, or a 10% owner, the exercise price per share of our common stock underlying each such stock option must be at least equal to 110% of the fair market value of a share of our common stock on the date of grant, and the term of each stock option may not exceed five years from the date of grant. The award agreement may, but need not, include a provision whereby the grantee may elect at any time while an employee, director or consultant to exercise any part or all of the stock option before full vesting of the stock option. Any unvested shares of common stock received in accordance with such exercise shall be subject to a repurchase right in favor of us or a related entity. The plan administrator determines the methods of payment of the exercise price of a stock option as specified in the applicable award agreement or later authorized by the plan administrator under the terms of the 2016 Plan.

Termination of Service. After a grantee's termination of service (other than a termination for cause and not in the event of a grantee's change of status from employee, director or consultant to any other status of), the grantee generally may exercise his or her stock options, to the extent vested as of such date of termination, for 30

days following such termination or such longer period of time as specified in the applicable award agreement; provided, that if the termination is due to death or disability, the stock option generally will remain exercisable, to the extent vested as of such date of termination, until the six month anniversary of such termination, or such longer post-termination exercise period as may be set forth in the award agreement or subsequently approved by the plan administrator in accordance with this 2016 Plan. In the event of termination of a grantee's continuous service as a result of transfer by us to an entity that is not a "related entity" (as defined in the 2016 Plan) or as a result of grantee's employer ceasing to be a related entity, the grantee may exercise the stock option within 30 days from the date of termination or such longer post-termination exercise period as may be set forth in the award agreement or subsequently approved by the plan administrator in accordance with the 2016 Plan.

Transferability or Assignability of Awards. Our awards are subject to transfer restrictions as the plan administrator may determine. The 2016 Plan generally does not allow for the transfer or assignment of options, other than by will or the laws of descent and distribution, or, with respect to nonqualified stock options, to a revocable trust. Only the recipient of an incentive stock option may exercise such an award during his or her lifetime.

Corporate Transaction. The 2016 Plan provides that upon the occurrence of a "corporate transaction" (as defined in the 2016 Plan), awards shall be treated in accordance with the agreement governing the corporate transaction. Options may be assumed, substituted for new awards of a successor entity, exercised within a period of time prior to the consummation of the corporate transaction or terminated at the effective time of such corporate transaction in exchange for a payment to holders of vested stock options equal to the excess of the fair market value of the shares (as of the effective date of the corporate transaction) and the aggregate exercise price. For awards subject to a repurchase right (including options with early exercise), the award shall be (i) assumed by the successor entity in connection with the corporate transaction, (ii) substituted by the successor entity in connection with the corporate transaction or (iii) repurchased, in which case the vesting of the award (or portion that has been substituted) shall terminate as of the consummation of the corporate transaction, and the repurchase right may be exercised before the corporate transaction subject to the consummation of the corporate transaction. Except as provided otherwise in an award agreement, in the event of a corporate transaction, each award that is at the time outstanding under the 2016 Plan shall automatically become fully vested and exercisable and be released from any restrictions on transfer and repurchase or forfeiture rights, immediately before the specified effective date of the corporate transaction, for all of the shares of common stock at the time represented by such award if the award is not assumed or substituted by the successor entity in connection with the corporate transaction. An individual award agreement may provide for vesting acceleration of an award in the event of any corporate transaction, subject to certain requirements in the 2016 Plan.

Certain Adjustments. In the event of certain changes in our capitalization, the number of shares available for future grants, the number of shares covered by each outstanding award and the exercise price of each outstanding option will be proportionately adjusted.

Plan Amendment or Termination. Our board of directors may amend, suspend, or terminate the 2016 Plan at any time, subject to stockholder approval where such approval is required by applicable law and provided any such amendment, suspension or termination does not affect granted awards (subject to certain exceptions).

2025 Equity Incentive Plan

In _____, our board of directors adopted, and our stockholders approved, our 2025 Plan. We expect our 2025 Plan will become effective upon the execution of the underwriting agreement for this offering. Our 2025 Plan is a successor to our 2016 Plan. Once our 2025 Plan becomes effective, no further grants will be made under our 2016 Plan and any shares of common stock reserved for future issuance under our 2016 Plan will be cancelled.

Types of Awards. Our 2025 Plan provides for the grant of incentive stock options (ISOs) to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options (NSOs), stock

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appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under our 2025 Plan after it becomes effective will not exceed _____ shares, which is the sum of (i) _____ new shares, plus (ii) _____ shares of our common stock available for issuance under our 2016 Plan; (iii) shares of our common stock that are subject to outstanding stock options or other stock awards granted under our 2016 Plan that, on or after the 2025 Plan becomes effective, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, if any, as such shares become available from time to time. In addition, the number of shares of our common stock reserved for issuance under our 2025 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2026 (assuming the 2025 Plan becomes effective in 2025) through January 1, 2035, in an amount equal to _____ % of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2025 Plan is _____ shares.

Shares subject to stock awards granted under our 2025 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2025 Plan. Additionally, shares become available for future grant under our 2025 Plan if they were issued stock awards under our 2025 Plan and we repurchase them or they are forfeited. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer our 2025 Plan. Our board of directors may also delegate to one or more persons or bodies the authority to do one or more of the following: (i) designate recipients (other than officers) of specified stock awards, provided that no person or body may be delegated authority to grant a stock award to themselves; (ii) determine the number of shares subject to such stock award; and (iii) determine the terms of such stock awards. Under our 2025 Plan, our board of directors has the authority to determine and amend the terms of awards and underlying agreements, including:

- recipients;
- the exercise, purchase or strike price of stock awards, if any;
- the number of shares subject to each stock award;
- the vesting schedule applicable to the awards, together with any vesting acceleration; and
- the form of consideration, if any, payable on exercise or settlement of the award.

Under the 2025 Plan, the board of directors also generally has the authority to effect, with the consent of any adversely affected participant:

- the reduction of the exercise, purchase, or strike price of any outstanding award;
- the cancellation of any outstanding award and the grant in substitution therefore of other awards, cash, or other consideration; or
- any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2025 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2025 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the option is not exercisable after the expiration of five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock units are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock units may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of our common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2025 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

Performance Awards. The 2025 Plan permits the grant of performance-based stock and cash awards. The plan administrator may structure awards so that the shares of our stock, cash, or other property will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. The performance criteria that will be used to establish such performance goals may be based on any one of, or combination of, the following as determined by the plan administrator: earnings (including earnings per share and net earnings); earnings before interest, taxes and depreciation; earnings before interest, taxes, depreciation and amortization; total stockholder return; return on equity or average stockholder's equity; return on assets, investment, or capital employed; stock price; margin (including gross margin); income (before or after taxes); operating income; operating income after taxes; pre-tax profit; operating cash flow; sales or revenue targets; increases in revenue or product revenue; expenses and cost reduction goals; improvement in or attainment of working capital levels; economic value added (or an equivalent metric); market share; cash flow; cash flow per share; share price performance; debt reduction; customer satisfaction; stockholder's equity; capital expenditures; debt levels; operating profit or net operating profit; workforce diversity; growth of net income or operating income; billings;

preclinical development related compound goals; financing; regulatory milestones, including approval of a compound; stockholder liquidity; corporate governance and compliance; product commercialization; intellectual property; personnel matters; progress of internal research or clinical programs; progress of partnered programs; partner satisfaction; budget management; clinical achievements; completing phases of a clinical trial (including the treatment phase); announcing or presenting preliminary or final data from clinical trials, in each case, whether on particular timelines or generally; timely completion of clinical trials; submission of INDs and BLAs and other regulatory achievements; partner or collaborator achievements; internal controls, including those related to the Sarbanes-Oxley Act of 2002; research progress, including the development of programs; investor relations, analysts and communication; manufacturing achievements (including obtaining particular yields from manufacturing runs and other measurable objectives related to process development activities); strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); establishing relationships with commercial entities with respect to the marketing, distribution and sale of our product candidates (including with group purchasing organizations, distributors and other vendors); supply chain achievements (including establishing relationships with manufacturers or suppliers of active pharmaceutical ingredients and other component materials and manufacturers of our product candidates); co-development, co-marketing, profit sharing, joint venture or other similar arrangements; individual performance goals; corporate development and planning goals; and other measures of performance selected by the plan administrator.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are “unusual” in nature or occur “infrequently” as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any fiscal year following the year in which the underwriting agreement for this offering is executed, including stock awards granted and cash fees paid by us to such non-employee director, will not exceed \$ _____ in total value, or in the event such non-employee director is first appointed or elected to the board during such fiscal year, \$ _____ in total value (in each case, calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes). Compensation will count towards this limit for the fiscal year in which it was granted or earned, and not later when distributed, in the event it is deferred.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2025 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the 2025 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2025 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the transaction (contingent upon the effectiveness of the transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the transaction). With respect to performance awards with multiple vesting levels depending on performance level, unless otherwise provided by an award agreement or by the administrator, the award will accelerate at 100% of target. If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by persons other than current participants, such awards will terminate if not exercised (if applicable) prior to the effective time of the transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the transaction. The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

In the event a stock award will terminate if not exercised prior to the effective time of a transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award over (ii) any exercise price payable by such holder in connection with such exercise.

Under our 2025 Plan, a corporate transaction is defined to include: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding before such transaction are converted or exchanged into other property by virtue of the transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder.

Change in Control. In the event of a change in control, as defined under our 2025 Plan, awards granted under our 2025 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Under the 2025 Plan, a change in control is defined to include: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a consummated merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not

own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity); (iii) the approval by the stockholders or the board of directors of a plan of our complete dissolution or liquidation, or the occurrence of our complete dissolution or liquidation, except for a liquidation into a parent corporation; (iv) a consummated sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders; and (v) an unapproved change in the majority of the board of directors.

Clawback. All awards granted under the 2025 Plan will be subject to recoupment in accordance with any clawback policy that we are required to adopt pursuant to the listing standards of any national securities exchange or association on which our securities are listed or as is otherwise required by the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, our board of directors may impose such other clawback, recovery or recoupment provisions in a stock award agreement as our board of directors determines necessary or appropriate.

Transferability. A participant may not transfer stock awards under our 2025 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2025 Plan.

Plan Amendment or Termination. Our board of directors has the authority to amend, suspend or terminate our 2025 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2025 Plan. No stock awards may be granted under our 2025 Plan while it is suspended or after it is terminated.

2025 Employee Stock Purchase Plan

Our board of directors adopted, and our stockholders approved, our 2025 Employee Stock Purchase Plan (ESPP) in . The ESPP will become effective upon the execution of the underwriting agreement for this offering. The purpose of the ESPP is to secure and retain the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible U.S. employees to purchase our ordinary shares in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the U.S. while complying with applicable foreign laws.

Share Reserve. Following this offering, the ESPP authorizes the issuance of shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2026 (assuming the ESPP becomes effective in 2025) through January 1, 2035, by the lesser of (i) % of the total number of shares of our capital stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors, or a duly authorized committee thereof, will administer our ESPP. Our board may delegate concurrent authority to administer the ESPP to our compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27

months and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to % of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (i) 85% of the fair market value of a share of our common stock on the first trading date of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (i) being customarily employed with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year; or (ii) continuous employment with us or one of our affiliates for a minimum period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to: (i) the number of shares reserved under the ESPP; (ii) the maximum number of shares by which the share reserve may increase automatically each year; (iii) the number of shares and purchase price of all outstanding purchase rights; and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, including: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately.

ESPP Amendment or Termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Non-Employee Director Compensation

The following table sets forth information regarding the compensation earned by or paid to our non-employee directors during fiscal year ended December 31, 2024. Sean Saint, our President and Chief Executive Officer is also a member of our board of directors, but does not receive any additional compensation

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for service as a director. The compensation earned by or paid to Sean Saint as a named executive officer for the fiscal year ended December 31, 2024 is set forth above under “Executive and Director Compensation—Summary Compensation Table.”

<u>Name</u>	<u>Fees Earned or Paid In Cash</u>	<u>Option Awards</u>	<u>Total</u>
Amanda Black	\$	\$	\$
Sean Carney			
James Parker Cassidy			
Francesco Draetta			
Westley Dupray			
Gilad Glick			
Lennox Ketner			
Adam Lezack			

Non-Employee Director Compensation Policy

We intend to adopt a non-employee director compensation policy, pursuant to which our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors, to be effective following the completion of this offering.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, will contain provisions that limit the liability of our current and former directors and officers for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director’s or officer’s duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws that will be in effect immediately prior to the closing of this offering will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws that will be in effect immediately prior to the closing of this offering will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director,

employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered into, or will enter into in connection with this offering, agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation.

We believe that our amended and restated certificate of incorporation and these amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect immediately prior to the closing of this offering may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2022, to which we have been a party, in which the amount involved in the transaction exceeded the lesser of \$120,000 or 1% of the average of our total assets as of December 31, 2022 and 2023, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock at the time of such transaction, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in the sections titled “Executive and Director Compensation” and “Executive and Director Compensation Non-Employee Director Compensation.”

Convertible Preferred Stock Financings

Series C Preferred Stock and Warrant Financing

In February 2022, we issued and sold to investors in a private placement (i) an aggregate of 410,186 shares of our Series C convertible preferred stock (Series C Preferred) in our Series C convertible preferred stock financing at a purchase price of \$139.0802 per share for aggregate cash proceeds of approximately \$57.0 million and (ii) warrants to purchase an aggregate of 102,539 shares of Series C Preferred (Series C Warrants). In August 2023, we effected a one-for-ten stock split for each outstanding share of Series C Preferred, resulting in an increase in the total number of shares of Series C Preferred sold from 410,186 to 4,101,860 and an increase in the total number of shares of Series C Preferred issuable pursuant to the exercise of Series C Warrants from 102,539 to 1,025,390.

The following table summarizes the shares of Series C Preferred purchased by holders of more than 5% of our capital stock and entities affiliated with our directors.

<u>Participants</u>	<u>Series C Preferred Stock (Post Stock-Split)</u>	<u>Total Purchase Price</u>
Entities affiliated with Eventide Asset Management ⁽¹⁾	1,078,500	\$ 14,999,799.57
Entities affiliated with RTW Investments ⁽²⁾	862,810	11,999,978.74
Entities affiliated with Soleus Capital ⁽³⁾	611,150	8,499,886.42
Zone Healthcare Holdings, LLC ⁽⁴⁾	539,250	7,499,899.79

- (1) The entities affiliated with Eventide Asset Management whose shares are aggregated for purposes of reporting share ownership information are Mutual Fund Series Trust on behalf of Eventide Gilead Fund and Mutual Fund Series Trust on behalf of Eventide Healthcare & Life Sciences Fund (collectively, Eventide). Eventide beneficially owns more than 5% of our outstanding capital stock, and Westley Dupray, a member of our board of directors, is a Research Analyst and Principal at Eventide.
- (2) The entities affiliated with RTW Investments whose shares are aggregated for purposes of reporting share ownership information are RTW Biotech Opportunities Ltd, RTW Innovation Master Fund, Ltd. and RTW Master Fund, Ltd. (collectively, RTW Investments). RTW Investments beneficially own more than 5% of our outstanding capital stock.
- (3) The entities affiliated with Soleus Capital whose shares are aggregated for purposes of reporting share ownership information are Soleus BB SPV, LLC, Soleus Private Equity Fund I, L.P. and Soleus Private Equity Fund II, L.P. (collectively, Soleus Capital). Soleus beneficially owns more than 5% of our outstanding capital stock, and Lennox Ketner, a member of our board of directors, is Managing Director at Soleus Capital.
- (4) Zone Healthcare Holdings, LLC, an affiliate of Farallon Capital, beneficially owns more than 5% of our outstanding capital stock, and Amanda Black is an Investment Director at Farallon Capital.

Series D Preferred Stock and Warrant Financing

From August to September 2023, we issued and sold to investors in a private placement (i) an aggregate of 12,107,140 shares of our Series D convertible preferred stock (Series D Preferred) in our Series D convertible preferred stock financing at a purchase price of \$8.40 per share for aggregate cash proceeds of approximately \$101.7 million and (ii) warrants to purchase an aggregate of 8,474,983 shares of common stock (Common Warrants).

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The following table summarizes the shares of Series D Preferred purchased by holders of more than 5% of our capital stock and entities affiliated with our directors.

Participants	Series D Preferred Stock	Total Purchase Price
Sands Capital Life Sciences Pulse Fund II, L.P. ⁽¹⁾	2,619,047	\$ 21,999,994.80
Zone Healthcare Holdings, LLC ⁽²⁾	2,238,095	18,799,998.00
Entities affiliated with Eventide Asset Management ⁽³⁾	1,190,476	9,999,998.40
Entities affiliated with RTW Investments ⁽⁴⁾	1,190,476	9,999,998.40
Entities affiliated with Soleus Capital ⁽⁵⁾	1,190,476	9,999,998.40
Omega Fund VII, L.P. ⁽⁶⁾	1,785,714	14,999,997.60

- (1) Sands Capital Life Sciences Pulse Fund II, L.P. (Sands Capital) beneficially owns more than 5% of our outstanding capital stock, and James Parker Cassidy, a member of our board of directors, is a Partner at Sands Capital.
- (2) Zone Healthcare Holdings, LLC, an affiliate of Farallon Capital, beneficially owns more than 5% of our outstanding capital stock, and Amanda Black is an Investment Director at Farallon Capital.
- (3) Eventide beneficially owns more than 5% of our outstanding capital stock, and Westley Dupray, a member of our board of directors, is a Research Analyst and Principal at Eventide.
- (4) RTW Investments beneficially own more than 5% of our outstanding capital stock.
- (5) Soleus Capital beneficially owns more than 5% of our outstanding capital stock, and Lennox Ketner, a member of our board of directors, is Managing Director at Soleus Capital.
- (6) Omega Fund VII, L.P. (Omega Fund) beneficially owns more than 5% of our outstanding capital stock, and Francesco Draetta, a member of our board of directors, is Managing Director at Omega Fund.

Investor Agreements

In connection with our convertible preferred stock financings, we entered into investors' rights, right of first refusal and co-sale and voting agreements, which contain, among other things, registration rights, information rights, voting rights and rights of first refusal, with certain holders of our capital stock, including entities affiliated with Eventide Asset Management, Sands Capital, L.P., Zone Healthcare Holdings, LLC, entities affiliated with RTW Investments, Omega Fund and entities affiliated with Soleus Capital. These agreements will terminate upon the closing of this offering, except for the registration rights granted under our investors' rights agreement, as more fully described in the section titled "Description of Capital Stock—Registration Rights." See also the section titled "Principal Stockholders" for additional information regarding beneficial ownership of our capital stock.

Our Relationship with Boston University

Edward Damiano, Ph.D., our Co-Founder and Executive Chairman, was affiliated with Boston University (BU) as of the time of the original execution and the amendments of the Device License Agreement and Control Algorithm Agreement. He currently serves as Research Professor of Biomedical Engineering at BU on a volunteer basis and has no time commitments to BU. Pursuant to the BU Intellectual Property Policy, BU is obligated to pay a specified percentage of royalties received from us on net sales of products licensed under the agreements to the inventors of the patentable inventions, which includes Dr. Damiano.

Device License Agreement

In December 2015, we and the Trustees of BU entered into a device license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the Device License Agreement). Under the Device License Agreement, we received a royalty-bearing license (with the right to sublicense) under certain of BU's patent rights related to a system and individual components thereof for delivering multiple medicaments to a patient without medicament mis-channeling to make, use, sell, and import products, and practice processes covered by the licensed patent rights (collectively, the Licensed Products and Licensed Processes).

In consideration for the licensed patent rights and other rights granted to us under the Device License Agreement, we issued 2,286 shares of our Class B common stock to BU, representing a specified ownership percentage on a fully diluted basis at the time of entering into the Device License Agreement, subject to anti-dilution adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock. We are also required to pay (i) quarterly royalties of a mid-single-digit percentage based on net sales of all Licensed Products and Licensed Processes by us or our affiliates, (ii) quarterly royalties of a low double-digit percentage based on net sales by our sublicensees (in each case (i) and (ii), which royalties are creditable against the minimum royalty amount), and (iii) agreed to make quarterly lump sum payments of a low-double-digit percentage based on certain non-royalty sublicensing revenue received by us from our sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. We also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if we assign the Device License Agreement in connection with the sale of all or substantially all of our assets relating to the licensed patent rights, we will be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment. For a further description of the Device License Agreement, see “Business—License and Collaboration Agreements—Device License Agreement with Boston University.”

Control Algorithm Agreement

In December 2015, we and the Trustees of BU entered into a control algorithm license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the Control Algorithm Agreement). Under the Control Algorithm Agreement, we received a royalty-bearing license (with the right to sublicense) to (i) make, use, sell, and import products, and practice processes, covered by certain of BU’s patent rights related to automated control systems for treatment of T1D and similar conditions, involving monitoring and/or delivering insulin, glucagon, and glucose (collectively, the Automated Control System Technology); and (ii) use, reproduce, prepare derivative works, perform, display, and distribute all or any part of the software, source code, object code and/or related documentation, covered by certain copyright rights, and related to (a) the Automated Control System Technology and (b) the iLet control algorithm.

In consideration for the licensed patent rights and other rights granted to us under the Control Algorithm Agreement, we issued 2,247 shares of our Class B common stock to BU, representing a specified ownership percentage on a fully diluted basis at the time of entering into the license agreement, subject to anti-dilution adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock to BU. We are also required to pay BU (i) quarterly royalties of a mid-single-digit percentage based on net sales by us and our affiliates, and royalties of a low double-digit percentage of net sales by sublicensees, in each case (i) and (ii), which royalties are creditable against the minimum royalty amount, and (iii) agreed to make quarterly lump sum payments of a low double-digit percentage of the non-royalty sublicensing revenue received by us from our sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. We also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if we undergo a change of control (as defined in the Control Algorithm Agreement) we will owe BU a one-time change of control payment of \$65,000. We will also be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment if we assign the Control Algorithm License Agreement in connection with the sale of all or substantially all of our assets relating to the licensed patent rights and copyright. For a further description of the Control Algorithm Agreement, see “Business—License and Collaboration Agreements—Control Algorithm Agreement with Boston University.”

Employment Arrangements and Indemnification Agreement

We have entered into employment agreements with certain of our executive officers. For more information regarding these agreements with our named executive officers, see “Executive and Director Compensation—Employment Arrangements with our Named Executive Officers.”

Our amended and restated certificate of incorporation upon the closing of this offering will contain provisions limiting the liability of directors, and our amended and restated bylaws that will be in effect upon the closing of this offering will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws upon the closing of this offering will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board.

In addition, we have entered, and intend to enter, into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them. For more information regarding these agreements, see the section titled “Executive and Director Compensation—Limitations of Liability and Indemnification Matters.”

Stock Option Grants to Directors and Executive Officers

We have granted stock options to our directors and executive officers, as more fully described in the section titled “Executive and Director Compensation.”

Policies and Procedures for Related Party Transactions

Prior to the completion of this offering, we will adopt a written related person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and continuing oversight of “related person transactions.” For purposes of our policy only, a “related person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are participants involving an amount that exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of our voting securities, including any of their immediate family members and affiliates, and entities owned or controlled by such persons or entities in which such person has a 5% or greater beneficial ownership interest.

Under the policy, where a transaction has been identified as a related person transaction, management must present information regarding the proposed related person transaction to our audit committee (or, where review by our audit committee would be inappropriate for reasons of conflict of interest or otherwise, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties or to employees generally and management’s recommendation. To identify related person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related person transactions, our audit committee or another independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director’s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our capital stock as of _____, 2024, as adjusted to reflect the sale of our common stock offered by us in this offering assuming no exercise of the underwriters' option to purchase additional shares, for:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on _____ shares of common stock outstanding as of _____, 2024, assuming (i) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock into shares of common stock upon the closing of this offering and (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into shares of common stock upon the closing of this offering, and excluding the conversion of the outstanding warrants. Applicable percentage ownership after the offering is based on (i) the conversion of all our outstanding warrants into _____ shares of common stock and (ii) the sale of _____ shares of common stock in this offering, assuming no exercise by the underwriters of their option to purchase additional shares. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of _____, 2024. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Beta Bionics, Inc., 11 Hughes, Irvine, California 92618. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

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The following table does not reflect any potential purchases by our executive officers, directors, their affiliated entities or holders of more than 5% of our common stock in this offering or any equity awards granted to our executive officers or directors contingent on this offering. If any shares are purchased by and to the extent any such equity awards have been granted to these persons or entities, the number and percentage of shares of our common stock beneficially owned by them after this offering will differ from the amounts set forth in the following table.

Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After Offering	
	Number	Percentage	Number	Percentage
5% or Greater Stockholders:				
Sands Capital ⁽¹⁾		%		%
Zone Healthcare Holdings, LLC ⁽²⁾		%		%
Entities affiliated with Eventide Asset Management ⁽³⁾		%		%
Entities affiliated with RTW Investments ⁽⁴⁾		%		%
Entities affiliated with Soleus Capital ⁽⁵⁾		%		%
Omega Fund ⁽⁶⁾		%		%
Edward Damiano, Ph.D. ⁽⁷⁾		%		%
Named Executive Officers and Directors:				
Sean Saint ⁽⁸⁾		%		%
(9)		%		%
(10)		%		%
Sean Carney ⁽¹¹⁾		%		%
Gilad Glick ⁽¹²⁾		%		%
Adam Lezack ⁽¹³⁾		%		%
Edward Damiano, Ph.D. ⁽⁷⁾		%		%
Amanda Black		%		%
James Parker Cassidy		%		%
Francesco Draetta		%		%
Westley Dupray		%		%
Lennox Ketner		%		%
All directors and executive officers as a group (13 persons) ⁽¹⁴⁾		%		%

* Represents beneficial ownership of less than 1%.

- (1) Consists of shares of common stock and shares of common stock issuable upon conversion of Series D preferred stock held by Sands Capital Life Sciences Pulse Fund II, L.P. (Pulse Fund II). The sole general partner of Pulse Fund II is Sands Capital Life Sciences Pulse Fund II-GP, L.P. (Pulse Fund II GP LP), and the sole general partner of Pulse Fund II GP LP is Sands Capital Life Sciences Pulse Fund II-GP, LLC (Pulse Fund II GP LLC). Sands Capital Ventures, LLC is the investment manager for Pulse Fund II and Frank M. Sands ultimately controls the activities of Sands Capital Ventures, LLC, therefore Mr. Sands may be deemed to have voting and investment power over the shares held by Pulse Fund II. The address of all entities and the individual referenced in this footnote is 1000 Wilson Boulevard, Suite 3000, Arlington, Virginia 22209.
- (2) Consists of shares of common stock, shares of common stock issuable upon conversion of our Series B-2 preferred stock, shares of common stock issuable upon conversion of our Series C preferred stock, shares of common stock issuable upon conversion of our Series D preferred stock and shares of common stock subject to warrants that are exercisable within 60 days of , 2024. The manager of Zone Healthcare Holdings, LLC (Zone) is Farallon Capital Management, L.L.C. (FCM), and may be deemed to be a beneficial owner of the shares held by Zone. Each of Joshua J. Dapice, Philip D. Dreyfuss, Hannah E. Dunn, Richard B. Fried, Varun N. Gehani, Nicolas Giauque, David T. Kim, Michael G. Linn, Rajiv A. Patel, Dr. Thomas G. Roberts, Jr., Edric C. Saito, William Seybold, Daniel S. Short, Andrew J.M. Spokes, John R. Warren, and Mark C. Wehrly, as a senior managing member or managing member (collectively, the Farallon Managing Members), as the case may be, of FCM, in each case with the power to exercise investment or voting discretion, may be deemed a beneficial owner of all such shares held by Zone. FCM and each of the Farallon Managing Members disclaim any beneficial ownership of all such shares. The address for Zone is c/o Farallon Capital Management, L.L.C., One Maritime Plaza, Suite 2100, San Francisco, California 94111.
- (3) Consists of (i) shares of common stock issuable upon conversion of our Series B preferred stock, shares of common stock issuable upon conversion of our Series B-2 preferred stock, shares of common stock issuable upon conversion of our Series C preferred stock, shares of common stock issuable upon conversion of our Series D preferred stock and shares of common stock subject to warrants that are exercisable within 60 days of , 2024, held by Mutual Fund Series Trust on behalf of Eventide Gilead Fund (Eventide Gilead) and (ii) shares of common stock issuable upon conversion of our Series B

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- preferred stock, shares of common stock issuable upon conversion of our Series B-2 preferred stock, shares of common stock issuable upon conversion of our Series C preferred stock, shares of common stock issuable upon conversion of our Series D preferred stock and shares of common stock subject to warrants that are exercisable within 60 days of , 2024, held by Mutual Fund Series Trust on behalf of Eventide Healthcare & Life Sciences Fund (Eventide Healthcare). Eventide Asset Management, LLC (Eventide Management), investment adviser to Eventide Gilead and Eventide Healthcare, holds voting and dispositive power over the shares held by Eventide Gilead and Eventide Healthcare. Finny Kuruvilla is the portfolio manager of Eventide Management. Eventide Management disclaims beneficial ownership of the shares held by Eventide Gilead and Eventide Healthcare, except to the extent of its respective pecuniary interests therein. The address for both Eventide Gilead and Eventide Healthcare is c/o Ultimus Fund Solutions, 80 Arkay Drive, Suite 110, Hauppauge, New York 11788.
- (4) Consists of (i) shares of common stock issuable upon conversion of our Series B preferred stock, (ii) shares of common stock issuable upon conversion of our Series B-2 preferred stock, (iii) shares of common stock issuable upon conversion of our Series C preferred stock, (iv) shares of common stock issuable upon conversion of our Series D preferred stock and (v) shares of common stock subject to warrants that are exercisable within 60 days of , 2024, in each case, held in the aggregate by RTW Master Fund, Ltd. (RTW Master Fund), RTW Innovation Master Fund, Ltd. (RTW Innovation Fund), and RTW Biotech Opportunities Operating Ltd (RTW Biotech), together with RTW Master Fund and RTW Innovation Fund, the RTW Funds). RTW Investments, LP (RTW), in its capacity as the investment manager of the RTW Funds, has the power to vote and the power to direct the disposition of the shares held by the RTW Funds. Accordingly, RTW may be deemed to be the beneficial owner of such securities. Roderick Wong, M.D., as the Managing Partner of RTW, has the power to direct the vote and disposition of the securities held by RTW. Dr. Wong disclaims beneficial ownership of the shares held by the RTW Funds, except to the extent of his pecuniary interest therein. The address and principal office of RTW Investments, LP is 40 10th Avenue, Floor 7, New York, NY 10014, and the address of Dr. Wong and each of the RTW Funds is c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014.
- (5) Consists of (i) shares of common stock issuable upon conversion of our Series B-2 preferred stock, shares of common stock issuable upon conversion of our Series C preferred stock, shares of common stock issuable upon conversion of our Series D preferred stock and shares of common stock subject to warrants that are exercisable within 60 days of , 2024, held by Soleus BB SPV, LLC (Soleus SPV), (ii) shares of common stock issuable upon conversion of our Series B-2 preferred stock, shares of common stock issuable upon conversion of our Series C preferred stock and shares of common stock subject to warrants that are exercisable within 60 days of , 2024, held by Soleus Private Equity Fund I, L.P. (PE Fund I), and (iii) shares of common stock issuable upon conversion of our Series C preferred stock, shares of common stock issuable upon conversion of our Series D preferred stock and shares of common stock subject to warrants that are exercisable within 60 days of , 2024, held by Soleus Private Equity Fund II, L.P. (PE Fund II). Soleus Private Equity GP I, LLC (Soleus PE GP I) is the sole general partner of PE Fund I and the sole managing member of Soleus SPV. Soleus PE GP I holds voting and dispositive power over the shares held by PE Fund I and Soleus SPV. Soleus Private Equity GP II, LLC (Soleus PE GP II) is the sole general partner of PE Fund II. Soleus PE GP II holds voting and dispositive power over the shares held by PE Fund II. Soleus PE GP I, LLC is the sole managing member of Soleus PE GP I, and Soleus PE GP II, LLC is the sole manager of Soleus PE GP II. Mr. Guy Levy is the sole managing member of each of Soleus PE GP I, LLC and Soleus PE GP II, LLC. Each of Mr. Guy Levy, Soleus PE GP I, LLC, Soleus PE GP II, LLC, Soleus PE GP I and Soleus PE GP II disclaims beneficial ownership of the shares held by Soleus SPV, PE Fund I and PE Fund II, except to the extent of their respective pecuniary interests therein. The address for Soleus BB SPV, LLC, Soleus Private Equity Fund I, L.P. and Soleus Private Equity Fund II, L.P. is c/o Soleus Capital Management, L.P., 104 Field Point Road, Greenwich, Connecticut 06830.
- (6) Consists of shares of common stock and shares of common stock issuable upon conversion of Series D preferred stock held by Omega Fund VII, L.P. (Omega Fund). Omega Fund VII GP Manager, Ltd. (Omega Ltd.) is the sole general partner of Omega Fund VII GP, L.P. (Omega GP), which is the sole general partner of Omega Fund; and each of Omega Ltd. and Omega GP may be deemed to own beneficially the shares held by Omega Fund. Claudio Nessi, Otello Stampacchia and Francesco Draetta are the directors of Omega Ltd. and, as a result, may be deemed to share voting and investment power over the shares held directly by Omega Fund. Each of Dr. Nessi, Dr. Stampacchia, Mr. Draetta, Omega Ltd. and Omega GP disclaims beneficial ownership of the shares held by Omega Fund, except to the extent of their pecuniary interest therein. The address for this entity is 888 Boylston Street, Suite 1111, Boston, Massachusetts 02199.
- (7) Consists of (i) shares of common stock and (ii) shares of common stock issuable upon conversion of our Series B preferred stock held by Dr. Damiano.
- (8) Consists of shares of common stock subject to options held by Mr. Saint that are exercisable within 60 days of , 2024.
- (9) Consists of shares of common stock subject to options held by that are exercisable within 60 days of , 2024.
- (10) Consists of shares of common stock subject to options held by that are exercisable within 60 days of , 2024.
- (11) Consists of shares of common stock subject to options held by Mr. Carney that are exercisable within 60 days of , 2024.
- (12) Consists of shares of common stock subject to options held by Mr. Glick that are exercisable within 60 days of , 2024.
- (13) Consists of shares of common stock subject to options held by Mr. Lezack that are exercisable within 60 days of , 2024.
- (14) Consists of (i) the shares described in notes (7) to (13) above and (ii) shares of shares of common stock subject to options held by that are exercisable within 60 days of , 2024.

DESCRIPTION OF CAPITAL STOCK

Upon the filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of _____ shares of common stock, par value \$0.0001 per share, and _____ shares of preferred stock, par value \$0.0001 per share. All of our authorized preferred stock upon the closing of this offering will be undesignated. The following is a summary of the rights of our common and preferred stockholders and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the closing of this offering, respectively, and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Common Stock

Outstanding Shares

As of September 30, 2024, there were:

- _____ shares of Class A common stock held of record by _____ stockholder, all of which will automatically convert into _____ shares of common stock in connection with the closing of this offering;
- _____ shares of Class B common stock held of record by _____ stockholders, all of which will automatically convert into _____ shares of common stock in connection with the closing of this offering; and
- _____ shares of Class C common stock held of record by _____ stockholders, all of which will automatically convert into _____ shares of common stock in connection with the closing of this offering.

These amounts exclude our outstanding shares of convertible preferred stock, which will convert into _____ shares of common stock in connection with the closing of this offering. Based on the number of shares of Class A common stock, Class B common stock and Class C common stock outstanding as of September 30, 2024 and giving effect to (i) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock into shares of our common stock; (ii) the conversion of all outstanding shares of our convertible preferred stock; (iii) the issuance by us of shares of common stock in this offering; and (iv) no exercise by the underwriters of their option to purchase additional shares, there will be _____ shares of common stock outstanding upon the closing of this offering.

Voting

Each holder of our Class A common stock and Class B common stock is entitled to one vote for each share of Class A common stock and Class B common stock held on all matters submitted to a vote of stockholders, except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law. The holders of our Class C common stock do not have voting rights. There are no cumulative voting rights.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of Class A common stock, Class B common stock and Class C common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding-up, holders of our Class A common stock, Class B common stock and Class C common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights, Preferences and Privileges

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our Class A common stock, Class B common stock and Class C common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Convertible Preferred Stock

As of September 30, 2024, there were shares of convertible preferred stock outstanding, held of record by stockholders.

In connection with the closing of this offering, all outstanding shares of convertible preferred stock will automatically convert into shares of our common stock. Immediately prior to the closing of this offering, our certificate of incorporation will be amended and restated and all of our previously outstanding shares of convertible preferred stock will be converted into shares of common stock.

Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Stock Options

As of September 30, 2024, shares of common stock were issuable upon the exercise of outstanding stock options, issued under our 2016 Plan, at a weighted-average exercise price of \$ per share. For information regarding the terms of our equity incentive plans, see the section titled “Executive and Director Compensation—Equity Benefit Plans.”

Warrants

As of September 30, 2024, we had (i) outstanding warrants to purchase shares of our Common Warrants, with an exercise price of \$0.01 per share and (ii) outstanding warrants to purchase an aggregate of shares of our Series C Warrants, with an exercise price of \$0.01 per share.

Upon the completion of this offering, the Common Warrants will be automatically net exercised for the purchase of an aggregate of shares of our common stock (based upon an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus).

Upon the completion of this offering, the Series C Warrants will be automatically net exercised for the purchase of an aggregate of shares of our common stock (based upon an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus).

Registration Rights

Upon the closing of this offering, certain holders of shares of our common stock, including those issuable upon the conversion of preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an amended and restated investors' rights agreement (investors' rights agreement) between us and holders of our preferred stock. The investors' rights agreement includes demand registration rights, Form S-3 registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Beginning 180 days after the effective date of the registration statement of which this prospectus is a part, certain holders of registrable securities are entitled to demand registration rights. Under the terms of the investors' rights agreement, we will be required, upon the written request of the holders of at least 40% of our outstanding registrable securities, as defined in the investors' rights agreement, to file a registration statement and use commercially reasonable efforts to effect the registration of all or a portion of their registrable securities for public resale. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement.

Form S-3 Registration Rights

Pursuant to the investors' rights agreement, if we are eligible to file a registration statement on Form S-3, we will be required, upon written request of the holders of at least 20% of our outstanding registrable securities, as defined in the investors' rights agreement, to register their registrable securities under the Securities Act so long as the total amount of registrable shares requested to be registered has an anticipated aggregate offering price to the public, net of selling expenses, of least \$2.5 million. We are required to effect only two registrations in any twelve-month period pursuant to this provision of the investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback Registration Rights

If we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration, subject to certain conditions and limitations, including the right of the underwriters to limit the number of shares included in such registration under specified circumstances.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Our Bylaws and Delaware Law

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law (Section 203). Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a “business combination” to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as any entity or person who beneficially owns, or within the three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its amended and restated certificate of incorporation or amended and restated bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the closing of this offering, respectively, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to _____ shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the Executive Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for: (i) any derivative claim or cause of action brought on our behalf, (ii) any claim or cause of action that is based upon a violation of a duty owed by any of our current or former director, officer, employees or stockholder, to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any claim or cause of action as to which the Delaware General

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Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by applicable law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided, however, that if the designation of such court as the sole and exclusive forum for a claim or action referred to in foregoing clauses (i) through (vi) would violate applicable law, then the United States District Court for the District of Delaware shall be the sole and exclusive forum for such claim or cause of action; and

- provide that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters for any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

Exchange Listing

We will apply to list our common stock on the _____ under the symbol “_____.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock immediately prior to the closing of this offering will be _____. The transfer agent and registrar's address is _____.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future. Although we intend to apply to have our common stock listed on _____, we cannot assure you that there will be an active public market for our common stock.

Following the closing of this offering, based on the number of shares of our common stock outstanding as of September 30, 2024 and assuming (i) the issuance of shares of common stock in this offering, (ii) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock into _____ shares of our common stock, (iii) the conversion of all outstanding shares of our convertible preferred stock into _____ shares of our common stock, which will automatically occur upon the closing of the offering, and (iv) no exercise of the underwriters' option to purchase additional shares, we will have an aggregate of approximately _____ shares of common stock outstanding.

Of these shares, all shares of common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares of common stock purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act or any shares subject to lock-up agreements. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock outstanding after this offering will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, each of which is summarized below and, if subject to lock-up agreements, may only be sold after the expiration of the 180-day lock-up period. We expect that substantially all of these shares will be subject to a 180-day lock-up period under the lock-up and market stand-off agreements described below.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may also be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition, investment or other transaction.

In addition, shares of common stock that are either subject to outstanding options or warrants or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for

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purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates will be entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately _____ shares immediately after this offering; or
- the average weekly trading volume in our common stock on _____ during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale, provided in each case that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below and in the section titled “Underwriting.”

Form S-8 Registration Statement

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under the 2016 Plan, the 2025 Plan and the ESPP. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Lock-Up Agreements

We, our directors, executive officers and the holders of substantially all of our equity securities, have agreed with the underwriters that for a period of 180 days after the date of this prospectus, subject to specified exceptions as detailed further in the section titled “Underwriting,” we or they will not, except with the prior written consent of BofA Securities, Inc., Piper Sandler & Co. and Leerink Partners LLC, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sale of or otherwise dispose of or transfer any shares of common stock or any securities

convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock, or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. Substantially all of our optionholders are subject to a market stand-off agreement with us which imposes similar restrictions.

Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See the sections titled “Registration Rights” below and “Description of Capital Stock—Registration Rights.”

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Registration Rights

Upon the closing of this offering and the expiration or release from the terms of applicable lock-up agreements, holders of an aggregate of shares of our common stock, which includes all of the shares of common stock issuable upon the conversion of our convertible preferred stock immediately prior to the closing of this offering, or their transferees, will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares subsequently purchased by affiliates. See the section titled “Description of Capital Stock—Registration Rights” for additional information.

After to the completion of the offering, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership, and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local, or non-U.S. tax laws, or any other U.S. federal tax laws. This discussion is based on the Code and applicable Treasury Regulations promulgated thereunder, published rulings and administrative pronouncements of the Internal Revenue Service (IRS), and judicial decisions, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under U.S. federal income tax laws, including but not limited to:

- certain former citizens or long-term residents of the United States;
- “controlled foreign corporations”;
- “passive foreign investment companies”;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in securities or foreign currencies;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own, or have owned, actually or constructively, more than 5% of our stock at any time;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of the partnership and the partners thereof generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, OR NON-U.S. TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of Non-U.S. holder

For purposes of this discussion, the term “non-U.S. holder” means any beneficial owner of our common stock that is not a “U.S. person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

We have not paid dividends on our common stock and do not anticipate paying dividends on our common stock for the foreseeable future. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the subsection titled “—Gain on Disposition of Our Common Stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding and Sections 1471 through 1474 of the Code (commonly referred to as FATCA), dividends paid to a non-U.S. holder generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our paying agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) and satisfy applicable certification and other requirements. This certification must be provided to us or our paying agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder’s U.S. trade or business (and, if required by an applicable tax treaty, are attributable to such holder’s permanent establishment in the United States), the non-U.S. holder will be exempt from U.S. federal withholding tax. To

claim the exemption, the non-U.S. holder generally must furnish a valid IRS Form W-8ECI (or applicable successor form) to us or our paying agent. However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a United States real property interest (USRPI) by reason of our status as a United States real property holding corporation (USRPHC), for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock.

The determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of worldwide real property interests and our other assets used or held for use in a trade or business. We believe that we are not currently and do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a non-U.S. holder will not be subject to U.S. federal income tax if our common stock is "regularly traded" (as defined by applicable Treasury Regulations) on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (unless an applicable income tax treaty provides for different treatment) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply regardless of whether such distributions constitute dividends and even if no withholding was required. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

FATCA

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock. Under applicable Treasury Regulations and administrative guidance, withholding under FATCA would have applied to payments of gross proceeds from the sale or other disposition of stock, but under proposed regulations (the preamble to which specifies that taxpayers are permitted to rely on such proposed regulations pending finalization), no withholding would apply with respect to payments of gross proceeds.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

UNDERWRITING

BofA Securities, Inc., Piper Sandler & Co. and Leerink Partners LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
Piper Sandler & Co.	
Leerink Partners LLC	
Stifel, Nicolaus & Company, Incorporated	
Lake Street Capital Markets, LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Total	
		Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discounts and commissions, are estimated at \$ and are payable by us. We have agreed to reimburse the underwriters for certain of their expenses, up to \$.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discounts and commissions. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders (each, a Lock-up Party) have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc., Piper Sandler & Co. and Leerink Partners LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common stock;
- sell any option or contract to purchase any common stock;
- purchase any option or contract to sell any common stock;
- grant any option, right or warrant for the sale of any common stock;
- lend or otherwise dispose of or transfer any common stock;
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any hedging, swap, loan or other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such hedging, swap, loan or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition (collectively, the Lock-up Securities).

Notwithstanding the foregoing, a Lock-up Party may transfer shares of common stock: (i) as a *bona fide* gift or gifts, including, without limitation, to a charitable organization or educational institution, or for *bona fide* estate planning purposes; (ii) by will, testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the Lock-up Party; (iii) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement; (iv) pursuant to an order of a court or regulatory agency having jurisdiction over the Lock-up Party; (v) to any corporation, partnership, limited liability company or other entity of which the Lock-up Party or the immediate family of the Lock-up Party are the legal and beneficial owner of all of the outstanding equity securities or similar interests; (vi) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (v) above; (vii) to any immediate family member or any trust, partnership, limited liability company or other entity for the direct or indirect benefit of the Lock-up Party or one or more immediate family members of the Lock-up Party, or if the Lock-up Party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust; (viii) if the Lock-up Party is a corporation, partnership, limited liability

company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act) of the Lock-up Party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the Lock-up Party or affiliates of the Lock-up Party (including, for the avoidance of doubt, where the Lock-up Party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership), or (B) as part of a distribution to limited partners, limited liability company members, managers, equityholders or stockholders of the Lock-up Party or holders of similar equity interests in the Lock-up Party; (ix) to us (A) upon the Lock-up Party’s death, disability or termination of employment or other service relationship with us, provided that such common stock were issued to the Lock-up Party pursuant to an agreement or equity award granted pursuant to an employee benefit plan, option, warrant or other right disclosed in the prospectus for the public offering, or (B) pursuant to agreements under which we have the option to repurchase shares (x) to us pursuant to the vesting, settlement or exercise of restricted stock units, restricted stock, options, warrants or other rights to purchase common stock (including, in each case, by way of “net” or “cashless” exercise), including for the payment of exercise price and tax and remittance payments due as a result of the vesting, settlement or exercise of such restricted stock units, restricted stock, options, warrants or rights, provided that any such restricted stock units, restricted stock, options, warrants or rights are held by the Lock-up Party pursuant to an agreement or equity award granted under a stock incentive plan or other equity award plan, each of which is disclosed in the prospectus for the public offering; or (xi) pursuant to a *bona fide* third party tender offer, merger, consolidation or other similar transaction, in one transaction or a series of related transactions, made to all holders of common stock that has been approved by our board of directors, which results in any person or group of persons becoming the beneficial owners (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of 50% of the outstanding voting securities of ours (or the surviving entity); provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Lock-up Securities shall remain subject to the provisions of this lock-up agreement; provided that (1) the representatives receive a signed lock-up agreement in the form of the lock-up agreement for the balance of the lock-up period from each donee, devisee, trustee, distributee, or transferee, as the case may be, (2) any such transfer shall not involve a disposition for value, (3) such transfers are not required to be reported during the lock-up period with the U.S. Securities and Exchange Commission on Form 4 or Form 5 in accordance with Section 16(a) of the Exchange Act, or, in the case of clause (i), (ii), (iii), (iv) and (x) above, any such required filing shall clearly indicate in the footnotes thereto that the filing relates to circumstances described in such a clause, and (4) the Lock-Up Party does not otherwise voluntarily effect any public filing or report regarding such transfers during the lock-up period.

In addition, the foregoing restrictions shall not prevent or restrict (i) the conversion of the outstanding shares of our preferred stock into common stock; provided that the common stock acquired upon such exercise shall be subject to the terms of the lock-up agreement; and (ii) the establishment of a trading plan that complies with Rule 10b5-1 under the Exchange Act (10b5-1 Trading Plan) for the transfer of Lock-up Securities, so long as there are no sales of Lock-up Securities under such plan during the lock-up period; and provided that the establishment of a 10b5-1 Trading Plan providing for sales of Lock-up Securities shall only be permitted if any public announcement or filing under the Exchange Act, if required or voluntarily made by or on behalf of the Lock-up Party or us regarding the establishment of such plan, shall include a statement to the effect that no transfer of Lock-up Securities may be made under such plan during the lock-up period.

Listing

We expect the shares to be approved for listing on the _____ under the symbol “ _____,” and the closing of this offering is contingent upon such listing.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discounts and commissions received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the , in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no Shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the Shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of Shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any Shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the Managers that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any Shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the Shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

In connection with the offering, the Managers are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom (UK), no Shares have been offered or will be offered pursuant to the offering to the public in the UK prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation and the FSMA, except that offers of Shares may be made to the public in the UK at any time under the following exemptions under the UK Prospectus Regulation and the FSMA:

- a. to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- c. at any time in other circumstances falling within section 86 of the FSMA,

provided that no such offer of Shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the UK who initially acquires any Shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the Managers that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any Shares being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented,

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acknowledged and agreed that the Shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the UK to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018, and the expression “FSMA” means the Financial Services and Markets Act 2000.

In connection with the offering, the Managers are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the Financial Promotion Order), (ii) are persons falling within Article 49(2)(a) to (d) (“high net worth companies, unincorporated associations etc.”) of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended (FSMA)) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as “relevant persons”). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type

specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (Corporations Act), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (Exempt Investors) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The Shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (ii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the Shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to Shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The Shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in

Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the Shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the Shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (SFA)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the Shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a. a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- b. a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the Shares pursuant to an offer made under Section 275 of the SFA except:

- a. to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- b. where no consideration is or will be given for the transfer;
- c. where the transfer is by operation of law; or
- d. as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The Shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the Shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (**NI 33-105**), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California. The underwriters are being represented by Latham & Watkins LLP, New York, New York.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2022 and 2023, and for each of the two years in the period ended December 31, 2023, as set forth in their report. We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection at the website of the SEC referred to above. We also maintain a website at www.betabionics.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements as of December 31, 2022 and 2023, and for the Years Ended December 31, 2022 and 2023

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Beta Bionics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Beta Bionics, Inc. (the Company) as of December 31, 2022 and 2023, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2023.

San Diego, California
September 13, 2024

BETA BIONICS, INC.

BALANCE SHEETS

(In thousands, except number of shares)

	December 31,	
	2022	2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 27,675	\$ 26,566
Short-term investments	—	70,179
Accounts receivable, net	—	4,448
Inventories	—	1,245
Prepaid expenses and other current assets	792	1,183
Total current assets	28,467	103,621
Property and equipment, net	3,319	2,476
Operating lease right-of-use asset	3,548	3,722
Restricted cash	100	100
Other long-term assets	93	121
Total assets	<u>\$ 35,527</u>	<u>\$ 110,040</u>
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 430	\$ 1,166
Accrued expenses and other current liabilities	6,327	8,128
Funded R&D liability—related party	1,140	—
Operating lease liabilities	976	1,224
Deferred revenue	—	87
Total current liabilities	8,873	10,605
Operating lease liabilities, net of current portion	3,157	2,999
Deferred revenue, net of current portion	—	255
Warrant liabilities	10,497	37,573
Total liabilities	<u>22,527</u>	<u>51,432</u>
Commitments and contingencies (Note 18)		
Convertible preferred stock (Series A, A-2, B, B-2, C and D), par value of \$0.0001 per share; 15,200,000 and 26,434,390 shares authorized at December 31, 2022 and 2023, respectively; 13,259,790 and 25,366,930 shares issued and outstanding at December 31, 2022 and 2023, respectively; liquidation preference of \$193,462 and \$295,162 at December 31, 2022 and 2023, respectively	183,034	261,713
Stockholders' deficit:		
Class A common stock, par value of \$0.0001 per share; 6,000,000 shares authorized at December 31, 2022 and 2023; 5,890,000 shares issued and outstanding at December 31, 2022 and 2023	1	1
Class B common stock, par value of \$0.0001 per share; 38,000,000 and 65,000,000 shares authorized at December 31, 2022 and 2023 respectively; 3,919,100 shares and 5,875,671 issued and outstanding at December 31, 2022 and 2023, respectively	—	—
Class C common stock, par value of \$0.0001 per share; 5,000,000 and 100,000 shares authorized at December 31, 2022 and 2023, respectively; 96,910 shares issued and outstanding at December 31, 2022 and 2023	—	—
Additional paid-in capital	15,530	26,421
Accumulated other comprehensive income	—	137
Accumulated deficit	(185,565)	(229,664)
Total stockholders' deficit	<u>(170,034)</u>	<u>(203,105)</u>
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 35,527</u>	<u>\$ 110,040</u>

The accompanying notes are an integral part of these financial statements.

BETA BIONICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except number of shares and per share data)

	Year Ended December 31,	
	2022	2023
Revenue:		
Net sales	\$ —	\$ 11,995
Collaboration revenue	179	—
Total revenue	179	11,995
Cost of sales	—	5,687
Gross profit	179	6,308
Operating expenses:		
Research and development	31,428	17,943
Sales and marketing	8,827	11,990
General and administrative	25,768	12,225
Total operating expenses	66,023	42,158
Loss from operations	(65,844)	(35,850)
Other income (expense), net:		
Interest income	196	1,777
Interest and other expense	(14)	(68)
Change in fair value of warrant liabilities	911	(9,958)
Total other income (expense), net	1,093	(8,249)
Net loss	\$ (64,751)	\$ (44,099)
Other comprehensive income (loss):		
Unrealized gain on short-term investments	—	137
Comprehensive loss	\$ (64,751)	\$ (43,962)
Net loss per share attributable to common stockholders, basic and diluted	\$ (6.58)	\$ (4.22)
Weighted-average common shares outstanding, basic and diluted	9,845,122	10,448,817

The accompanying notes are an integral part of these financial statements.

BETA BIONICS, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except number of shares)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	9,157,930	\$138,049	9,665,040	\$ 1	\$ 9,041	\$ —	\$ (120,814)	\$ (111,772)
Issuance of Series C preferred stock, net of issuance costs of \$656 and net of warrant liabilities of \$11,408	4,101,860	44,985	—	—	—	—	—	—
Stock option exercises	—	—	240,970	—	389	—	—	389
Stock-based compensation expense	—	—	—	—	6,100	—	—	6,100
Net loss	—	—	—	—	—	—	(64,751)	(64,751)
Balance at December 31, 2022	13,259,790	183,034	9,906,010	1	15,530	—	(185,565)	(170,034)
Issuance of Series D preferred stock, net of issuance costs of \$700 and net of warrant liabilities of \$22,321	12,107,140	78,679	—	—	—	—	—	—
Common B warrant exercises	—	—	1,954,161	—	5,223	—	—	5,223
Stock option exercises	—	—	2,410	—	10	—	—	10
Stock-based compensation expense	—	—	—	—	5,658	—	—	5,658
Unrealized gain on short-term investments	—	—	—	—	—	137	—	137
Net loss	—	—	—	—	—	—	(44,099)	(44,099)
Balance at December 31, 2023	<u>25,366,930</u>	<u>\$261,713</u>	<u>11,862,581</u>	<u>\$ 1</u>	<u>\$ 26,421</u>	<u>\$ 137</u>	<u>\$ (229,664)</u>	<u>\$ (203,105)</u>

The accompanying notes are an integral part of these financial statements.

BETA BIONICS, INC.
STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2022	2023
Cash flows from operating activities:		
Net loss	\$(64,751)	\$ (44,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,345	1,226
Provision for expected credit losses	—	46
Stock-based compensation expense	6,100	5,658
Provision for excess and obsolete inventory	—	(58)
Change in fair value of warrant liabilities	(911)	9,958
Accretion of discount on short-term investments	—	(747)
Amortization of operating lease right-of-use asset	742	865
Loss on disposal of property and equipment	43	11
Deferred offering costs	14	—
Changes in operating assets and liabilities:		
Accounts receivable	—	(4,494)
Inventories	—	(1,187)
Prepaid expenses and other current assets	119	(391)
Other long-term assets	86	(28)
Accounts payable	(77)	716
Accrued expenses and other current liabilities	(2,007)	1,825
Funded R&D liability—related party	—	(1,140)
Operating lease liability	(732)	(948)
Deferred revenue	(179)	342
Net cash used in operating activities	<u>(60,208)</u>	<u>(32,445)</u>
Cash flows from investing activities:		
Purchases of short-term investments	—	(69,295)
Proceeds on disposal of property and equipment	3	4
Purchases of property and equipment	(772)	(402)
Net cash used in investing activities	<u>(769)</u>	<u>(69,693)</u>
Cash flows from financing activities:		
Proceeds from the issuance of convertible preferred stock, net of issuance costs	56,393	101,000
Proceeds from stock option exercises	389	10
Proceeds from common stock warrants exercise	—	19
Net cash provided by financing activities	<u>56,782</u>	<u>101,029</u>
Net decrease in cash, cash equivalents and restricted cash	(4,195)	(1,109)
Cash, cash equivalents and restricted cash at beginning of period	31,970	27,775
Cash, cash equivalents and restricted cash at end of period	<u>\$ 27,775</u>	<u>\$ 26,666</u>
Supplemental disclosure of non-cash investing and financing information:		
Purchases of property and equipment included in accounts payable	\$ —	\$ 20
Purchases of property and equipment included in accrued expenses	\$ 24	\$ —
Series C convertible preferred stock warrants included in issuance costs	\$ 11,408	\$ —
Common B warrants issued in connection with Series D convertible preferred stock	\$ —	\$ 22,321
Supplemental disclosure of cash flow information:		
Operating lease right-of-use asset obtained in exchange for operating lease obligations	\$ 4,290	\$ 1,038
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	\$ 27,675	\$ 26,566
Restricted cash	100	100
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	<u>\$ 27,775</u>	<u>\$ 26,666</u>

The accompanying notes are an integral part of these financial statements.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

Beta Bionics, Inc. (the “Company”) is a commercial-stage medical device company engaged in the design, development, and commercialization of innovative solutions to improve the health and quality of life of insulin-requiring people with diabetes (“PWD”) by utilizing advanced adaptive algorithms to simplify and improve the treatment of their disease. The Company was incorporated as a Massachusetts benefit corporation on October 21, 2015, and converted to a Delaware corporation in August 2024.

The Company’s product, the iLet Bionic Pancreas (“iLet”), was cleared by the U.S. Food and Drug Administration (“FDA”) for the treatment of type 1 diabetes (“T1D”) in adults and children six years of age and older in May 2023, and it began commercializing the iLet in the United States in May 2023. The iLet is the first adaptive closed-loop algorithm insulin dosing system that does not require T1D users to keep a daily tabulation of their carbohydrate intake or perform calculations to determine the correct dose of insulin to take.

From its inception to December 31, 2023, the Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, capital raising, establishing and engaging in collaborations, performing research and development, advancing and scaling up manufacturing capabilities, commercializing its products, establishing a sales infrastructure and providing general and administrative support for these activities. The Company’s operations to date have been funded primarily through the issuance and sale of convertible preferred stock and sales of the iLet.

Basis of Presentation

The Company’s financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as found in the Accounting Standards Codification (“ASC”) and pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”).

On August 30, 2024, the Company converted from a Massachusetts benefit corporation to a Delaware corporation. All outstanding shares of preferred stock, common stock, options and warrants of the Massachusetts benefit corporation were converted into an equivalent share, option or warrant of the Delaware corporation and the par value of the Company’s preferred stock and common stock was adjusted to \$0.0001. As this conversion was completed subsequent to balance sheet date but prior to the financial statement issuance date, the impact of the change has been given retroactive effect in the financial statements and the accompanying notes.

Emerging Growth Company Status

The Company is an emerging growth company (“EGC”), as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”), enacted in 2012. Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS*****Stock Split.***

The board of directors of the Company (the “Board”) approved a ten-for-one stock split (the “Stock Split”) of the Company’s authorized, issued and outstanding shares of stock, effective on August 25, 2023. All share and per share information included in these financial statements and notes thereto have been retroactively adjusted to give effect to the Stock Split.

2. Significant Accounting Policies***Use of Estimates***

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, certain judgements regarding revenue recognition, inventory valuation, valuation of common stock and stock-based awards, and convertible preferred stock and common stock warrants. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalents in accounts at multiple accredited financial institutions and short-term investments in custodian accounts, in excess of federally insured limits. Additionally, the Company has established guidelines regarding investment instruments and their maturities, which are designed to maintain preservation of principal and liquidity. The Company does not believe that it is subject to unusual risk beyond the normal credit risk associated with commercial banking relationships.

The Company is exposed to concentration risk as it relates to its customers. The following table summarizes the percentages of total sales and accounts receivable, net for customers who accounted for 10% or more of the respective amounts for the periods presented:

	<u>Total Sales</u> <u>Year Ended</u> <u>December 31,</u> <u>2023</u>	<u>Accounts</u> <u>Receivable,</u> <u>Net</u> <u>December 31,</u> <u>2023</u>
Distributor A	20.6%	28.9%
Distributor B	19.0%	24.5%
Distributor C	16.3%	12.3%
Distributor D	14.2%	*

* Amount related to the respective customer represented less than 10% for the period presented.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

The Company relies on certain materials used in its development and manufacturing processes, some of which are procured from only one or a few sources. The failure of one of these suppliers to deliver on schedule could delay or interrupt the manufacturing or commercialization process and would adversely affect the Company's operating results. In addition, a disruption in the commercial supply of, or a significant increase in the cost of one of the Company's materials from these sources could have a material adverse effect on the Company's business, financial position and results of operations.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and all highly liquid investments purchased with original maturities of three months or less.

Short-Term Investments

In accordance with ASC 320, *Investments – Debt Securities*, the Company classifies its short-term investments as available-for-sale securities. Available-for-sale securities are carried at fair market value with net unrealized gains and losses reported as a component of accumulated other comprehensive income in stockholders' deficit and as a component of other comprehensive loss within the statements of operations and comprehensive loss. The Company determines realized gains or losses on the sale of available-for-sale securities using the specific identification method and includes net realized gains and losses as a component of other income or expense within the statements of operations and comprehensive loss. The Company periodically evaluates its short-term investments for credit losses, considering the significance of the decline in value and the market and economy in general. The Company has not recognized any impairment losses related to its short-term investments during the years ended December 31, 2022 and 2023. All short-term investments are classified as current based on the nature of the investments and their availability for use in current operations.

Accounts Receivable and Allowance for Credit Losses

Accounts receivable consist of amounts billed and currently due from customers. The Company maintains an allowance for its current estimate of expected credit losses and reassesses quarterly based on management's expectations of the asset's collectability. Provisions for expected credit losses are based upon specific reserves for known collection issues, as well as a general reserve. Determining the allowance for credit losses involves estimation and is subject to uncertainty. The Company's allowance for credit losses is developed by using relevant available information including historical collection and loss experience, current economic conditions, and evaluations of customer balances. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

Inventories

Inventories are valued at the lower of cost or net realizable value, determined by the first-in, first-out method. Capitalized inventory costs include raw materials, labor, and manufacturing overhead expenses associated with the production process. The Company periodically reviews inventories for potential impairment and adjusts inventory for potentially excess or obsolete goods to state inventories at their net realizable value. Factors influencing these adjustments include quantities on hand and firm purchase commitments, expectations of future use, judgments based on quality control testing data, and assessments of the likelihood of scrapping or obsoleting certain inventories based on future demand for its products and market conditions.

In addition, prior to receiving FDA clearance for the iLet in May 2023, the costs associated with the manufacture of the iLet inventory were expensed as incurred as research and development costs. This resulted in

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS**

approximately \$1.9 million in inventory being sold during the year ended December 31, 2023, for which the associated costs had been previously expensed as research and development costs. As of December 31, 2023, the Company has approximately \$0.4 million remaining in inventory with no cost basis (that was previously expensed) and expects this to continue to impact the cost of sales within the next year as the remaining pre-FDA inventory is sold to customers.

Restricted Cash

In connection with the Company's lease agreement entered into in May 2019, the Company is required to maintain a letter of credit of \$0.1 million for the benefit of the landlord. As of December 31, 2022 and 2023, this amount was guaranteed by a deposit in a money market fund and classified as restricted cash on the balance sheets.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. The Company performs fair value measurements in accordance with ASC 820, *Fair Value Measurement*. ASC 820 defines fair value as the price received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at their fair values, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the assets or liabilities, such as inherent risk, transfer restrictions and risk of nonperformance. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1— Quoted prices in active markets for identical assets or liabilities.
- Level 2— Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

The Company's cash equivalents, short-term investments and restricted cash are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The carrying value and estimated fair value of certain of the Company's common stock and preferred stock warrants were determined using the Black-Scholes pricing model as of December 31, 2023 (see Note 4). The fair values of the Company's accounts receivables, accounts payable and accrued expenses approximate their carrying values due to the short-term nature of these assets and liabilities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense are calculated using the straight-line method over the estimated useful life of the related assets, generally two to five years. Leasehold improvements are amortized over the shorter of the estimated useful life of the assets or the remaining lease term. Repairs and maintenance costs are charged to expense as incurred.

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS**

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Upon retirement or sale, the cost of assets disposed of, and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance that do not improve or extend the life of the respective asset are charged to expense as incurred.

Impairment of Long-lived Assets

Long-lived assets consist of property and equipment. The Company continually evaluates long-lived assets to be held and used for potential impairment whenever events or changes in circumstances indicate the carrying value of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. The Company did not recognize any impairment losses during the years ended December 31, 2022 or 2023.

Leases

Effective January 1, 2022, the Company adopted ASC 842, *Leases*, using the modified retrospective transition method. Under ASC 842, leases include all agreements in which the Company obtains control of an identified asset. A lease liability is recognized at commencement date based on the present value of the lease payments over the lease term. When available, the Company uses the rate implicit in the lease to discount lease payments to present value; otherwise, the Company estimates the incremental borrowing rate to discount the lease payments based on information available at lease commencement.

Upon adoption, the Company elected the relief package of practical expedients permitted under the transition guidance within the new standard, as well as the short-term lease recognition exemption for all leases that qualified, meaning the Company will recognize expense on a straight-line basis and will not recognize a right-of-use asset or lease liability for these leases, upon adoption. The Company also elected to combine lease and non-lease components for all classes of underlying assets. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of right-to-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

If a lease includes options to extend the lease term, the Company only includes the periods it is reasonably certain to exercise as of the lease commencement date. The Company monitors its plans to renew its material leases each reporting period. The Company's lease portfolio consists of office, laboratory, and manufacturing facilities. All of the Company's leases are classified as operating leases, and therefore the expense is captured in income from operations each period.

The Company's leases have non-cancelable initial lease terms of approximately two to seven years, some of which include options to extend the leases for up to five years. To the extent the Company is not reasonably certain of exercising options to extend a lease, the additional term provided by options is excluded from the measurement of the right-of-use asset and lease liability. The exercise of lease renewal options is at the Company's sole discretion. Leases with an initial term of 12 months or less are expensed and not recorded on the balance sheet. The Company's leases provide for fixed rental payments with annual rent escalations. Variable lease costs, such as maintenance, real estate taxes, insurance and utility costs, are excluded from the measurement of the lease liability. The Company does not have any leases that are classified as financing leases.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

Classification and Accretion of Convertible Preferred Stock

The Company's convertible preferred stock is classified outside of stockholders' deficit on the balance sheets because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock. The Company's Series A convertible preferred stock (the "Series A Preferred Stock"), Series A-2 convertible preferred stock (the "Series A-2 Preferred Stock"), Series B convertible preferred stock (the "Series B Preferred Stock"), Series B-2 convertible preferred stock (the "Series B-2 Preferred Stock"), Series C convertible preferred stock (the "Series C Preferred Stock"), and Series D convertible preferred stock (the "Series D Preferred Stock") are not redeemable, except in the event of a deemed liquidation (see Note 11). Since convertible preferred stock is neither currently redeemable, nor probable of becoming redeemable, the carrying values of the convertible preferred stock are not being accreted to their redemption values. Subsequent adjustments to the carrying values of the convertible preferred stock would be made only when and if it either becomes currently redeemable or probable of becoming redeemable.

The issuance costs from equity financings are netted against the gross proceeds received from the equity financings.

Warrant Liabilities

Preferred Stock Warrants

The Company has classified warrants to purchase its Series C Preferred Stock as a liability on the balance sheets as these warrants are freestanding financial instruments that are exercisable for preferred stock that is contingently redeemable outside of the Company's control (see Note 4).

Common Stock Warrants

The Company has classified warrants to purchase Class B common stock issued in connection with its Series D Preferred Stock financing as a liability on the balance sheets as these warrants are freestanding financial instruments that are not indexed to the Company's common stock (see Note 4).

Contingencies

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters. The Company records accruals for those loss contingencies when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. The Company does not recognize gain contingencies until realized. As of December 31, 2022 and 2023, no liabilities were recorded for loss contingencies (see Note 18).

Segment Information

An operating segment is defined as a component of a business with discrete financial information that is evaluated by the chief operating decision maker decisions ("CODM") in making decisions regarding the level of resource allocation and performance assessment. The Company operates as single segment, focused on the development, manufacture and sale of the iLet. The results of this single operating segment are regularly reviewed by the Company's CODM, the President and Chief Executive Officer. The Company's CODM does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's overall operating results.

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS*****Revenue Recognition******Net Sales***

Revenue is generated primarily from sales of the iLet and single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, and infusion sets that connect the iLet to a user's body through a network of distributors and pharmacies that resell the products to insulin-requiring PWD. In accordance with ASC 606, *Revenue from Contracts with Customers*, the Company recognizes revenue when it transfers control of the promised goods or services to its distributor and pharmacy customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services, net of estimated returns and estimated variable consideration adjustments, including rebates, patient assistance and chargebacks.

Revenue Recognition for Arrangements with Multiple Performance Obligations

The Company considers the individual deliverables in its contracts with customers as separate performance obligations. The iLet and single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, and infusion sets that connect the iLet to a user's body, are deemed performance obligations that are satisfied at a point in time when the customer obtains control of the promised good, which typically is upon shipment. The Company has determined that the user's ability to access the mobile application and receive unspecified software updates through the mobile application are considered distinct performance obligations that are satisfied over time, as access and support are provided throughout the typical four-year warranty period of the iLet. Accordingly, revenue related to access to the mobile application and unspecified software updates are deferred and recognized ratably over a four-year period. Given that access to the mobile application and unspecified software updates follow the same pattern of transfer to the customer and are provided over the same four-year period, the Company recognizes revenue for these performance obligations as if they were a single performance obligation.

The transaction price is determined based on the consideration expected to be received, based on the stated value in contractual arrangements. The Company allocates the consideration to the individual performance obligations based on the estimated relative standalone selling price of the performance obligations and recognizes the consideration based on when the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. Where there is no observable standalone selling price, the Company estimates standalone selling price by applying the expected cost plus a margin approach.

Variable Consideration

The amount of variable consideration that is included in the transaction price is included in revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company estimates reductions to revenues for rebates paid to pharmacy benefit managers ("PBM"). Rebates are based on contractual arrangements, which may vary by customer. The estimates are based on products sold, historical experience, trends, specific known market events and, as available, channel inventory data. Provisions for rebates and patient assistance are accounted for as a reduction of sales when revenue is recognized and are included within accrued expenses and other current liabilities within the balance sheets. Provisions for chargebacks are accounted for as a reduction of sales when revenue is recognized and are included as a reduction of accounts receivable, net within the balance sheets, as the right of offset exists. If the actual amounts of consideration that the Company receives differ from estimates, the Company adjusts these estimates, which affects reported revenue, in the period that such variances become known or at the end of each reporting period.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

Sales Returns

The Company offers a 90-day right of return to customers from the date of shipment of its iLet from one of its authorized distributors, provided a physician's confirmation of the good faith medical reason for the return is received. Estimated allowances for sales returns are based on historical returned quantities as compared to iLet shipments in those same periods of return, adjusted for known or expected changes in the marketplace when appropriate. Actual product returns have not differed materially from estimated amounts recorded in the accompanying financial statements.

Contract Costs

The Company recognizes an asset for incremental costs of obtaining a contract with a customer if it expects to recover those costs. Amounts paid under the Company's sales incentive compensation plan qualify for capitalization since the plan is directly related to sales achieved during a period of time. However, the Company has elected the practical expedient to expense the costs as they are incurred, within sales and marketing expenses, since the amortization period is less than one year.

Product Warranty

The Company provides a four-year warranty on the iLet to end-users to replace any iLets that do not function as intended in accordance with the product specifications. Estimated warranty costs are recorded at the time of shipment. Warranty costs are estimated primarily based on the current expected product replacement cost and expected replacement rates utilizing management's understanding of the hardware. Although the Company's history of product sales is limited, management also utilizes historical warranty cost data to reevaluate the estimated warranty obligation on a regular basis. Product returns and warranty replacements to date have been consistent with amounts accrued and have not been significant. Warranty expense is recorded as a component of cost of sales in the statements of operations and comprehensive loss.

Shipping and Handling Costs

Shipping and handling costs associated with product delivery are included within cost of sales in the Company's statements of operations and comprehensive loss. The Company does not generally separately charge customers for shipping and handling costs, but any amounts billed to a customer for shipping and handling are reported as revenues.

Collaboration Revenue

The Company evaluates its license and/or collaboration arrangements to determine whether the arrangement (or part of the arrangement) represents a collaborative arrangement pursuant to ASC 808, *Collaborative Arrangements*. The Company considers the nature and contractual terms of collaborative arrangements and assesses whether the arrangement (or any part of the arrangement) involves joint operating activities pursuant to which the Company is an active participant in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. The Company also considered whether the relationship with the counterparty to the arrangement is more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers*. If the Company is an active participant, is exposed to significant risks and rewards with respect to the arrangement, and the counterparty is not a customer, the Company accounts for the arrangement as a collaboration under ASC 808.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

Research and Development Costs

All research and development costs are expensed as incurred in accordance with ASC 730, *Research and Development*, which primarily consist of salaries and benefits associated with research and development personnel, overhead and occupancy costs, contract services costs and license costs for technology used in research and development without alternative future uses.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses in the statements of operations and comprehensive loss and expensed as incurred as recoverability of such expenditures is uncertain.

Stock-Based Compensation

The cost of a stock-based award is measured at the grant date based on the estimated fair value of the award, and is recognized as expense on a straight-line basis over the requisite service period of the award. Forfeitures of awards are recognized as they occur. The fair value of stock options is estimated using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including the fair value of the underlying Class B common stock, expected volatility, expected term, risk-free interest rate, and expected dividend yield. As the Company's stock has never been publicly traded, the expected volatility was derived from the average historical volatilities of several comparable public companies within the Company's industry over a period equivalent to the expected term of the stock-based awards. Due to the lack of historical exercise history, the expected term of the Company's stock options is determined using the "simplified" method. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. treasury notes with maturities approximately equal to expected term of the stock options. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The fair value of Class B common stock underlying the Company's stock options was estimated by the Board, which considered, among other things, valuations of the Company's common stock.

Compensation expense for non-employee awards is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally the vesting period of the respective award.

The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders, including unrealized gains and losses on marketable securities. For the year ended December 31, 2022, there was no difference between net loss and comprehensive loss. For the year ended December 31, 2023, the unrealized gain on short-term investments, approximately \$0.1 million, was recorded in other comprehensive income.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

Net Loss Per Share

The holders of Class A common stock, Class B common stock and Class C common stock participate in earnings and losses equally on a per share basis, as if all shares of common stock were of a single class. Therefore, undistributed earnings and losses are allocated on a proportionate basis and the resulting loss per share will be the same for Class A common stock, Class B common stock, and Class C common stock on an individual or combined basis.

The Company's liability classified warrants to purchase Series C preferred stock and Class B common stock are exercisable to the holder at an exercise price of \$0.01. The Company does not consider the exercise price of these warrants to be for a nominal amount of consideration as in addition to the exercise price received from the holder, the consideration received as a result of the exercise of a warrant also includes the value of the extinguishment of the associated warrant liabilities. Therefore, the Company does not consider the warrants to be contingently issuable shares and does not include the warrants in the calculation of weighted-average common shares outstanding in the computation of basic loss per share.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in any dividends declared. Therefore, convertible preferred shares are considered to be participating securities. The Company's warrants to purchase shares of Series C Preferred Stock and Class B common stock contractually require the Board to provide advanced notice to warrant holders in the event that a dividend will be declared. As a result, warrant holders would be economically compelled to exercise their warrants prior to the declaration of the dividend. Therefore, the warrants are considered to be participating securities. During periods in which the Company reports net income, the Company allocates a proportional share of net income to participating securities determined by dividing the total weighted-average participating securities by the sum of the total weighted-average common shares and participating securities (the "two-class method"). Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods where the Company reports a net loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in losses.

Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial statements and tax basis of assets and liabilities. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income. To the extent the Company believes that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, respectively, in the period such determination is made.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS*****Recently Adopted Accounting Pronouncements***

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Updates (“ASU”) No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”), and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively, “Topic 326”). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. For public entities that are SEC filers, excluding entities eligible to be emerging growth companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for emerging growth companies to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted Topic 326 on January 1, 2023 and the adoption of this guidance did not have a material impact on the Company’s financial statements.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (“ASU 2023-09”). ASU 2023-09 is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in this ASU address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The amendments in the ASU are effective for fiscal years beginning after December 15, 2024, on a prospective basis. Early adoption is permitted. The Company is currently evaluating the potential effects of adopting the provisions of ASU No. 2023-09.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (“ASU No. 2023-07”). ASU 2023-07 requires that an entity disclose significant segment expenses, a description of “other segment items,” and the title and position of the chief operating decision maker along with an explanation of how the reported segment profit or loss is assessed and allocated. The amendments in the ASU are effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The amendments in this ASU will be applied retrospectively for all prior periods presented in the financial statements. The Company is currently evaluating the potential effects of adopting the provisions of ASU No. 2023-07.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40)*. The standard addresses issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The standard reduces the number of accounting models for convertible debt instruments and convertible preferred stock resulting in fewer embedded conversion features being separately recognized from the host contract. The standard is effective for public companies, excluding entities eligible to be smaller reporting companies, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The FASB specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The Company is currently evaluating the potential effects of adopting the provisions of ASU No. 2020-06 using the modified retrospective adoption method.

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS****3. Revenue*****Net Sales***

The Company disaggregates its revenue from contracts with customers by sales channel as management believes these categories depict how the nature, amount, and timing of revenues and cash flows are affected by economic factors. Revenues are generated through the durable medical equipment (“DME”) channel and the pharmacy benefit plan (“PBP”) channel. The following table summarizes the Company’s disaggregated revenues:

	Year Ended December 31, 2023 (in thousands)
DME channel	\$ 11,260
PBP channel	735
Total net sales	<u>\$ 11,995</u>

In the year ended December 31, 2023 the Company’s revenues were derived from sales of the iLet and single-use products that are used together with the iLet, including cartridges for storing and delivering insulin, and infusion sets that connect the iLet to a user’s body. The Company’s primary customers are distributors and pharmacies who sell these products to insulin-requiring PWD. For the year ended December 31, 2023, the majority of the Company’s sales were through the DME channel. The Company recognizes revenue at a point in time once control has transferred to the customer, as well as over time for performance obligations that may include an obligation to provide ongoing services such as unspecified software updates. During the year ended December 31, 2022, the Company recognized no revenue from contracts with customers.

At December 31, 2023, \$0.3 million was allocated to performance obligations that were not yet satisfied and is recorded in deferred revenue on the balance sheet. Of the performance obligations not yet satisfied, \$0.1 million is expected to be recognized as revenue in the next 12 months, with the remainder expected to be recognized thereafter. The \$0.3 million relates to amounts deferred associated with the unspecified software updates promised to users and the user’s access to the mobile application.

Collaboration Revenue

Prior to FDA 510(k) clearance on May 19, 2023, the Company’s source of revenue was from research, clinical and collaboration agreements with various academic, pharmaceutical and biotechnology companies.

The Company entered into an agreement with Novo Nordisk (the “Novo Collaboration Agreement”) in September 2017 and concluded that its relationship with Novo Nordisk does not represent a customer relationship. The purpose of the collaboration agreement is to produce clinical data using Novo Nordisk’s fast-acting insulin to support its compatibility and integration with the iLet. Under the terms of the original agreement, the Company was eligible to receive potential payments based on the achievement of certain milestones. The contract was amended in December 2019, February 2021 and April 2021 resulting in additional potential payments to be received and an extension of certain milestone achievement dates.

Based on the nature of the agreement, the Company recognized collaboration revenue ratably over the estimated period of performance. The work described under the agreement was completed in 2022 and as of December 31, 2022, and 2023 no amounts were due as accounts receivable. Further, \$0.2 million and \$0 of revenue was recognized related to the Novo Collaboration Agreement during the years ended December 31, 2022 and 2023, respectively.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

4. Financial Instruments and Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis:

Assets	Fair Value Measurements at December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market fund	\$24,651	\$ —	\$ —	\$ 24,651
Restricted cash:				
Money market fund	100	—	—	100
Total assets	<u>\$24,751</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 24,751</u>
Liabilities				
Series C warrant liabilities	\$ —	\$ —	\$10,497	\$ 10,497
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$10,497</u>	<u>\$ 10,497</u>

Assets	Fair Value Measurements at December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Cash equivalents:				
Money market fund	\$24,414	\$ —	\$ —	\$ 24,414
Restricted cash:				
Money market fund	100	—	—	100
Short-term investments				
U.S. Treasury bills	70,179	—	—	70,179
Total assets	<u>\$94,693</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 94,693</u>
Liabilities				
Series C warrant liabilities	\$ —	\$ —	\$ 9,447	\$ 9,447
Common B warrant liabilities	—	—	28,126	28,126
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$37,573</u>	<u>\$ 37,573</u>

Money market funds and U.S. Treasury bills were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no changes to the valuation methods during the years ended December 31, 2022 and 2023. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1 or Level 2 during the years ended December 31, 2022 and 2023.

Warrant Liabilities

In connection with the August 2023 Series D Preferred Stock financing (see Note 11), the Company granted warrants to purchase up to 8,474,983 shares of Common B common stock equal to 70% of the shares of Series D Preferred Stock purchased by the purchaser at an exercise price of \$0.01 per share and expire on the earliest to occur of (i) August 28, 2033, (ii) immediately prior to the sale of the Company or a transaction that qualifies as a Deemed Liquidation Event (as defined in the Company's certificate of incorporation) or

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS**

(iii) immediately prior to the consummation of a qualifying initial public offering or a SPAC Transaction (as defined in the Company's certificate of incorporation). The Common B warrants have been recorded as a liability as they represent freestanding financial instruments that are not indexed to the Company's common stock and are required to be remeasured to fair value at each reporting date. Additionally, the Common B warrants do not meet the definition of a derivative.

In connection with the February 2022 Series C Preferred Stock financing (see Note 11), the Company granted warrants to purchase up to 1,025,390 shares of Series C Preferred Stock at a price per share equal to \$0.01 and with a term ending on the earliest to occur of (i) February 16, 2032, (ii) immediately prior to the sale of the Company or a transaction that qualifies as a Deemed Liquidation Event or (iii) immediately prior to the consummation of a qualifying initial public offering or a SPAC transaction. As the warrants are exercisable for preferred stock that is contingently redeemable outside of the Company's control, the warrants have been recorded as a liability and are required to be remeasured to fair value at each reporting date.

As there are significant inputs that are not observable in the market, the warrant valuations represent a Level 3 measurement within the fair value hierarchy. The Company's valuations of the preferred stock and Common B warrants utilized the Black-Scholes option pricing model, which incorporates assumptions and estimates to value the preferred stock and Common B warrant.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock and common stock warrant liabilities include the fair value per share of the underlying stock, expected volatility of the price of the underlying stock, the remaining contractual term of the warrant, risk-free interest rate, and expected dividend yield. The most significant assumption in the Black-Scholes option pricing model impacting the fair value of the preferred stock and common stock warrant liabilities is the fair value of the Company's Series C Preferred Stock and Class B common stock as of each remeasurement date. The Company determines the fair value per share of the underlying preferred stock by taking into consideration its most recent sales of its convertible preferred stock. Further, the Board values the Company's Class B common stock taking into consideration the most recent sales of the Company's preferred stock, results obtained from third-party valuations and additional factors the Company deems relevant and which may have changed since the date of the most recent valuation through the effective date of the warrant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates the expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

The following table presents the assumptions used in the Black-Scholes option pricing model to determine the fair value of the preferred stock warrant liabilities as of December 31, 2022 and 2023:

	December 31,	
	2022	2023
Fair value of Series C Preferred Stock	\$10.23	\$ 9.22
Strike price	\$ 0.01	\$ 0.01
Risk-free interest rate	4.40%	4.69%
Expected term (in years)	2.30	1.30
Expected volatility	87.00%	78.00%
Expected dividend yield	0%	0%

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

The following table presents the assumptions used in the Black-Scholes option pricing model to determine the fair value of the common stock warrant liabilities as of the date of issuance and as of December 31, 2023:

	August 28, 2023	December 31, 2023
Fair value of Class B common stock	\$ 2.64	\$ 4.32
Strike price	\$ 0.01	\$ 0.01
Risk-free interest rate	4.20%	3.88%
Expected term (in years)	10	9.70
Expected volatility	72.69%	74.64%
Expected dividend yield	0%	0%

The Company did not have any common stock warrant liabilities as of December 31, 2022.

The Company recognizes changes in the fair value of the warrant liabilities as a component of other income (expense), net in its statements of operations and comprehensive loss. The Company will continue to recognize changes in the fair value of the warrant liabilities until the warrants are exercised, expire, or qualify for equity classification.

A reconciliation of the Level 3 warrant liabilities is as follows:

	Series C Warrant Liability (in thousands)
Balance at December 31, 2021	\$ —
Issuance of Series C preferred stock warrants	11,408
Change in fair value	(911)
Balance at December 31, 2022	10,497
Change in fair value	(1,050)
Balance at December 31, 2023	<u>\$ 9,447</u>

	Common B Warrant Liability (in thousands)
Balance at December 31, 2022	\$ —
Issuance of Common B warrants in connection with Series D preferred stock	22,321
Common B warrant exercises	(5,203)
Change in fair value	11,008
Balance at December 31, 2023	<u>\$ 28,126</u>

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

5. Short-Term Investments

The following represents a summary of the estimated fair value of short-term investments at December 31, 2023:

	At December 31, 2023			Estimated Fair Value
	Amortized Cost	Unrealized Gains	Unrealized Losses	
	(in thousands)			
Short-term investments				
U.S. Treasury bills	\$ 70,042	\$ 137	\$ —	\$ 70,179
Total	<u>\$ 70,042</u>	<u>\$ 137</u>	<u>\$ —</u>	<u>\$ 70,179</u>

The Company did not have short-term investments at December 31, 2022.

6. Accounts Receivable, Net

Accounts receivable, net consisted of the following:

	December 31, 2023 (in thousands)
Accounts receivable	\$ 4,494
Less: allowance for credit losses	(46)
Accounts receivable, net	<u>\$ 4,448</u>

The following table provides a reconciliation of the changes in the allowance for estimated credit losses for the year ended December 31, 2023:

	Year Ended December 31, 2023 (in thousands)
Balance at beginning of period	\$ —
Provision for expected credit losses	46
Write-offs and adjustments, net of recoveries	—
Balance at end of period	<u>\$ 46</u>

The Company did not have accounts receivable, net or an allowance for credit losses at December 31, 2022.

BETA BIONICS, INC.

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7. Inventories

Inventories consisted of the following:

	December 31, 2023 (in thousands)
Raw materials	\$ 803
Work in process	34
Finished goods	408
Inventories	<u>\$ 1,245</u>

The Company did not have inventories at December 31, 2022.

8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2022	2023 (in thousands)
Prepaid expenses	\$ 542	\$ 908
Other current assets	250	275
Prepaid expenses and other current assets	<u>\$ 792</u>	<u>\$ 1,183</u>

9. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31, 2022	2023 (in thousands)
Manufacturing equipment	\$ 4,008	\$ 4,386
Leasehold improvements	951	951
Furniture	924	924
Computer equipment	628	468
Construction in progress	182	167
Total cost	6,693	6,896
Less: Accumulated depreciation and amortization	(3,374)	(4,420)
Property and equipment, net	<u>\$ 3,319</u>	<u>\$ 2,476</u>

Depreciation and amortization expense for the years ended December 31, 2022 and 2023 was \$1.3 million and \$1.2 million, respectively.

BETA BIONICS, INC.

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10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2022	2023
	(in thousands)	
Accrued employee compensation and benefits	\$5,381	\$5,475
Accrued professional fees	762	963
Accrued sales returns, rebates and patient assistance	—	592
Accrued inventory in transit	—	342
Accrued royalties	—	294
Other current liabilities	184	462
Accrued expenses and other current liabilities	<u>\$6,327</u>	<u>\$8,128</u>

Reconciliations of the changes in the Company's product warranty liability, which is included in other current liabilities, were as follows:

	Year Ended December 31, 2023
	(in thousands)
Product warranty liability at beginning of year	\$ —
Warranty expense	84
Changes in estimates	—
Warranty fulfillment	(62)
Product warranty liability at end of year	<u>\$ 22</u>

The Company did not have product warranty liability as of December 31, 2022 or during the year ended December 31, 2022.

11. Convertible Preferred Stock and Warrants

The Company has issued Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock and Series D Preferred Stock (collectively, the "Preferred Stock").

Upon issuance of each class of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each class of Preferred Stock.

In August 2023, the Company issued and sold 12,107,140 shares of Series D Preferred Stock, at a price of \$8.40 per share, for gross proceeds of \$101.7 million. The Company incurred issuance costs in connection with this transaction of \$0.7 million. Each purchaser of the Series D Preferred Stock also received warrants to purchase up to a certain number of shares of Class B common stock equal to 70% of the shares of Series D Preferred Stock purchased by the purchaser. The Common B warrants are exercisable at any time, at an exercise

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

price of \$0.01 per share (subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization) and expire on the earliest to occur of (i) August 28, 2033, (ii) immediately prior to the sale of the Company or a transaction that qualifies as a Deemed Liquidation Event as described below or (iii) immediately prior to the consummation of a qualifying initial public offering or a SPAC transaction. During the year ended December 31, 2023, a total of 1,954,161 of the Common B warrants were exercised. The Series D Preferred Stock has an Original Issue Price and Conversion Price (each as defined in the Company's certificate of incorporation) per share of \$8.40.

In February 2022, the Company issued and sold 4,101,860 shares of Series C Preferred Stock, at a price of \$13.91 per share, for gross proceeds of \$57.0 million. The Company incurred issuance costs in connection with this transaction of \$0.7 million. Each purchaser of the Series C Preferred Stock also received a warrant to purchase additional shares of Series C Preferred Stock equal to 25% of the shares of Series C Preferred Stock purchased by the purchaser, which in the aggregate permits the purchase of up to 1,025,390 shares of Series C Preferred Stock (the "Series C Warrants"). The Series C Warrants are exercisable at any time, at an exercise price of \$0.01 per share (subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization) and expire on the earliest to occur of (i) February 16, 2032, (ii) immediately prior to the sale of the Company or a transaction that qualifies as a Deemed Liquidation Event as described below or (iii) immediately prior to the consummation of a qualifying initial public offering or a SPAC transaction. The Series C Preferred Stock has an Original Issue Price and Conversion Price per share of \$13.90.

As part of the Series D Preferred Stock issuance, the Company increased the number of shares of Class B common stock authorized for issuance from 38,000,000 shares to 65,000,000 shares and increased the number of shares of preferred stock authorized for issuance from 15,200,000 shares to 26,434,390 shares, of which 12,107,140 shares were designated as Series D Preferred Stock.

At the balance sheet dates, Preferred Stock consisted of the following:

	December 31, 2022				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value (in thousands)	Liquidation Preference (in thousands)	Common Stock Issuable Upon Conversion
Series A Preferred Stock	500,000	500,000	\$ 6,589	\$ 5,000	500,000
Series A-2 Preferred Stock	500,000	500,000	6,626	5,000	500,000
Series B Preferred Stock	4,200,000	4,197,930	61,606	63,053	4,398,610
Series B-2 Preferred Stock	4,500,000	3,960,000	63,228	63,360	4,184,470
Series C Preferred Stock	5,500,000	4,101,860	44,985	57,049	4,101,860
	<u>15,200,000</u>	<u>13,259,790</u>	<u>\$ 183,034</u>	<u>\$ 193,462</u>	<u>13,684,940</u>

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	December 31, 2023				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value (in thousands)	Liquidation Preference (in thousands)	Common Stock Issuable Upon Conversion
Series A Preferred Stock	500,000	500,000	\$ 6,589	\$ 5,000	624,571
Series A-2 Preferred Stock	500,000	500,000	6,626	5,000	624,571
Series B Preferred Stock	4,200,000	4,197,930	61,606	63,053	5,931,111
Series B-2 Preferred Stock	4,000,000	3,960,000	63,228	63,360	5,697,891
Series C Preferred Stock	5,127,250	4,101,860	44,985	57,049	5,499,867
Series D Preferred Stock	12,107,140	12,107,140	78,679	101,700	12,107,140
	<u>26,434,390</u>	<u>25,366,930</u>	<u>\$ 261,713</u>	<u>\$ 295,162</u>	<u>30,485,151</u>

The holders of Preferred Stock have the following rights, preferences and privileges:

Voting

The holders of the Preferred Stock are entitled to vote, together with the holders of Class A common stock and Class B common stock as a single class, on all matters submitted to stockholders for a vote. Each holder of Preferred Stock is entitled to the number of votes equal to the number of shares of Class B common stock into which each share of Preferred Stock is convertible as of the record date for determining stockholders entitled to vote on such matters. The holders of Class C common stock do not have voting rights. The holders of record of the Series D Preferred shares are entitled to elect five members of the Board jointly designated from time to time by the holders of a majority of the outstanding shares of Series D Preferred Stock, exclusively and voting as a separate series, (i) one of whom shall be designated by Sands Capital Life Sciences Pulse Fund II, L.P. and its affiliates, (ii) one of whom shall be designated by Omega Fund VII, L.P. and its affiliates; (iii) one of whom shall be designated by Soleus Private Equity Fund II, L.P. and its affiliates; (iv) one of whom shall be designated by Eventide Gilead Fund and Eventide Healthcare & Life Sciences Fund and affiliates of the foregoing; and (v) one of whom shall be designated by Zone Healthcare Holdings, LLC and its affiliates. The holders of record of the shares of Series C Preferred Stock, exclusively and as a separate class, shall be entitled to elect one director of the Company. The holders of record of the shares of Series B Preferred Stock and Series B-2 Preferred Stock, voting together as a single class, on an as-converted basis, shall be entitled to elect one director of the Company. The holders of record of the shares of Class A common stock, exclusively and as a separate class, shall be entitled to elect one director of the Company.

The CEO shall also serve as a director.

Conversion

Each series of Preferred Stock will automatically convert into shares of Class B common stock at the then applicable conversion rate in the event of (i) the closing of the sale of common stock to the public at a price per share equal to at least \$7.41177 (subject to adjustments for stock dividends, splits, combinations and similar events) and gross proceeds to the Company of not less than \$75.0 million (a "Qualified IPO"); (ii) the closing of a Qualified SPAC Transaction; or (iii) upon the written consent of the Requisite Holders. The conversion ratio of each series of Preferred Stock is determined by dividing the Original Issue Price of each series by the Conversion Price of each series. The Original Issue Price is \$10.00 per share for Series A Preferred Stock, \$10.00 per share for Series A-2 Preferred Stock, \$15.02 per share for Series B Preferred Stock, \$16.00 per share for Series B-2 Preferred Stock, \$13.90 per share for share for Series C Preferred Stock and \$8.40 per share for Series D Preferred Stock. The Conversion Price is \$8.0055 per share for Series A Preferred Stock, \$8.0055 per share for

BETA BIONICS, INC.

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Series A-2 Preferred Stock, \$10.63084 per share for Series B Preferred Stock, \$11.11989 per share for Series B-2 Preferred Stock, \$10.37275 per share for Series C Preferred Stock and \$4.94118 per share for Series D Preferred Stock, each subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization and other adjustments as set forth in the Company's certificate of incorporation.

In the event the Company at any time after the Series B-2 Preferred Stock original issuance date issues additional shares of common stock without consideration or for a consideration per share less than the applicable Conversion Price of each series in effect immediately prior to such issuance, the applicable Conversion Price of each series of Preferred Stock will be reduced, concurrently with such issue, to the appropriate price that will effectuate anti-dilution of existing holders of Preferred Stock.

The Series D Preferred Stock issuance triggered down round protection for existing holders of the Preferred Stock, as set forth in the Company's certificate of incorporation. As a result, as of December 31, 2023, each outstanding share of Series A Preferred Stock and Series A-2 Preferred Stock was convertible into Class B common stock on a 1.24914:1 basis, each outstanding share of Series B Preferred Stock was convertible into Class B common stock on a 1.41287:1 basis, each outstanding share of Series B-2 Preferred Stock was convertible into Class B common stock on a 1.43886:1 basis and each outstanding share of Series C Preferred Stock was convertible into Class B common stock on a 1.34082:1 basis. In connection with the triggering of the down round protections for existing holders of Preferred Stock, the Company evaluated the redemption features of the Preferred Stock, which becomes redeemable in the event of a Deemed Liquidation Event (as described below). As of December 31, 2023, the Deemed Liquidation Event was not probable and no remeasurement of the redemption price was recognized.

Dividends

The holders of shares of Series D Preferred Stock, Series A Preferred Stock and Series A-2 Preferred Stock are entitled to receive, when, as and if declared by the Board on a *pari passu* basis, non-cumulative cash dividends of 4% per annum of each respective Original Issue Price, and the holders of Series B Preferred Stock, B-2 Preferred Stock and Series C Preferred Stock are entitled to receive, when, as and if declared by the Board on a *pari passu* basis, non-cumulative cash dividends of 2% per annum of each respective Original Issue Price (the Annual Dividend, for each respective series).

The Company shall not declare, pay or set aside any dividends on shares of any other class or series of stock of the Company unless the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to the greater of: (i) in the case of a dividend on common stock or any class or series of stock that is convertible into common stock, a dividend per share of Preferred Stock that would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of a share of Preferred Stock; or (ii) in the case of a dividend on any class or series of stock that is not convertible into common stock, at a rate per share of Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of stock by the Original Issue Price of such class or series of stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the Original Issue Price of such class or series. If the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of stock of the Company, the dividend payable to the holders of the Preferred Stock will be calculated based upon the dividend on the class or series of stock that would result in the highest Preferred Stock dividend.

BETA BIONICS, INC.

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Through December 31, 2023, no dividends had been declared on any series or class of shares.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company or Deemed Liquidation Event (as described below), the holders of shares of Series D Preferred Stock are entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payments are made to the holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock. The holders of shares of Series D Preferred Stock are entitled to an amount per share equal to the greater of (i) the Original Issue Price per share of the Series D Preferred Stock, plus any dividends declared but unpaid thereon, or (ii) the amount that would have been payable had all shares of Series D Preferred Stock been converted to common stock immediately prior to the liquidation, dissolution, winding-up or Deemed Liquidation Event. If upon any such liquidation event, the assets of the Company available for distribution are insufficient to pay the holders of the Series D Preferred Stock the full amount to which they are entitled, the holders of Series D Preferred Stock will share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would be otherwise payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares of Series D Preferred Stock were paid in full.

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company or Deemed Liquidation Event (as described below), after the payment in full to the holders of shares of the Series D Preferred Stock, the holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock are entitled to be paid out of the assets of the Company available for distribution to its stockholders *pari passu* before any payments are made to holders of the common stock. The holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock are entitled to an amount per share equal to the greater of (i) the applicable Original Issue Price per share of each respective share of Preferred Stock, plus any dividends declared but unpaid thereon, or (ii) the amount that would have been payable had all shares of the series been converted to common stock immediately prior to the liquidation, dissolution, winding-up or Deemed Liquidation Event. If upon any such liquidation event, the assets of the Company available for distribution are insufficient to pay the holders of Preferred Stock the full amount to which they are entitled, the holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock will share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would be otherwise payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Unless both (i) the holders of at least a majority of the outstanding shares of Series D Preferred Stock, voting as a separate class, which majority shall include at least one of the “Lead Investors” and (ii) the holders of at least a majority of the outstanding shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock Series B-2 Preferred Stock and Series C Preferred Stock, voting together as a single class on an as-converted basis, elect otherwise, a Deemed Liquidation Event shall include a merger, consolidation, or share exchange (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

12. Common Stock

The voting, dividend and liquidation rights of the holders of the Company’s common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above.

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS**

The Company was issued a certificate of incorporation in connection with its conversion from a Massachusetts benefit corporation to a Delaware corporation. Per the certificate of incorporation, the holders of Class A common stock and Class B common stock are entitled to one vote for each share of Class A common stock and Class B common stock held.

Per the certificate of incorporation, the events requiring the automatic conversion of all shares of outstanding preferred stock into Class B common stock are defined as (i) the closing of a firm-commitment underwritten public offering of common stock at a price of at least \$7.41177 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization), resulting in at least \$75.0 million of gross proceeds to the Company, (ii) the closing of a qualifying SPAC transaction or (iii) the vote or written consent of the holders of at least a majority of the then-outstanding shares of Preferred Stock, voting together as a single class on an as-converted basis.

The holders of Class C common stock do not have voting rights.

Class B common stock reserved for the potential conversion of shares of Preferred Stock into common stock and the exercise of outstanding and available for grant stock options consisted of the following:

	December 31, 2023
Convertible preferred stock	30,485,151
Common stock options granted and outstanding	10,249,904
Shares available for issuance under the 2016 Stock Incentive Plan	1,643,800
Total common stock reserved for future issuance	42,378,855

In connection with its conversion from a Massachusetts benefit corporation to a Delaware corporation, the Company also amended and restated its 2016 Stock Incentive Plan (see Note 13). As amended, the number of shares of Class B common stock reserved for the exercise of outstanding and available-for-grant stock options increased by 252,250 shares, from 11,893,704 to 12,145,954.

13. Stock-Based Compensation***2016 Stock Incentive Plan***

The Company's 2016 Stock Incentive Plan, as amended (the "2016 Plan"), provides for the Company to grant stock options and restricted stock awards to employees, officers, directors and consultants of the Company. The 2016 Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated.

The Company grants equity classified stock options for the purchase of Class B common stock. Stock options granted under the 2016 Plan with service-based vesting conditions typically vest over four years based on continuous service and expire after ten years. The total number of shares of Class B common stock that may be issued under the 2016 Plan was 12,145,954 shares as of December 31, 2023, of which 1,643,800 shares remained available for future issuance as of December 31, 2023. Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future grant under the 2016 Plan.

The exercise price for stock options granted may not be less than the fair value of Class B common stock as determined by the Board as of the date of grant. The Board values the Company's Class B common stock taking into consideration the most recent sales of the Company's preferred stock, results obtained from

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contemporaneous third-party valuations and additional factors the Company deems relevant and which may have changed since the date of the most recent valuation through the date of grant.

Stock Option Cancellation and Regrant

On March 2, 2023, and in accordance with the terms of the Company's 2016 Plan, the Board approved a stock option cancel and regrant (the "2023 Cancel and Regrant"), wherein 4,478,020 previously granted stock options to acquire shares of the Company's common stock that were issued from December 2019 through December 2022 to 85 grantees were canceled and regrant at the price of the Company's common stock valuation on March 2, 2023. As of that date, the Company's common stock fair value was \$3.805 per share. Aside from the reduced strike price, all regrant options kept the same terms and conditions of the canceled stock options, including vested amounts and vesting schedules. Upon the cancel and regrant, the Company recognized additional stock-based compensation from vested options of \$0.4 million and a total of \$0.4 million as unvested options continued to vest during the year ended December 31, 2023. The Company will recognize an additional \$1.1 million stock-based compensation expense from the date of the modification through the third quarter of 2027, based on the requisite service period, as the remaining unvested options continue to vest.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option pricing model to determine the grant-date fair value of stock options granted:

	Year Ended December 31,	
	2022	2023
Fair value of common stock	\$ 3.81	\$ 4.32
Risk-free interest rate	2.96%	3.06%
Expected term (in years)	6.01	5.39
Expected volatility	79.40%	75.12%
Expected dividend yield	0%	0%

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	6,732,850	\$ 6.40	7.4	\$ 1,870
Granted	8,661,383	3.27		
Exercised	(2,410)	3.96		
Forfeited or cancelled	(5,141,919)	7.08		
Outstanding at December 31, 2023	10,249,904	\$ 3.41	8.1	\$ 535
Vested and expected to vest at December 31, 2023	10,249,904	\$ 3.41	8.1	\$ 535
Options exercisable at December 31, 2023	4,095,302	\$ 3.92	6.4	\$ 525

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Class B common stock for those stock options that had exercise prices lower than the fair value of the Company's Class B common stock. The total intrinsic value of options exercised ended December 31, 2022 and 2023, was \$1.5 million and \$0, respectively.

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The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2022 and 2023 was \$2.73 per share and \$2.16 per share, respectively. The total fair value of shares vested during the years ended December 31, 2022 and 2023 was \$3.2 million and \$2.5 million, respectively.

The following table summarizes the non-vested stock options that were outstanding as of December 31, 2022 and 2023:

	Number of Options	Weighted- Average Exercise Price
Non-vested options, December 31, 2022	3,432,110	\$ 7.67
Non-vested options, December 31, 2023	6,154,602	\$ 3.07

Stock-Based Compensation Expense

Stock-based compensation expense related to the stock options was included in the Company's statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2022	2023
	(in thousands)	
Cost of sales	\$ —	\$ 239
Research and development	1,554	1,781
Sales and marketing	384	610
General and administrative	4,162	3,028
Total stock-based compensation expense	<u>\$6,100</u>	<u>\$5,658</u>

For the year ended December 31, 2022, stock-based compensation expense included \$1.1 million related to the modification of stock options held by two executives in connection with separation agreements, included in general and administrative expense.

As of December 31, 2023, total unrecognized stock-based compensation expense related to the unvested stock-based awards was \$13.8 million, which is expected to be recognized over a weighted-average period of 3.1 years.

14. Employee Benefit Plan

The Company maintains a 401(k) retirement plan (the "401(k) Plan") for the benefit of eligible employees. Each participant may elect to contribute up to 100% of his or her compensation to the 401(k) Plan each year, subject to certain Internal Revenue Service limitations. Under the terms of the Plan, the Company matches 100% of the first 6% of employee contributions. During the years ended December 31, 2022 and 2023, the Company contributed \$1.1 million and \$1.2 million, respectively, to the 401(k) Plan.

15. Income Taxes

During the years ended December 31, 2022 and 2023, the Company did not record income tax benefits for the net operating losses ("NOLs") incurred or for the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those items. The Company does not have any foreign operations and therefore has not provided for any foreign income taxes.

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A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2023
Federal statutory income tax rate	21.0%	21.0%
State income tax, net of federal benefit	0.7%	2.2%
Federal and state research and development tax credits	1.6%	2.1%
Change in fair value of warrant liabilities	— %	(4.8)%
Stock-based compensation	— %	(1.1)%
Non-deductible items	(0.1)%	(0.1)%
State rate change	— %	1.3%
Uncertain tax positions	— %	(2.2)%
Other	0.3%	0.4%
Change in deferred tax asset valuation allowance	(23.5)%	(18.8)%
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

The Company's net deferred tax assets consisted of the following:

	December 31,	
	2022	2023
	(in thousands)	
Deferred tax assets:		
NOL carryforwards	\$ 30,592	\$ 35,419
Capitalized research and development expenditures	6,099	8,281
Research and development tax credit carryforwards	4,192	4,148
Stock-based compensation	1,786	2,735
Operating lease liabilities	899	1,007
Accruals and other temporary differences	863	1,256
Total deferred tax assets	44,431	52,846
Valuation allowance	(43,632)	(51,903)
Deferred tax assets	799	943
Deferred tax liabilities:		
Depreciation and intangibles	(27)	—
Operating lease right-of-use asset	(772)	(888)
Other	—	(55)
Total deferred tax liabilities	(799)	(943)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2023, the Company had U.S. federal NOL carryforwards of \$158.3 million, which may be available to reduce future taxable income, of which \$11.5 million expire at various dates beginning in 2035 while the remaining \$146.8 million do not expire but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2023, the Company had state NOL carryforwards of \$33.9 million, which may be available to reduce future taxable income, of which \$31.9 million expire at various dates beginning in 2029, while \$2.0 million do not expire. As of December 31, 2023, the Company also had U.S. federal and state research and development tax credit carryforwards of \$3.0 million and

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS**

\$2.7 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2032, respectively, with \$2.3 million of state research and development tax credits carrying forward indefinitely.

Utilization of the U.S. federal and state NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382 of the Code, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382 of the Code, at any time since inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company’s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before their utilization.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company’s history of cumulative net losses incurred since inception, results of recent commercial operations, and projected future taxable income and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2022 and 2023. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets related primarily to the increase in NOL carryforwards and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,	
	2022	2023
	(in thousands)	
Valuation allowance as of beginning of year	\$ 28,427	\$ 43,632
Increases	15,205	8,271
Valuation allowance as of end of year	<u>\$ 43,632</u>	<u>\$ 51,903</u>

As of December 31, 2022 and 2023, the Company had unrecognized tax benefits of zero and \$1.1 million, respectively, none of which would affect the effective tax rate due to the existence of the valuation allowance. The Company’s policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2022 and 2023, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company’s statements of operations and comprehensive loss. The Company does not anticipate a significant change in the balance of unrecognized tax benefits within the next 12 months.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

The changes in the Company's unrecognized tax benefits are summarized as follows:

	December 31, 2023 (in thousands)
Beginning balance	\$ —
Increases related to prior year tax positions	854
Increases related to current year tax positions	199
Ending balance	<u>\$ 1,053</u>

The Company files income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. As of December 31, 2022 and 2023, there were no pending tax examinations. The Company is open to future tax examination under statute by the U.S. Internal Revenue Service from 2020 to present and by most state tax authorities from 2019 to present. However, to the extent allowed by law, the taxing authorities may have the right to examine periods where NOLs and research and development credits were generated and carried forward and make adjustments to the amount of the NOL and research credits carryforwards.

16. Net Loss Per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities.

Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding, including all potentially dilutive common shares. The impact of all potentially dilutive shares which are anti-dilutive are excluded from the calculation of net loss per share. Potentially dilutive common stock equivalents are comprised of convertible preferred stock, calculated using the if-converted method, stock options to purchase Class B common stock, warrants to purchase Series C Preferred Stock and warrants to purchase Class B common stock, each calculated using the treasury stock method. Potentially dilutive securities not included in the calculation of diluted net loss per share, are as follows (in common stock equivalent shares):

	Year Ended December 31,	
	2022	2023
Convertible preferred stock (as converted into shares of Class B common stock)	13,684,940	30,485,151
Stock options to purchase Class B common stock	6,732,850	10,249,904
Warrants to purchase Series C convertible preferred stock	1,025,390	1,374,866
Warrants to purchase Class B common stock	—	6,520,822
Total	<u>21,443,180</u>	<u>48,630,743</u>

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

The following table sets forth the computation of basic and diluted net loss per share attributable to Class A, Class B and Class C common stockholders:

	Year Ended December 31,	
	2022	2023
	(in thousands, except share and per share data)	
Numerator:		
Net loss attributable to Class A, Class B and Class C common stockholders, basic and diluted	\$ (64,751)	\$ (44,099)
Denominator:		
Weighted-average Class A common stock outstanding, basic and diluted	5,904,767	5,890,000
Weighted-average Class B common stock outstanding, basic and diluted	3,843,445	4,461,907
Weighted-average Class C common stock outstanding, basic and diluted	96,910	96,910
Weighted-average Class A, Class B, Class C common stock outstanding, basic and diluted	9,845,122	10,448,817
Net loss per share attributable to Class A, Class B and Class C common stockholders, basic and diluted	\$ (6.58)	\$ (4.22)

17. Leases

In May and November 2023, the Company entered into two separate lease agreements for approximately 8,500 total square feet of office space in San Diego, California, which expire in July 2025 and February 2027. The larger of the two leases has one option to extend the lease term for an additional five years. The option to extend the lease term was not included in the right-of-use asset and lease liability as it was not reasonably certain of being exercised. The Company recognized operating lease right-of-use asset and associated operating lease liability of \$1.0 million on the balance sheets in 2023.

The components of lease expense were as follows:

	Year Ended December 31,	
	2022	2023
	(in thousands)	
Operating lease cost—fixed	\$ 916	\$ 1,008
Operating lease cost—variable	143	138
Short-term lease expense	6	13
Total lease expense	\$ 1,065	\$ 1,159

Cash paid for amounts included in the measurement of operating lease liabilities was \$1.1 million for the years ended December 31, 2023. No cash payments were included in the measurement of operating lease liabilities for the year ended December 31, 2022.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

The weighted-average remaining lease term and discount rate were as follows:

	December 31, 2023
Weighted-average remaining lease term	3.2 years
Weighted-average discount rate	4.75%

Future lease payments under non-cancellable leases as of December 31, 2023 were as follows:

(in thousands) Year Ending December 31,	
2024	\$1,258
2025	1,484
2026	1,432
2027	389
Total future lease payments	4,563
Less: imputed interest	(340)
Total lease liabilities	<u>\$4,223</u>

18. Commitments and Contingencies

Research Supply Agreement

In March 2020, the Company entered into a research supply agreement with the Jaeb Center for Health Research Foundation (the “Jaeb Center”), a contract research organization, for the regulatory sponsorship and coordination of the iLet insulin-only configuration pivotal trial. The agreement was amended in May and December 2020 to include minimum purchase commitments to fund a portion of the total costs of the pivotal trial. In June 2021 and April 2022, the agreement was further amended to provide funding for the pivotal trial.

During the year ended December 31, 2022, the Company paid the Jaeb Center \$0.3 million. As of December 31, 2022, the Company did not have any remaining purchase commitments under the research supply agreement.

Separation Agreements

In August 2022, the Company terminated employment of two executives. In connection with the termination of employment, the Company extended the post-termination exercise period of all stock options. The stock-based compensation expense related to the modification of the stock options of the former executives was \$1.1 million and was recognized as general and administrative expense during the year ended December 31, 2022.

In August 2022, the Company undertook a reorganization program, including a reduction in force. The Company incurred a charge totaling \$4.2 million, representing employee severance and benefit-related costs to be paid over the next 12 months. The remaining liability for accrued severance costs under the reorganization program was \$2.1 million, which was included in accrued expenses and other current liabilities in the balance sheet as of December 31, 2022. The liability for the accrued severance costs under the reorganization program was paid in full as of December 31, 2023.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

Legal Proceedings

From time to time, the Company may become involved in various legal proceedings, including those that may arise in the ordinary course of business.

The Company believes there is no litigation pending that could have, individually, or in the aggregate, have a material adverse effect on the results of its operations, financial condition or cash flows.

19. Related Party Transactions

Boston University

Device License Agreement with Boston University

In December 2015, the Company and the Trustees of Boston University (“BU”) entered into a device license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the “Device License Agreement”). Under the Device License Agreement, the Company received a royalty-bearing license (with the right to sublicense) under certain of BU’s patent rights related to a system and individual components thereof for delivering multiple medicaments to a patient without medicament mis-channeling to make, use, sell, and import products, and practice processes covered by the licensed patent rights (collectively, the “Licensed Products and Licensed Processes”). The rights granted to the Company by BU under the Device License Agreement are exclusive, subject to certain reserved rights, including BU’s right to practice and/or use the licensed patent rights for non-profit purposes such as sponsored research and collaborations, government rights and other third party rights. Furthermore, at BU’s request, the Company will be required to negotiate a sublicense in good faith with a third party if the Company is unable or unwilling to use the patent rights licensed to the Company under the Device License Agreement to address the unmet needs of neglected people or geographic areas that such party is willing and able to address. The exclusivity may be terminated by BU if the Company fails to meet a specified percentage of the applicable minimum royalty amount for a given calendar year.

In consideration for the licensed patent rights and other rights granted to the Company under the Device License Agreement, the Company issued 2,286 shares of Class B common stock to BU, which were valued at \$0.9 million, representing a specified ownership percentage on a fully diluted basis at the time of entering into the Device License Agreement, subject to anti-dilution adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock. The Company is also required to pay (i) quarterly royalties of a mid-single-digit percentage based on net sales of all Licensed Products and Licensed Processes by the Company and its affiliates, (ii) quarterly royalties of a low double-digit percentage based on net sales by the Company’s sublicensees (in each case (i) and (ii), which royalties are creditable against the minimum royalty amount), and (iii) agreed to make quarterly lump sum payments of a low-double-digit percentage based on certain non-royalty sublicensing revenue received by the Company from its sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. The Company also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if the Company assigns the Device License Agreement in connection with the sale of all or substantially all of the Company’s assets relating to the licensed patent rights, the Company will be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment.

BETA BIONICS, INC.**NOTES TO FINANCIAL STATEMENTS***Control Algorithm License Agreement with Boston University*

In December 2015, the Company and BU entered into a control algorithm license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the “Control Algorithm Agreement”). Under the Control Algorithm Agreement, the Company received a royalty-bearing license (with the right to sublicense) to (i) make, use, sell, and import products, and practice processes, covered by certain of BU’s patent rights related to automated control systems for treatment of T1D and similar conditions, involving monitoring and/or delivering insulin, glucagon, and glucose (collectively, the “Automated Control System Technology”); and (ii) use, reproduce, prepare derivative works, perform, display, and distribute all or any part of the software, source code, object code and/or related documentation, covered by certain copyright rights, and related to (a) the Automated Control System Technology and (b) the iLet control algorithm. The licenses granted by BU to the Company pursuant to the Control Algorithm Agreement are exclusive, subject to certain reserved rights including BU, BU’s third party licensors’ and other not-for profit institutions’ rights to practice and/or use the patent rights for non-profit purposes such as sponsored research and collaborations and to permit other academic, government and not-for-profit institutions to make use of the same for educational purposes. Furthermore, at BU’s request, the Company will be required to negotiate a sublicense in good faith with a third party if the Company is unable or unwilling to use the technology licensed to the Company under the Control Algorithm Agreement to address the unmet needs of neglected people or geographic areas that such third party is willing to address. The exclusivity may be terminated by BU if the Company fails to meet a specified percentage of the applicable minimum royalty amount for a given calendar year. Additionally, under the Control Algorithm Agreement, the Company granted a perpetual, non-exclusive, royalty-free license back to BU with respect to the copyrights and patents covering any derivative works of the licensed software for BU’s educational and academic purposes and to practice their reserved rights.

In consideration for the licensed patent rights and other rights granted to the Company under the Control Algorithm Agreement, the Company issued 2,247 shares of Class B common stock to BU, representing a specified ownership percentage on a fully diluted basis at the time of entering into the license agreement, subject to anti-dilution adjustments, which have been satisfied and extinguished by the issuance of additional shares of Class B common stock to BU. The Company is also required to pay BU (i) quarterly royalties of a mid-single-digit percentage based on net sales by the Company and its affiliates, and royalties of a low double-digit percentage of net sales by sublicensees, in each case (i) and (ii), which royalties are creditable against the minimum royalty amount, and (iii) agreed to make a quarterly lump sum payments of a low double-digit percentage of the non-royalty sublicensing revenue received by the Company from the Company’s sublicensees. The foregoing payments are subject to customary increase under certain specified circumstances. The Company also granted BU board observer rights and agreed to bear the patent costs, including prior patent costs incurred by BU in respect of the licensed patent rights. Additionally, if the Company undergoes a change of control (as defined in the Control Algorithm Agreement), the Company will owe BU a one-time change of control payment of \$65,000. The Company will also be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment if the Company assigns the Control Algorithm License Agreement in connection with the sale of all or substantially all of the Company’s assets relating to the licensed patent rights and copyright.

The Company incurred \$0.5 million of royalties expense under the Control Algorithm Agreement during the year ended December 31, 2023, which was included as a component of cost of sales in the Company’s statements of operations and comprehensive loss.

Under the agreements, the Company is responsible for all costs related to the amendment, prosecution and maintenance of the licensed patent rights. During the years ended December 31, 2022 and 2023, the Company paid BU \$0.1 million and \$0.2 million, respectively, for reimbursed legal costs in connection with the agreements.

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

As of December 31, 2022 and 2023, \$0.2 million and \$0.3 million, respectively, was due to BU from the Company.

20. Subsequent Events

For the financial statements as of and for the year ended December 31, 2023, the Company evaluated subsequent events through September 13, 2024, the date on which these financial statements were issued.

Research Supply Agreement

In February 2024, the Company entered into an investigator-initiated research supply agreement (the “Supply Agreement”) with the Jaeb Center. The Company will provide products for the conduct of a clinical study in which the Jaeb Center will be the sponsor-investigator. The Jaeb Center will purchase the iLet and supplies at the contracted amount, totaling approximately \$0.7 million, over the expected twelve-month enrollment period. The Supply Agreement is effective until six months after the completion of the clinical study at all study sites.

Collaboration and License Agreement

In May 2024, the Company and Xeris Pharmaceuticals, Inc. (“Xeris”) entered into a collaboration and license agreement (“Collaboration and License Agreement”). Under the Collaboration and License Agreement, the Company received a worldwide, exclusive, royalty-bearing, sublicensable license under certain patent rights and know-how related to Xeris’ proprietary non-aqueous formulation technology and technology developed during the collaboration (“Xeris Technology”) to develop and commercialize glucagon products that are reformulated using the Xeris Technology and developed by Xeris under a development plan under the Collaboration and License Agreement for use in a pump product or system for glycemic control (“Glucagon Products”) in the field of chronic glycemic control in diabetes mellitus, excluding single-dose, one-time use form for treatment of severe hypoglycemia and diagnostic uses (“Field”). The Company also received a worldwide, exclusive, sublicensable manufacturing license under the Xeris Technology to manufacture Glucagon Products in the Field following a future manufacturing transfer date to be agreed with Xeris and subject to a separate commercial supply agreement.

In consideration for the licenses and other rights granted to the Company under the Collaboration and License Agreement, the Company paid Xeris a one-time payment of \$0.5 million and the Company will pay Xeris a one-time milestone payment of \$3.0 million upon its achievement of a certain development milestone event. In addition, the Company is required to pay Xeris tiered royalties of low double-digit percentages based on net sales of Glucagon Products by the Company or its sublicensees, subject to certain customary reductions. The Company’s obligation to pay Xeris royalties will commence, on a Glucagon Product-by-Glucagon Product and country-by-country basis, on the first commercial sale of such Glucagon Product in such country and expire on the later of (i) ten years after the first commercial sale of such Glucagon Product in such applicable country; (ii) expiration of the last valid claim of a specified patent right licensed by Xeris covering such Glucagon Product in such country; and (iii) expiration or termination or regulatory exclusivity for such Glucagon Product in the applicable country.

Through and including _____, 2025, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer’s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares

Beta Bionics

Common Stock

PROSPECTUS

BofA Securities

Piper Sandler

Leerink Partners

Stifel

Lake Street

PART II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the Financial Industry Regulatory Authority, Inc. (FINRA), filing fee and the exchange listing fee.

	Amount Paid or to Be Paid
SEC registration fee	*
FINRA filing fee	*
Exchange listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Transfer agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	<u>\$</u> *

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

As permitted by Sections 102 and 145 of the Delaware General Corporation Law, we have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our bylaws provide that:

- we may indemnify our directors, officers, employees and other agents to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;

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- we may advance expenses to our directors, officers and employees in connection with a legal proceeding, subject to limited exceptions; and
- the rights provided in our bylaws are not exclusive.

Our certificate of incorporation and our bylaws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended (Securities Act).

We have purchased and currently intend to maintain insurance on behalf of each and every person who is one of our directors or officers, within the limits and subject to the terms and conditions thereof, against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The form of underwriting agreement to be entered into in connection with this initial public offering provides for indemnification by the underwriters of us and our officers and directors who sign this registration statement for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding unregistered securities issued by us since January 1, 2021 to the date of this registration statement. Also included is the consideration received by us for such securities and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

- (1) In February 2022, we issued and sold to investors in a private placement (i) an aggregate of 410,186 shares of our Series C convertible preferred stock (Series C Preferred) in our Series C convertible preferred stock financing at a purchase price of \$139.0802 per share for aggregate cash proceeds of approximately \$57.0 million and (ii) warrants to purchase an aggregate of 102,539 shares of Series C Preferred (Series C Warrants). In August 2023, we effected a one-for-ten stock split for each outstanding share of Series C Preferred, resulting in an increase in the total number of shares of Series C Preferred sold from 410,186 to 4,101,860 and an increase in the total number of shares of Series C Preferred issuable pursuant to the exercise of Series C Warrants from 102,539 to 1,025,390.
- (2) From August to September 2023, we issued and sold to investors in a private placement (i) an aggregate of 12,107,140 shares of our Series D convertible preferred stock in our Series D convertible preferred stock financing at a purchase price of \$8.40 per share for aggregate cash proceeds of approximately \$101.7 million and (ii) warrants to purchase an aggregate of 8,474,983 shares of common stock.
- (3) From January 2021 through the date of this registration statement, we granted under our 2016 Stock Incentive Plan stock options to purchase an aggregate of shares of our common

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stock at a weighted average exercise price of \$ _____ per share. From January 2021 through the date of this registration statement, we have issued an aggregate of _____ shares of our common stock upon exercise of stock options for an approximate aggregate consideration of \$ _____ million.

The offers, sales and issuances of the securities described in paragraphs (1) and (2) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) (or Regulation D promulgated thereunder). The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was able to bear the investment's economic risk and had access to the type of information normally provided in a prospectus for a registered securities offering.

The offers, sales and issuances of the securities described in paragraph (3) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or Section 4(a)(2). The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2016 Stock Incentive Plan.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description of Exhibit
1.1+	Form of Underwriting Agreement.
3.1	Certificate of Incorporation, as currently in effect.
3.2+	Form of Amended and Restated Certificate of Incorporation, to be effective upon the completion of this offering.
3.3	Bylaws, as currently in effect.
3.4+	Form of Amended and Restated Bylaws, to be effective upon the completion of this offering.
4.1+	Form of Common Stock Certificate
4.2+	Amended and Restated Investors' Rights Agreement, dated August 28, 2023, as amended, by and among the Registrant and certain of its stockholders.
5.1+	Opinion of Cooley LLP.
10.1+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.
10.2*	Beta Bionics, Inc. Amended and Restated 2016 Stock Incentive Plan.
10.3*	Forms of Option Agreement, Notice of Stock Option Grant and Exercise Notice under the Beta Bionics, Inc. Amended and Restated 2016 Stock Incentive Plan.
10.4*+	Beta Bionics, Inc. 2025 Equity Incentive Plan.
10.5*+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Beta Bionics, Inc. 2025 Equity Incentive Plan.

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Exhibit Number	Description of Exhibit
10.6*+	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Beta Bionics, Inc. 2025 Equity Incentive Plan.
10.7*+	Beta Bionics, Inc. 2025 Employee Stock Purchase Plan.
10.8*+	Non-Employee Director Compensation Policy.
10.9*+	Employment Agreement between the Registrant and Sean Saint.
10.10*+	Employment Agreement between the Registrant and Stephen Feider.
10.11*+	Employment Agreement between the Registrant and Steven Russell.
10.12*+	Employment Agreement between the Registrant and Mike Mensinger.
10.13	Lease Agreement, dated February 3, 2020, by and between Pacific Industrial Partners, LLC and the Registrant.
10.14#	Device License Agreement, dated December 16, 2015, by and between Trustees of Boston University and the Registrant, as amended by the First Amendment dated December 11, 2017, the Second Amendment dated September 21, 2020, and the Third Amendment dated February 14, 2022.
10.15#	Control Algorithm License Agreement, dated December 23, 2015, by and between Trustees of Boston University and the Registrant, as amended by the First Amendment dated December 11, 2017, the Second Amendment dated September 21, 2020, and the Third Amendment dated February 14, 2022.
10.16#	Collaboration and License Agreement, dated May 2, 2024, by and between Xeris Pharmaceuticals, Inc. and the Registrant.
10.17#+	Commercialization Agreement, dated July 25, 2023, by and between DexCom, Inc. and the Registrant.
10.18#	Development and Commercialization Agreement, dated April 2, 2024, by and between Abbott Diabetes Care Inc. and the Registrant.
23.1+	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.2+	Consent of Cooley LLP (included in Exhibit 5.1).
24.1+	Power of Attorney.
107+	Filing Fee Table.

+ To be filed by amendment.
Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, portions of this exhibit (indicated by [***]) have been omitted because the registrant has determined that the information is both not material and is the type that the registrant treats as private or confidential. The registrant hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.
* Indicates a management contract or any compensatory plan, contract or arrangement.

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or the notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, California, on _____, 2025.

BETA BIONICS, INC.

By: _____
Sean Saint
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Sean Saint and Stephen Feider and each of them, as his true and lawful attorneys-in-fact and agents, and each of them, with the full power of substitution, for him and in his name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Sean Saint	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	_____, 2025
_____ Stephen Feider	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	_____, 2025
_____ Edward Damiano, Ph.D.	Executive Chairman and Director	_____, 2025
_____ Amanda Black	Director	_____, 2025
_____ Sean Carney	Director	_____, 2025
_____ James Parker Cassidy	Director	_____, 2025
_____ Francesco Draetta	Director	_____, 2025

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
Westley Dupray	Director	, 2025
Gilad Glick	Director	, 2025
Lennox Ketner	Director	, 2025
Adam Lezack	Director	, 2025

**CERTIFICATE OF INCORPORATION
OF
BETA BIONICS, INC.**

The undersigned, a natural person (the “***Sole Incorporator***”), for the purpose of organizing a corporation to conduct the business and promote the purposes hereinafter stated, under the provisions and subject to the requirements of the laws of the State of Delaware hereby certifies that:

ARTICLE 1. NAME

The name of this corporation is Beta Bionics, Inc. (the “***Corporation***”). The registered office of the corporation in the State of Delaware is located at 131 Continental Drive, Suite 301, Newark, Delaware 19713-4323, and the name of the registered agent of the Corporation in the State of Delaware at such address is Incorp Services, Inc.

ARTICLE 2. PURPOSE

The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporation Law (the “***General Corporation Law***”).

ARTICLE 3. AUTHORIZED CAPITAL

The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 6,000,000 shares of Class A Common Stock, \$0.0001 par value per share (“***Class A Common Stock***”), (ii) 65,000,000 shares of Class B Common Stock, \$0.0001 par value per share (“***Class B Common Stock***”), (iii) 100,000 shares of Class C Common Stock, \$0.0001 par value per share (“***Class C Common Stock***” and, together with the Class A Common Stock and Class B Common Stock, the “***Common Stock***”), (iv) 500,000 shares of Series A Preferred Stock, \$0.0001 par value per share (“***Series A Preferred Stock***”), (v) 500,000 shares of Series A-2 Preferred Stock, \$0.0001 par value per share (“***Series A-2 Preferred Stock***”), (vi) 4,200,000 shares of Series B Preferred Stock, \$0.0001 par value per share (“***Series B Preferred Stock***”), (vii) 4,000,000 shares of Series B-2 Preferred Stock, \$0.0001 par value per share (“***Series B-2 Preferred Stock***”), (viii) 5,127,250 shares of Series C Preferred Stock, \$0.0001 par value per share (“***Series C Preferred Stock***”), and (ix) 12,107,140 shares of Series D Preferred Stock, \$0.0001 par value per share (“***Series D Preferred Stock***” and, together with the Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock and Series D Preferred Stock, the “***Preferred Stock***”).

**ARTICLE 4. RIGHTS, PREFERENCES, PRIVILEGES
AND RESTRICTIONS OF CAPITAL STOCK**

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK.

The Common Stock shall have the following rights, preferences, powers, privileges and restrictions, qualifications and limitations.

1. **General.** The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. **Voting for Class A Common Stock and Class B Common Stock.** The holders of the Class A Common Stock are entitled to one vote for each share of Class A Common Stock, and the holders of the Class B Common Stock are entitled to one vote for each share of Class B Common Stock held at as of the applicable record date for each meeting of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate of Incorporation (this “**Certification of Incorporation**”) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation or pursuant to the General Corporation Law. There shall be no cumulative voting. Except as set forth in Section 3(b) of Part B of Article 4, Class A Common Stock and Class B Common Stock shall vote together as a single class (together, the “**Voting Common Stock**”). The number of authorized shares of Common Stock (including any of the Class A Common Stock, Class B Common Stock or Class C Common Stock) may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of this Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

3. **No Voting Rights and No Notice Rights for Class C Common Stock.** The holders of Class C Common Stock shall not have the right to vote on any matter submitted to a vote of the Corporation’s stockholders, whether at a meeting of stockholders or otherwise. The holders of Class C Common Stock shall not have the right to receive notice of any meeting (unless required by law), vote or request for unanimous consent by the Corporation’s holders of stock with voting rights. In all other respects, Class C Common Stock shall be identical to Common Stock.

B. PREFERRED STOCK.

The Preferred Stock shall have the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to “Sections” in this Part B of Article 4 refer to sections of this Part B of Article 4.

1. **Dividends.** The Series D Preferred Stock, prior and in preference to any declaration or payment of any other dividend, shall be entitled to a non-cumulative dividend of four percent of the “Series D Original Issue Price” (as defined below), the Series A Preferred Stock and Series A-2 Preferred Stock shall be entitled to a noncumulative dividend of four percent of the applicable Original Issue Price (as defined below), and the Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock shall be entitled to a noncumulative dividend of two percent of the applicable Original Issue Price, in each case, per year, out of any funds and assets legally available therefor, if, when and as declared by the Board on a pari passu basis prior and in preference to any declaration or payment of any other dividends (including dividends on the Common Stock) (collectively, the “**Annual Dividend**”). The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in this Certificate of Incorporation) the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to the applicable Annual Dividend plus (i) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Preferred Stock as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (B) the number of shares of Common Stock issuable upon conversion of a share of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (ii) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the applicable Original Issue Price; provided, however, that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Preferred Stock pursuant to this Section 1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Preferred Stock dividend. The “**Series A Original Issue Price**” shall mean \$10.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split combination or other similar recapitalization with respect to the Series A Preferred Stock. The “**Series A-2 Original Issue Price**” shall mean \$10.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A-2 Preferred Stock. The “**Series B Original Issue Price**” shall mean \$15.02 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock. The “**Series B-2 Original Issue Price**” shall mean \$16.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B-2 Preferred Stock. The “**Series C Original Issue Price**” shall mean \$13.89859 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C Preferred Stock. The “**Series D Original Issue Price**” shall mean \$8.40 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series D Preferred Stock. The term “Original Issue Price” shall refer to the Series A Original Issue Price, the Series A-2 Original Issue Price, the Series B Original Issue Price, the Series B-2 Original Issue Price, the Series C Original Issue Price or the Series D Original Issue Price, or all of them, as applicable.

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

(a) **Preferential Payments to Holders of Series D Preferred Stock.** In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the holders of shares of Series D Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, and in the event of a “Deemed Liquidation Event” (as defined below), the holders of shares of Series D Preferred Stock then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such Deemed Liquidation Event or out of the “Available Proceeds” (as defined below), as applicable, before any payment shall be made to the holders of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock or Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series D Original Issue Price, plus any dividends declared but unpaid thereon or (ii) such amount per share as would have been payable had all shares of Series D Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (the amount payable pursuant to this sentence is hereinafter referred to as the “**Series D Liquidation Amount**”). If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series D Preferred Stock the full amount to which they shall be entitled under this Section 2(a), the holders of shares of Series D Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares of Series D Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares of Series D Preferred Stock were paid in full.

(b) **Preferential Payments to Holders of Preferred Stock.** In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, after the payment in full of the Series D Liquidation Amounts required to be paid to the holders of shares of Series D Preferred Stock pursuant to Section 2(a) above, the holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock then outstanding shall be entitled to be paid out of the remaining assets of the Corporation available for distribution to its stockholders, and in the event of a Deemed Liquidation Event, the holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock then outstanding shall be entitled to be paid out of the remaining consideration payable to stockholders in such Deemed Liquidation Event or out of the Available Proceeds, as applicable, in each case on a pari passu basis, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable Original Issue Price, plus any dividends declared but unpaid thereon or (ii) such amount per share as would have been payable had all shares of such series of Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (the amount payable pursuant to this sentence is hereinafter referred to as the “**Series A Liquidation Amount**”, “**Series A-2 Liquidation Amount**”, “**Series B Liquidation Amount**”, “**Series B-2 Liquidation Amount**”, or “**Series C Liquidation Amount**,” as applicable, and, collectively, the “**Series A, B and C Liquidation Amounts**” and together with the Series D Liquidation Amount, the “**Liquidation Amounts**”). If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Preferred Stock the full amount to which they shall be entitled under this Section 2(b), the holders of shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock were paid in full.

(c) **Payments to Holders of Common Stock.** In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, after the payment in full of all Liquidation Amounts required to be paid to the holders of shares of Preferred Stock pursuant to Sections 2(a) and 2(b) above, the remaining assets of the Corporation available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, the consideration not payable to the holders of shares of Preferred Stock pursuant to Sections 2(a) and 2(b) or the remaining Available Proceeds, as the case may be, shall be distributed among the holders of shares of Common Stock pro rata based on the number of shares held by each such holder.

(d) **Deemed Liquidation Events.**

(i) **Definition.** Each of the following events shall be considered a “**Deemed Liquidation Event**” unless both (a) the holders of a majority of the then outstanding shares of Series D Preferred Stock, voting as a separate class, which majority shall include at least one of the “Lead Investors” (as such term is defined in that certain Series D Preferred Stock and Warrant Purchase Agreement dated on or around August 23, 2023, by and among the Beta Bionics, Inc. and the Purchasers party thereto) (the “**Requisite Series D Majority**”), and (b) the holders of a majority of the then outstanding shares of Preferred Stock, voting together as a single class on an as-converted to Common Stock basis (together with the Requisite Series D Majority, the “**Requisite Holders**”), elect otherwise by written notice sent to the Corporation at least five days prior to the effective date of any such event:

(1) a merger, consolidation or share exchange in which (A) the Corporation is a constituent party or (B) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of the surviving or resulting corporation, or if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation;

(2) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation; or

(3) the Corporation’s outstanding shares of capital stock being exchanged for or otherwise converted into securities that are publicly listed on a securities exchange (the “**Public Shares**”) through a merger, acquisition, business combination, or similar transaction, in each case with a vehicle commonly known as a special purpose acquisition company (i.e., a blank check company with no operations) (a “**SPAC Transaction**”), other than a Qualified SPAC Transaction. A “**Qualified SPAC Transaction**” means a SPAC Transaction where (i) the aggregate value of the Public Shares received (as set forth in the transaction agreement for the SPAC Transaction) with respect to each share of Series D Preferred Stock (or the Common Stock issuable upon conversion of one share of Series D Preferred) at such closing is equal to at least \$7.41177 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), (ii) the public company surviving or resulting from the SPAC Transaction has available cash immediately after the consummation of the SPAC Transaction of at least \$75,000,000 in the aggregate (which may include the proceeds of a private investment in public equity, or PIPE, transaction that is substantially contemporaneous with or conditioned on the SPAC Transaction), and (iii) the Public Shares are listed for trading on the Nasdaq Stock Market’s National Market or the New York Stock Exchange.

(ii) **Effecting a Deemed Liquidation Event.**

(1) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Section 2(d)(i)(1)(A) unless the agreement or plan of merger or consolidation for such transaction (the “**Merger Agreement**”) provides that the consideration payable to the stockholders of the Corporation in such Deemed Liquidation Event shall be allocated to the holders of capital stock of the Corporation in accordance with Sections 2(a), 2(b) and 2(c).

(2) In the event of a Deemed Liquidation Event referred to in Sections 2(d)(i)(1)(B), 2(d)(i)(2) or 2(d)(i)(3), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within 30 days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the 30th day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right), pursuant to the terms of the following clause, to require the redemption of such shares of Preferred Stock, and (ii) unless the Requisite Holders request otherwise in a written instrument delivered to the Corporation, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the “**Available Proceeds**”), on the 60th day after such Deemed Liquidation Event, to redeem all outstanding shares of Preferred Stock at the applicable Liquidation Amount. Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall first ratably redeem each holder’s shares of Series D Preferred Stock to the fullest extent of such Available Proceeds, and second, to the extent there are Available Proceeds remaining, shall ratably redeem each holder’s shares of Series A Preferred Stock and/or Series A-2 Preferred Stock and/or Series B Preferred Stock and/or Series B-2 Preferred Stock and/or Series C Preferred Stock, as applicable, to the fullest extent of such Available Proceeds, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders. Prior to the distribution or redemption provided for in this Section 2(d)(ii)(2), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event.

(3) **Amount Deemed Paid or Distributed.** If the amount deemed paid or distributed under this Section 2(d) is made in property other than in cash, the value of such distribution shall be the fair market value of such property, determined as follows: (a) for securities not subject to investment letters or other similar restrictions on free marketability, (i) if traded on a securities exchange, the value shall be deemed to be the average of the closing prices of the securities on such exchange or market over the 30 day period ending three days prior to the closing of such transaction; (ii) if actively traded over-the-counter, the value shall be deemed to be the average of the closing bid prices over the 30 day period ending three days prior to the closing of such transaction; or (iii) if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Board; and (b) the method of valuation of securities subject to investment letters or other similar restrictions on free marketability (other than restrictions arising solely by virtue of a stockholder’s status as an affiliate or former affiliate) shall take into account an appropriate discount (as determined in good faith by the Board) from the market value as determined pursuant to clause (a) above so as to reflect the approximate fair market value thereof.

(iii) **Allocation of Escrow and Contingent Consideration.** In the event of a Deemed Liquidation Event pursuant to Section 2(d)(i)(1)(A) or 2(d)(i)(1)(B), if any portion of the consideration payable to the stockholders of the Corporation is payable only upon satisfaction of contingencies (the “**Additional Consideration**”), the Merger Agreement (or other applicable agreement) shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the “**Initial Consideration**”) shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2(a), 2(b) and 2(c) as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event; and (b) any Additional Consideration which becomes payable to the stockholders of the Corporation upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2(a), 2(b) and 2(c) after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Section 2(d)(iii), consideration placed into escrow or retained as a holdback to be available for satisfaction of indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Additional Consideration. For the avoidance of doubt, the Liquidation Amounts shall not be decreased (i) irrespective of whether any Additional Consideration is forfeited or (ii) irrespective of whether any Additional Consideration is paid to holders of Common Stock.

3. *Voting.*

(a) **General.** On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Class B Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of this Certificate of Incorporation, holders of Preferred Stock shall vote together with the holders of Class A Common Stock and Class B Common Stock as a single class and on an as-converted to Common Stock basis.

(b) **Election of Directors.** (i) The holders of record of the shares of Series D Preferred Stock, exclusively and as a separate class, shall be entitled to elect five directors of the Corporation (the “**Series D Directors**”); (ii) the holders of record of the shares of Series C Preferred Stock, exclusively and as a separate class, shall be entitled to elect one director of the Corporation; and (iii) the holders of record of the shares of Series B Preferred Stock and Series B-2 Preferred Stock, voting together as a single class on an as-converted basis, shall be entitled to elect one director of the Corporation; and (iv) the holders of record of the shares of Class A Common Stock, exclusively and as a separate class, shall be entitled to elect one director of the Corporation. Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Preferred Stock or Common Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Section 3(b), then any directorship not so filled shall remain vacant until such time as the holders of Preferred Stock or Common Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Voting Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class on an as converted to Common Stock basis, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or classes or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Section 3(b), a vacancy in any directorship filled by the holders of any class or classes or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or classes or series pursuant to this Section 3(b).

(c) **Preferred Stock Protective Provisions.** At any time when any shares of Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, share exchange, consolidation, recapitalization, reclassification or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Preferred Stock, voting together as a single class on an as-converted basis, given in writing or by vote at a meeting, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) amend, alter or repeal any provision of this Certificate of Incorporation or the Amended and Restated Bylaws of the Corporation (the “**Bylaws**”) in a manner that adversely affects the powers, preferences or rights of the holders of any series of Preferred Stock;

(ii) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the existing classes or series of Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of any series or class of Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock of the Corporation unless the same ranks junior to the existing classes or series of Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption;

(iii) (1) reclassify, alter or amend any existing security of the Corporation that is *pari passu* with any class or series of the Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the existing classes or series of Preferred Stock in respect of any such right, preference, or privilege or (2) reclassify, alter or amend any existing security of the Corporation that is junior to the Series B Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock and Series D Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or *pari passu* with the Series B Preferred Stock, Series B-2 Preferred Stock, Series C Preferred Stock or Series D Preferred Stock in respect of any such right, preference or privilege;

(iv) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than (1) redemptions of or dividends or distributions on the Preferred Stock as expressly authorized herein, (2) dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock, or (3) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof;

(v) create, or authorize the creation of, or issue, or authorize the issuance of any debt security or create any lien or security interest (except for purchase money liens or statutory liens of landlords, mechanics, materialmen, workmen, warehousemen and other similar persons arising or incurred in the ordinary course of business) or incur other indebtedness for borrowed money, including but not limited to obligations and contingent obligations under guarantees, or permit any subsidiary to take any such action with respect to any debt security lien, security interest or other indebtedness for borrowed money, if the aggregate indebtedness of the Corporation and its subsidiaries for borrowed money following such action would exceed \$1,000,000;

(vi) create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or permit any subsidiary to create, or authorize the creation of, or issue or obligate itself to issue, any shares of any class or series of capital stock, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary;

(vii) enter into any transaction with any affiliate of the Corporation or any individual in the role of senior management of the Corporation, except for compensatory agreements entered into in the ordinary course of business, or enter into any transaction with a private company in which any individual in the role of senior management of the Corporation holds a seat on the board of directors or has at least one percent of the outstanding equity; or

(viii) change the business in which the Corporation is presently engaged.

(d) ***Series A Preferred Stock Protective Provisions.*** At any time when at least 250,000 shares of Series A Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, share exchange, consolidation, recapitalization, reclassification or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series A Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) amend, alter or repeal any provision of this Certificate of Incorporation or Bylaws of the Corporation in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Stock;

(ii) create, or authorize the creation of, any additional class or series of capital stock that ranks senior to the Series A Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series A Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock that ranks senior to the Series A Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, for the avoidance of doubt, nothing in this Certificate of Incorporation shall prevent the Board from creating, or authorizing the creation of, any additional class of Common or Preferred Stock that ranks junior or pari passu to Series A Preferred Stock;

(iii) (1) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A Preferred Stock in respect of any such right, preference, or privilege or (2) reclassify, alter or amend any existing security of the Corporation that is junior to the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A Preferred Stock in respect of any such right, preference or privilege;

(iv) purchase or redeem (or permit any subsidiary to purchase or redeem) any shares of capital stock of the Corporation other than (1) redemptions of the Preferred Stock as expressly authorized herein or (2) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof; or

(v) pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock, provided, however, that this protective provision will terminate upon the termination of the rights set forth in Section 4(d).

(e) **Series A-2 Preferred Stock Protective Provisions.** At any time when at least 250,000 shares of Series A-2 Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A-2 Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment merger, share exchange, recapitalization, recapitalization, reclassification or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series A-2 Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) amend, alter or repeal any provision of this Certificate of Incorporation or Bylaws of the Corporation in a manner that adversely affects the powers, preferences or rights of the Series A-2 Preferred Stock;

(ii) create, or authorize the creation of, any additional class or series of capital stock that ranks senior to the Series A-2 Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series A-2 Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock that ranks senior to the Series A-2 Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, for the avoidance of doubt, nothing in this Certificate of Incorporation shall prevent the Board from creating, or authorizing the creation of, any additional class of Common or Preferred Stock that ranks junior or pari passu to Series A-2 Preferred Stock;

(iii) (1) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Series A-2 Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A-2 Preferred Stock in respect of any such right, preference, or privilege or (2) reclassify, alter or amend any existing security of the Corporation that is junior to the Series A-2 Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A-2 Preferred Stock in respect of any such right, preference or privilege;

(iv) purchase or redeem (or permit any subsidiary to purchase or redeem) any shares of capital stock of the Corporation other than (1) redemptions of the Preferred Stock as expressly authorized herein or (2) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof; or

(v) pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock, provided, however, that this protective provision will terminate upon the termination of the rights set forth in Section 4(d).

(f) **Series B Preferred Stock Protective Provisions.** At any time when at least 100,000 shares of Series B Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, share exchange, recapitalization, reclassification or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series B Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) amend, alter or repeal any provision of this Certificate of Incorporation or Bylaws of the Corporation in a manner that adversely affects the powers, preferences or rights of the Series B Preferred Stock;

(ii) create, or authorize the creation of, any additional class or series of capital stock that ranks senior or pari passu to the Series B Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series B Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock that ranks senior or pari passu to the Series B Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, for the avoidance of doubt, nothing in this Certificate of Incorporation shall prevent the Board from creating, or authorizing the creation of, any additional class of Common or Preferred Stock that ranks junior to Series B Preferred Stock;

(iii) (1) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Series B Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series B Preferred Stock in respect of any such right, preference, or privilege or (2) reclassify, alter or amend any existing security of the Corporation that is junior to the Series B Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu to the Series B Preferred Stock in respect of any such right, preference or privilege;

(iv) purchase or redeem (or permit any subsidiary to purchase or redeem) any shares of capital stock of the Corporation other than (1) redemptions of the Preferred Stock as expressly authorized herein or (2) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof;

(v) pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock, provided, however, that this protective provision will terminate upon the termination of the rights set forth in Section 4(d);

(vi) increase or decrease the number of authorized shares of Series B Preferred Stock; or

(vii) increase or decrease the number of authorized directors constituting the Board, change the number of votes entitled to be cast by any director or directors on any matter, or adopt any provision inconsistent with Article 6.

(g) **Series B-2 Preferred Stock Protective Provisions.** At any time when at least 100,000 shares of Series B-2 Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B-2 Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, share exchange, recapitalization, reclassification or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series B-2 Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) amend, alter or repeal any provision of this Certificate of Incorporation or Bylaws of the Corporation in a manner that adversely affects the powers, preferences or rights of the Series B-2 Preferred Stock;

(ii) create, or authorize the creation of, any additional class or series of capital stock that ranks senior or pari passu to the Series B-2 Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series B-2 Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock that ranks senior or pari passu to the Series B-2 Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, for the avoidance of doubt, nothing in this Certificate of Incorporation shall prevent the Board from creating, or authorizing the creation of, any additional class of Common or Preferred Stock that ranks junior to Series B-2 Preferred Stock;

(iii) (1) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Series B-2 Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series B-2 Preferred Stock in respect of any such right, preference, or privilege or (2) reclassify, alter or amend any existing security of the Corporation that is junior to the Series B-2 Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu to the Series B-2 Preferred Stock in respect of any such right, preference or privilege;

(iv) purchase or redeem (or permit any subsidiary to purchase or redeem) any shares of capital stock of the Corporation other than (1) redemptions of the Preferred Stock as expressly authorized herein or (2) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof;

(v) pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock, provided, however, that this protective provision will terminate upon the termination of the rights set forth in Section 4(d);

(vi) increase or decrease the number of authorized shares of Series B- 2 Preferred Stock; or

(vii) increase or decrease the number of authorized directors constituting the Board, change the number of votes entitled to be cast by any director or directors on any matter, or adopt any provision inconsistent with Article 6.

(h) ***Series C Preferred Stock Protective Provisions.*** At any time when at least 100,000 shares of Series C Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, share exchange, recapitalization, reclassification or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of a majority of the then outstanding shares of Series C Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) amend, alter or repeal any provision of this Certificate of Incorporation or Bylaws of the Corporation in a manner that adversely affects the powers, preferences or rights of the Series C Preferred Stock;

(ii) create, or authorize the creation of, any additional class or series of capital stock that ranks senior or pari passu to the Series C Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series C Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock that ranks senior or pari passu to the Series C Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, for the avoidance of doubt, nothing in this Certificate of Incorporation shall prevent the Board from creating, or authorizing the creation of, any additional class of Common or Preferred Stock that ranks junior to Series C Preferred Stock;

(iii) (1) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Series C Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series C Preferred Stock in respect of any such right, preference, or privilege or (2) reclassify, alter or amend any existing security of the Corporation that is junior to the Series C Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu to the Series C Preferred Stock in respect of any such right, preference or privilege;

(iv) purchase or redeem (or permit any subsidiary to purchase or redeem) any shares of capital stock of the Corporation other than (1) redemptions of the Preferred Stock as expressly authorized herein or (2) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof;

(v) pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock;

(vi) increase or decrease the number of authorized shares of Series C Preferred Stock;

(vii) consummate a sale of shares of Common Stock to the public in an initial firm-commitment underwritten public offering (“**IPO**”) pursuant to an effective registration statement under the Securities Act of 1933, as amended (the “**Securities Act**”) that is not a “Qualified IPO” (as defined below);

(viii) consummate a SPAC Transaction that is not a Qualified SPAC Transaction;

(ix) increase or decrease the number of authorized directors constituting the Board, change the number of votes entitled to be cast by any director or directors on any matter, or adopt any provision inconsistent with Article 6; or

(x) create, adopt, amend, terminate or repeal any equity (or equity-linked) compensation plan or amend or waive any of the terms of any option or other grant pursuant to any such plan.

(i) **Series D Preferred Stock Protective Provisions.** At any time when at least 200,000 shares of Series D Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series D Preferred Stock) are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, share exchange, recapitalization, reclassification or otherwise, do any of the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the Requisite Series D Majority, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event (other than a IPO or SPAC Transaction), or effect any other transaction or series of related transactions in which a person and/or entity, or a group of related persons and/or entities, acquires from stockholders of the Corporation capital stock of the Corporation representing a majority of the outstanding voting power of the Corporation (other than an IPO or SPAC Transaction), in each case unless the per share consideration received by the holders of shares of Series D Preferred Stock is at least \$9.88236 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization);

(ii) waive (1) the liquidation preference set forth in Section 2(a) with respect to the Series D Preferred Stock, (2) the treatment of any transaction as a Deemed Liquidation Event as set forth in Section 2(d) with respect to the rights of the Series D Preferred Stock, or (3) the anti-dilution adjustments set forth in Section 4(d)(iv) of this Certificate of Incorporation with respect to the Series D Preferred Stock.

(iii) amend, alter or repeal any provision of this Certificate of Incorporation or Bylaws of the Corporation in a manner that adversely affects the powers, preferences or rights of the Series D Preferred Stock;

(iv) create, or authorize the creation of, any additional class or series of capital stock that ranks senior or pari passu to the Series D Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series D Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock that ranks senior or pari passu to Series D Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, for the avoidance of doubt, nothing in this Certificate of Incorporation shall prevent the Board from creating, or authorizing the creation of, any additional class of Common or Preferred Stock that ranks junior to Series D Preferred Stock;

(v) (1) reclassify, alter or amend any existing security of the Corporation that is pari passu with the Series D Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series D Preferred Stock in respect of any such right, preference, or privilege or (2) reclassify, alter or amend any existing security of the Corporation that is junior to the Series D Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu to the Series D Preferred Stock in respect of any such right, preference or privilege;

(vi) purchase or redeem (or permit any subsidiary to purchase or redeem) any shares of capital stock of the Corporation other than (1) redemptions of the Preferred Stock as expressly authorized herein or (2) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof;

(vii) pay or declare any dividend or make any distribution on, any shares of capital stock of the Corporation other than dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock;

(viii) increase or decrease the number of authorized shares of Series D Preferred Stock;

(ix) consummate an IPO pursuant to an effective registration statement under the Securities Act that is not a

Qualified IPO;

(x) consummate a SPAC Transaction that is not a Qualified SPAC Transaction;

(xi) increase or decrease the number of authorized directors constituting the Board, change the number of votes entitled to be cast by any director or directors on any matter, or adopt any provision inconsistent with Article 6; or

(xii) create, adopt, amend, terminate or repeal any equity (or equity-linked) compensation plan or amend or waive any of the terms of any option or other grant pursuant to any such plan.

(j) **Super Majority Protective Provisions.** At any time when any shares of Voting Common Stock or Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, share exchange, recapitalization, reclassification or otherwise, do the following without (in addition to any other vote required by law or this Certificate of Incorporation) the written consent or affirmative vote of the holders of at least 60% of the then outstanding shares of Voting Common Stock and Preferred Stock, voting together as a single class, on an as-converted to Common Stock basis, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

(i) liquidate, dissolve or wind-up the business and affairs of the Corporation, effect any merger or consolidation or any other Deemed Liquidation Event (other than a IPO or SPAC Transaction), or effect any other transaction or series of related transactions in which a person and/or entity, or a group of related persons and/or entities, acquires from stockholders of the Corporation capital stock of the Corporation representing a majority of the outstanding voting power of the Corporation (other than an IPO or SPAC Transaction).

4. **Optional Conversion.** The holders of Preferred Stock shall have conversion rights as follows (the “**Conversion Rights**”):

(a) **Right to Convert.**

(i) **Conversion Ratio.** Each share of Preferred Stock (other than the Series D Preferred Stock) shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Class B Common Stock as is determined by dividing the applicable Original Issue Price by the applicable “Conversion Price” (as defined below) in effect at the time of conversion. Each share of Series D Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Class B Common Stock as is determined by dividing \$4.94118 by the “Series D Conversion Price” (as defined below) in effect at the time of conversion. The “**Series A Conversion Price**” shall initially be equal to \$8.0055. The “**Series A-2 Conversion Price**” shall initially be equal to \$8.0055. The “**Series B Conversion Price**” shall initially be equal to \$10.63084. The “**Series B-2 Conversion Price**” shall initially be equal to \$11.11989. The “**Series C Conversion Price**” shall initially be equal to \$10.37275. The “**Series D Conversion Price**” shall initially be equal to \$4.94118. The “**Conversion Price**” shall refer to either the Series A Conversion Price, the Series A-2 Conversion Price, the Series B Conversion Price, the Series B-2 Conversion Price, the Series C Conversion Price or the Series D Conversion Price, or all of them, as applicable. Such Conversion Price, and the rate at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

(ii) **Termination of Conversion Rights.** In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock, provided that the foregoing termination of Conversion Rights shall not affect the amount(s) otherwise paid or payable in accordance with Sections 2(a), 2(b) and 2(c) to holders of Preferred Stock pursuant to such liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event.

(b) **Fractional Shares.** No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

(c) **Mechanics of Conversion.**

(i) **Notice of Conversion.** In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall (1) provide written notice to the Corporation's transfer agent at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder's shares of Preferred Stock and, if applicable, any event on which such conversion is contingent and (2) if such holder's shares are certificated, surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder's name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the "**Conversion Time**"), and the shares of Common Stock issuable upon conversion of the specified shares shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (1) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, (2) pay in cash such amount as provided in Section 4(b) in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion, and (iii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.

(ii) **Reservation of Shares.** The Corporation shall at all times when the Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to this Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the applicable Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of the Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted Conversion Price.

(iii) **Effect of Conversion.** All shares of Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Section 4(b) and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

(iv) **No Further Adjustment.** Upon any such conversion, no adjustment to the Conversion Price shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

(v) **Taxes.** The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

(d) **Adjustments to Conversion Price for Diluting Issues.**

(i) **Special Definitions.** For purposes of this Article 4, the following definitions shall apply:

(1) “**Additional Shares of Common Stock**” shall mean all shares of Common Stock issued (or, pursuant to Section 4(d)(iii) below, deemed to be issued) by the Corporation after the Original Issue Date, other than the following shares of Common Stock and shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (collectively, “**Exempted Securities**”): (A) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on Preferred Stock; (B) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Sections 4(e), 4(f), 4(g) or 4(h); (C) shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Corporation’s Board of Directors (the “**Board of Directors**”) including a majority of the Series D Directors; (D) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security; (E) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing or real property leasing transaction approved by the Board of Directors including a majority of the Series D Directors; (F) shares of Common Stock, Options or Convertible Securities issued to suppliers or third party service providers as consideration for the provision of goods or services pursuant to transactions approved by the Board of Directors including a majority of the Series D Directors; (G) shares of Common Stock, Options or Convertible Securities issued as consideration for sponsored research, collaboration, technology license, development, OEM, marketing or other similar agreements or strategic partnerships approved by the Board of Directors including a majority of the Series D Directors; or (H) shares of Preferred Stock and Options issued pursuant to the Series D Preferred Stock Agreement among Beta Bionics, Inc. and the other parties thereto dated on or about the Original Issue Date.

(2) “**Convertible Securities**” shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(3) “**Option**” shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(4) “**Original Issue Date**” shall mean the date on which the first share of Series D Preferred Stock was issued.

(ii) **No Adjustment of Conversion Price.**

(1) No adjustment in the Series A Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of Series A Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

(2) No adjustment in the Series A-2 Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of Series A-2 Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

(3) No adjustment in the Series B Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of Series B Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

(4) No adjustment in the Series B-2 Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of Series B-2 Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

(5) No adjustment in the Series C Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the holders of a majority of the then outstanding shares of Series C Preferred Stock agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

(6) No adjustment in the Series D Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Series D Majority agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

(iii) ***Deemed Issue of Additional Shares of Common Stock.***

(1) If the Corporation at any time or from time to time after the Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(2) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Conversion Price pursuant to the terms of Section 4(d)(iv), are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the applicable Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Conversion Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (2) shall have the effect of increasing the Conversion Price to an amount which exceeds the lower of (A) the applicable Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (B) the Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(3) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the applicable Conversion Price pursuant to the terms of Section 4(d)(iv) (either because the consideration per share (determined pursuant to Section 4(d)(v)) of the Additional Shares of Common Stock subject thereto was equal to or greater than the applicable Conversion Price then in effect, or because such Option or Convertible Security was issued before the Original Issue Date), are revised after the Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (A) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (B) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Section 4(d)(iii)(1)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(4) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the applicable Conversion Price pursuant to the terms of Section 4(d)(iv), the Conversion Price shall be readjusted to such Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(5) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the applicable Conversion Price provided for in this Section 4(d)(iii) shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (2) and (3) of this Section 4(d)(iii). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the applicable Conversion Price that would result under the terms of this Section 4(d)(iii) at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the Conversion Price that such issuance or amendment took place at the time such calculation can first be made.

(iv) ***Adjustment of Conversion Price Upon Issuance of Additional Shares of Common Stock.*** In the event the Corporation shall at any time after the Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 4(d)(iii)), without consideration or for a consideration per share less than the Series D Conversion Price in effect immediately prior to such issuance or deemed issuance, then the applicable Conversion Price of each series of Preferred Stock shall be reduced, concurrently with such issuance or deemed issuance, to a price (calculated to the nearest one-hundredth of a cent), (1) with respect to the Series D Preferred Stock, to the consideration per share received by the Corporation for such issue or deemed issue of the Additional Shares of Common Stock; provided that if such issuance or deemed issuance was without consideration, then the Corporation shall be deemed to have received an aggregate of \$0.001 of consideration for all such Additional Shares of Common Stock issued or deemed to be issued, and (2) with respect to the Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock, Series B-2 Preferred Stock and Series C Preferred Stock, determined in accordance with the following formula:

$$CP_2 = CP_1 * (A + B) \div (A + C).$$

For purposes of the foregoing formula, the following definitions shall apply:

(1) “**CP₂**” shall mean the applicable Conversion Price in effect immediately after such issuance or deemed issuance of Additional Shares of Common Stock;

(2) “**CP₁**” shall mean the applicable Conversion Price in effect immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock;

(3) “**A**” shall mean the number of shares of Common Stock outstanding immediately prior to such issuance or deemed issuance of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issuance or deemed issuance or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(4) “**B**” shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued or deemed issued at a price per share equal to CP₁ (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP₁); and

(5) “**C**” shall mean the number of such Additional Shares of Common Stock issued in such transaction.

(v) **Determination of Consideration.** For purposes of this Section 4(d), the consideration received by the Corporation for the issuance or deemed issuance of any Additional Shares of Common Stock shall be computed as follows:

(1) **Cash and Property.** Such consideration shall: (A) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest; (B) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors; and (C) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (A) and (B) above, as determined in good faith by the Board of Directors.

(2) **Options and Convertible Securities.** The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Section 4(d)(iii), relating to Options and Convertible Securities, shall be determined by dividing: (A) the total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by (B) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

(vi) **Multiple Closing Dates.** In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the applicable Conversion Price pursuant to the terms of Section 4(d)(iv) and such issuance dates occur within a period of no more than 90 days from the first such issuance to the final such issuance then, upon the final such issuance, such Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

(e) **Adjustment for Stock Splits and Combinations.** If the Corporation shall at any time or from time to time after the Original Issue Date effect a subdivision of the outstanding Common Stock, the Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Original Issue Date combine the outstanding shares of Common Stock, the Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this Section 4(e) shall become effective at the close of business on the date the subdivision or combination becomes effective.

(f) **Adjustment for Certain Dividends and Distributions.** In the event the Corporation at any time or from time to time after the Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Conversion Price then in effect by a fraction:

(i) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(ii) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the applicable Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Conversion Price shall be adjusted pursuant to this Section 4(f) as of the time of actual payment of such dividends or distributions; and (b) that no such adjustment shall be made if the holders of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

(g) **Adjustments for Other Dividends and Distributions.** In the event the Corporation at any time or from time to time after the Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

(h) **Adjustment for Merger or Reorganization.** Subject to the provisions of Section 2(d), if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Sections 4(d), 4(e), 4(f) or 4(g)), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Preferred Stock. For the avoidance of doubt, nothing in this Section 4(h) shall be construed as preventing the holders of Preferred Stock from seeking any appraisal rights to which they are otherwise entitled under the General Corporation Law in connection with a merger triggering an adjustment hereunder, nor shall this Section 4(h) be deemed conclusive evidence of the fair value of the shares of Preferred Stock in any such appraisal proceeding.

(i) **Certificate as to Adjustments.** Upon the occurrence of each adjustment or readjustment of the applicable Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than 10 days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than 10 days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the Conversion Price then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of Preferred Stock.

(j) **Notice of Record Date.** In the event:

(i) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security;

(ii) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(iii) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of the Preferred Stock a notice specifying, as the case may be, (1) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (2) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to the Preferred Stock and the Common Stock. Such notice shall be sent at least 10 days prior to the record date or effective date for the event specified in such notice.

5. **Mandatory Conversion.**

(a) **Trigger Events.** Upon either (i) the closing of the sale of Common Stock to the public at a price per share of at least \$7.41177 (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act resulting in at least \$75,000,000 of gross proceeds to the Corporation and in connection with such offering the Common Stock is listed for trading on the Nasdaq Stock Market's National Market or the New York Stock Exchange (a "**Qualified IPO**"), (ii) the closing of a Qualified SPAC Transaction, or (iii) the date and time, or the occurrence of an event, specified by vote or written consent of (1) the holders of a majority of the then outstanding shares of Preferred Stock, voting together as a single class on an as-converted to Common Stock basis, and (2) the Requisite Series D Majority (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "**Mandatory Conversion Time**"), then all outstanding shares of Preferred Stock shall automatically be converted into shares of Class B Common Stock at the then effective conversion rate as calculated pursuant to Section 4(a)(i) and such shares may not be reissued by the Corporation.

(b) **Procedural Requirements.** All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Section 5(a), including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Section 5(b). As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall (i) issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (ii) pay cash as provided in Section 4(b) in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

6. **Redeemed or Otherwise Acquired Shares.** Any shares of Preferred Stock that are redeemed, converted or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption, conversion or acquisition.

7. **Waiver.** Except as otherwise set forth herein, any of the rights, powers, preferences and other terms of any series of Preferred Stock set forth herein may be waived on behalf of all holders of such series of Preferred Stock by the affirmative written consent or vote of the holders of at least a majority of the shares of such series of Preferred Stock then outstanding.

8. **Notices.** Any notice required or permitted by the provisions of this Article 4 to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

ARTICLE 5. RESTRICTIONS ON TRANSFER

There shall be no restrictions imposed by this Certificate of Incorporation upon the transfer of shares of stock of any class.

ARTICLE 6. OTHER PROVISIONS

Other lawful provisions are as follows.

A. BYLAWS

Subject to any additional vote required by this Certificate of Incorporation or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the Bylaws of the Corporation.

B. BOARD OF DIRECTORS

Subject to any additional vote required by this Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation, however, at no time shall the number of directors of the Corporation be less than three or more than ten. Each director shall be entitled to one vote on each matter presented to the Board.

C. ELECTION OF DIRECTORS

Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

D. MEETINGS OF STOCKHOLDERS

Meetings of stockholders may be held within or outside of the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside of the State of Delaware at such place or places as may be designated from time to time by the Board or in the Bylaws of the Corporation.

E. LIMITATION OF DIRECTOR LIABILITY

To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Part E of Article 6 to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended. Any repeal or modification of the foregoing provisions of this Part E of Article 6 by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

F. INDEMNIFICATION

The following indemnification provisions shall apply to the persons enumerated below.

1. ***Right to Indemnification of Directors and Officers.*** The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an “***Indemnified Person***”) who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a “***Proceeding***”) by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys’ fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Part F of Article 6, the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board.

2. ***Prepayment of Expenses of Directors and Officers.*** The Corporation shall pay the expenses (including attorneys’ fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Part F of Article 6 or otherwise.

3. ***Claims by Directors and Officers.*** If a claim for indemnification or advancement of expenses under this Part F of Article 6 is not paid in full within 30 days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law,

4. ***Indemnification of Employees and Agents.*** The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys’ fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non- director or officer employees or agents shall be made in such manner as is determined by the Board in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board.

5. ***Advancement of Expenses of Employees and Agents.*** The Corporation may pay the expenses (including attorneys’ fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board.

6. ***Non-Exclusivity of Rights.*** The rights conferred on any person by this Part F of Article 6 shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of this Certificate of Incorporation, the Bylaws of the Corporation or any agreement, or pursuant to any vote of stockholders or disinterested directors or otherwise.

7. **Other Indemnification.** The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another Corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person may collect as indemnification from such other Corporation, partnership, limited liability company, joint venture, trust organization or other enterprise.

8. **Insurance.** The Board may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance; (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Part F of Article 6; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Part F of Article 6.

9. **Amendment or Repeal.** Any repeal or modification of the foregoing provisions of this Part F of Article 6 shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

G. EXCLUDED OPPORTUNITIES

The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An "**Excluded Opportunity**" is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee, affiliate or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, the persons referred to in clauses (i) and (ii) are "**Covered Persons**"), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation.

ARTICLE 7. INCORPORATOR

The name and mailing address of the Sole Incorporator is Sean Saint, 11 Hughes, Irvine, California 92618.

IN WITNESS WHEREOF, the undersigned, for the purpose of forming a corporation under the laws of the State of Delaware, does hereby make, file and record this Certificate of Incorporation and accordingly has executed this Certificate of Incorporation on August 30, 2024.

By: /s/ Sean Saint
Sean Saint, Sole Incorporator

**BY-LAWS OF
BETA BIONICS, INC.,
A DELAWARE CORPORATION**

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ARTICLE I STOCKHOLDERS

Section 1. Annual Meeting. Beta Bionics, Inc. (the “**Corporation**”) shall hold an annual meeting of stockholders at a time fixed by the members (the “**Directors**”) of the Board of Directors of the Corporation (the “**Board of Directors**”) within six months after the end of the Corporation’s fiscal year. The purposes for which the annual meeting is to be held, in addition to those prescribed by the Certificate of Incorporation, shall be for electing directors and for such other purposes as shall be specified in the notice for the meeting, and only business within such purposes may be conducted at the meeting. In the event an annual meeting is not held at the time fixed in accordance with these By-laws or the time for an annual meeting is not fixed in accordance with these By-laws to be held within 13 months after the last annual meeting was held, the Corporation may designate a special meeting held thereafter as a special meeting in lieu of the annual meeting, and the meeting shall have all of the effect of an annual meeting.

Section 2. Special Meetings. Special meetings of the stockholders may be called by the President or by the Directors, and shall be called by the Secretary, or in case of the death, absence, incapacity or refusal of the Secretary, by another officer, if the holders of at least 10 per cent, or such lesser percentage as the Certificate of Incorporation permit, of all the votes entitled to be cast on any issue to be considered at the proposed special meeting sign, date, and deliver to the Secretary one or more written demands for the meeting describing the purpose for which it is to be held. Only business within the purpose or purposes described in the meeting notice may be conducted at a special stockholders’ meeting.

Section 3. Place of Meetings. All meetings of stockholders shall be held at the principal office of the Corporation unless a different place is specified in the notice of the meeting or the meeting is held solely by means of remote communication in accordance with Section 11 of this Article.

Section 4. Requirement of Notice. A written notice of the date, time, and place of each annual and special stockholders’ meeting describing the purposes of the meeting shall be given to stockholders entitled to vote at the meeting (and, to the extent required by law or the Certificate of Incorporation, to stockholders not entitled to vote at the meeting) no fewer than seven nor more than 60 days before the meeting date. If an annual or special meeting of stockholders is adjourned to a different date, time or place, notice need not be given of the new date, time or place if the new date, time or place, if any, is announced at the meeting before adjournment. If a new record date for the adjourned meeting is fixed, however, notice of the adjourned meeting shall be given under this Section to persons who are stockholders as of the new record date.

Section 5. Waiver of Notice. A stockholder may waive any notice required by law, the Certificate of Incorporation, or these By-laws before or after the date and time stated in the notice. The waiver shall be in writing, be signed by the stockholder entitled to the notice, and be delivered to the Corporation for inclusion with the records of the meeting. A stockholder’s attendance at a meeting: (a) waives objection to lack of notice or defective notice of the meeting, unless the stockholder at the beginning of the meeting objects to holding the meeting or transacting business at the meeting; and (b) waives objection to consideration of a particular matter at the meeting that is not within the purpose or purposes described in the meeting notice, unless the stockholder objects to considering the matter when it is presented.

Section 6. Quorum; Adjournment.

(a) Unless otherwise provided by law, or in the Certificate of Incorporation, these By-laws or a resolution of the Directors requiring satisfaction of a greater quorum requirement for any voting group, a majority of the votes entitled to be cast on the matter by a voting group constitutes a quorum of that voting group for action on that matter. As used in these By-laws, a voting group includes all shares of one or more classes or series that, under the Certificate of Incorporation or the Delaware General Corporation Law, as in effect from time to time (the “DGCL”), are entitled to vote and to be counted together collectively on a matter at a meeting of stockholders. The announcement of a quorum by the officer presiding at the meeting shall constitute a conclusive determination that a quorum is present. The absence of such an announcement shall have no significance.

(b) A share once represented for any purpose at a meeting is deemed present for quorum purposes for the remainder of the meeting and for any adjournment of that meeting unless (1) the stockholder attends solely to object to lack of notice, defective notice or the conduct of the meeting on other grounds and does not vote the shares or otherwise consent that they are to be deemed present, or (2) in the case of an adjournment, a new record date is or shall be set for that adjourned meeting.

(c) If a quorum is not present or represented, the stockholders present or represented and entitled to vote at such meeting, by a majority vote, may adjourn the meeting from time to time, without notice other than announcement at the meeting until a quorum is present or represented. At any adjourned meeting at which there is a quorum, any business may be transacted which might have been transacted if the meeting had been held as originally called.

Section 7. Voting and Proxies.

(a) Unless the Certificate of Incorporation provide otherwise, each outstanding share, regardless of class, is entitled to one vote on each matter voted on at a stockholders’ meeting. Unless the Certificate of Incorporation provide otherwise, redeemable shares are not entitled to vote after notice of redemption is given to the holders and a sum sufficient to redeem the shares has been deposited with a bank, trust company, or other financial institution under an irrevocable obligation to pay the holders the redemption price upon surrender of the shares. Absent special circumstances, shares are not entitled to vote if they are owned, directly or indirectly, by another entity of which the corporation owns, directly or indirectly, a majority of the voting interests, unless such shares are held in a fiduciary capacity. The Corporation may establish procedures for voting by the beneficial owners of shares that are registered in the names of nominees.

(b) A stockholder may vote his or her shares in person or may appoint a proxy to vote or otherwise act for him or her by signing an appointment form, either personally or by his or her attorney-in-fact. An appointment of a proxy is effective when received by the Secretary or other officer or agent authorized to tabulate votes. Unless otherwise provided in the appointment form, an appointment is valid for a period of 11 months from the date the stockholder signed the form or, if it is undated, from the date of its receipt by the officer or agent. An appointment of a proxy is revocable by the stockholder unless the appointment form conspicuously states that it is irrevocable and the appointment is coupled with an interest, as defined in the DGCL. An appointment made irrevocable is revoked when the interest with which it is coupled is extinguished. The death or incapacity of the stockholder appointing a proxy shall not affect the right of the Corporation to accept the proxy’s authority unless notice of the death or incapacity is received by the Secretary or other officer or agent authorized to tabulate votes before the proxy exercises his or her authority under the appointment. A transferee for value of shares subject to an irrevocable appointment may revoke the appointment if he or she did not know of its existence when he or she acquired the shares and the existence of the irrevocable appointment was not noted conspicuously on the certificate representing the shares or on the information statement for shares without certificates. Subject to the provisions of the DGCL and to any express limitation on the proxy’s authority appearing on the face of the appointment form, the Corporation is entitled to accept the proxy’s vote or other action as that of the stockholder making the appointment.

Section 8. Action at Meeting. If a quorum of a voting group exists, favorable action on a matter, other than the election of Directors, is taken by a voting group if the votes cast within the group favoring the action exceed the votes cast opposing the action, unless a greater number of affirmative votes is required by law, or the Certificate of Incorporation, these By-laws or a resolution of the Board of Directors requiring receipt of a greater affirmative vote of the stockholders, including more separate voting groups. Directors are elected by a plurality of the votes cast by the shares entitled to vote in the election at a meeting at which a quorum is present. No ballot shall be required for such election or any other matter unless requested by a stockholder present or represented at the meeting and entitled to vote in the election.

Section 9. Action without Meeting by Written Consent.

(a) Action taken at a stockholders' meeting may be taken without a meeting if the action is taken either: (1) by all stockholders entitled to vote on the action; or (2) to the extent permitted by the Certificate of Incorporation, by stockholders having not less than the minimum number of votes necessary to take the action at a meeting at which all stockholders entitled to vote on the action are present and voting. The action shall be evidenced by one or more written consents that describe the action taken, are signed by stockholders having the requisite votes, bear the date of the signatures of such stockholders, and are delivered to the Corporation for inclusion with the records of meetings within 60 days of the earliest dated consent delivered to the Corporation as required by this Section. A consent signed under this Section has the effect of a vote at a meeting.

Section 10. Record Date. The Directors may fix the record date in order to determine the stockholders entitled to notice of a stockholders' meeting, to demand a special meeting, to vote, or to take any other action. If a record date for a specific action is not fixed by the Board of Directors, and is not supplied by law, the record date shall be the close of business either on the day before the first notice is sent to stockholders, or, if no notice is sent, on the day before the meeting or, in the case of action without a meeting by written consent, the date the first stockholder signs the consent. A record date fixed under this Section may not be more than 70 days before the meeting or action requiring a determination of stockholders. A determination of stockholders entitled to notice of or to vote at a stockholders' meeting is effective for any adjournment of the meeting unless the Board of Directors fixes a new record date, which it shall do if the meeting is adjourned to a date more than 120 days after the date fixed for the original meeting.

Section 11. Meetings by Remote Communications. Unless otherwise provided in the Certificate of Incorporation, if authorized by the Directors: any annual or special meeting of stockholders need not be held at any place but may instead be held solely by means of remote communication; and subject to such guidelines and procedures as the Board of Directors may adopt, stockholders and proxyholders not physically present at a meeting of stockholders may, by means of remote communications: (a) participate in a meeting of stockholders; and (b) be deemed present in person and vote at a meeting of stockholders whether such meeting is to be held at a designated place or solely by means of remote communication, provided that: (1) the Corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxyholder; (2) the Corporation shall implement reasonable measures to provide such stockholders and proxyholders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings; and (3) if any stockholder or proxyholder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the Corporation.

Section 12. Form of Stockholder Action.

(a) Any vote, consent, waiver, proxy appointment or other action by a stockholder or by the proxy or other agent of any stockholder shall be considered given in writing, dated and signed, if, in lieu of any other means permitted by law, it consists of an electronic transmission that sets forth or is delivered with information from which the Corporation can determine (i) that the electronic transmission was transmitted by the stockholder, proxy or agent or by a person authorized to act for the stockholder, proxy or agent; and (ii) the date on which such stockholder, proxy, agent or authorized person transmitted the electronic transmission. The date on which the electronic transmission is transmitted shall be considered to be the date on which it was signed. The electronic transmission shall be considered received by the Corporation if it has been sent to any address specified by the Corporation for the purpose or, if no address has been specified, to the principal office of the Corporation, addressed to the Secretary or other officer or agent having custody of the records of proceedings of stockholders.

(b) Any copy, facsimile or other reliable reproduction of a vote, consent, waiver, proxy appointment or other action by a stockholder or by the proxy or other agent of any stockholder may be substituted or used in lieu of the original writing for any purpose for which the original writing could be used, but the copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

Section 13. Stockholders List for Meeting.

(a) After fixing a record date for a stockholders' meeting, the Corporation shall prepare an alphabetical list of the names of all its stockholders who are entitled to notice of the meeting. The list shall be arranged by voting group, and within each voting group by class or series of shares, and show the address of and number of shares held by each stockholder, but need not include an electronic mail address or other electronic contact information for any stockholder.

(b) The stockholders list shall be available for inspection by any stockholder, beginning two business days after notice is given of the meeting for which the list was prepared and continuing through the meeting: (1) at the Corporation's principal office or at a place identified in the meeting notice in the city where the meeting will be held; or (2) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting. If the meeting is to be held solely by means of remote communication, the list shall be made available on an electronic network.

(c) A stockholder, his or her agent, or attorney is entitled on written demand to inspect and, subject to the requirements of Section 2(c) of Article VI of these By-laws, to copy the list, during regular business hours and at his or her expense, during the period it is available for inspection.

(d) The Corporation shall make the stockholders list available at the meeting, and any stockholder or his or her agent or attorney is entitled to inspect the list at any time during the meeting or any adjournment.

Section 14. Inspectors of Election. One or more inspectors may be appointed by the Board or Directors before or at each meeting of stockholders, or, if no such appointment shall have been made, the presiding officer may make such appointment at the meeting. At the meeting for which they are appointed, such inspectors shall open and close the polls, receive and take charge of the proxies and ballots, and decide all questions touching on the qualifications of voters, the validity of proxies and the acceptance and rejection of votes. If any inspector previously appointed shall fail to attend or refuse or be unable to serve, the presiding officer may appoint an inspector in his or her place.

ARTICLE II DIRECTORS

Section 1. Powers. All corporate power shall be exercised by or under the authority of, and the business and affairs of the Corporation shall be managed under the direction of, its Board of Directors, subject to any limitation set forth in the Certificate of Incorporation.

Section 2. Number and Election. The Board of Directors shall consist of one or more individuals. The number of directors who shall constitute the Board of Directors shall initially be equal to the number of directors elected by the incorporator of the Corporation. Thereafter, such number may be fixed by the stockholders at the annual meeting or by the Board of Directors, but, unless otherwise provided in the Certificate of Incorporation, if the Corporation has more than one stockholder, the number of Directors shall not be less than three, except that whenever there shall be only two stockholders, the number of Directors shall not be less than two. Except as otherwise provided in these By-laws or the Certificate of Incorporation, the Directors shall be elected by the stockholders at the annual meeting.

Section 3. Vacancies. If a vacancy occurs on the Board of Directors, including a vacancy resulting from an increase in the number of Directors: (a) the stockholders may fill the vacancy; (b) the Board of Directors may fill the vacancy; or (c) if the Directors remaining in office constitute fewer than a quorum of the Board, they may fill the vacancy by the affirmative vote of a majority of all the Directors remaining in office. A vacancy that will occur at a specific later date may be filled before the vacancy occurs but the new Director may not take office until the vacancy occurs. If the vacant office was held by a Director elected by a voting group of stockholders, only the holders of shares of that voting group or the Directors elected by that voting group are entitled to vote to fill the vacancy.

Section 4. Change in Size of the Board of Directors. The number of Directors may be fixed or changed from time to time by the stockholders or the Board of Directors, and the Board of Directors may increase or decrease the number of Directors last approved by the stockholders.

Section 5. Tenure. The terms of all Directors shall expire at the next annual stockholders' meeting following their election. A decrease in the number of Directors does not shorten an incumbent Director's term. The term of a Director elected to fill a vacancy shall expire at the next stockholders' meeting at which Directors are elected. Despite the expiration of a Director's term, he or she shall continue to serve until his or her successor is elected and qualified or until there is a decrease in the number of Directors.

Section 6. Resignation. A Director may resign at any time by delivering written notice of resignation to the Board of Directors, its chairman, or to the Corporation. A resignation is effective when the notice is delivered unless the notice specifies a later effective date.

Section 7. Removal. The stockholders may remove one or more Directors with or without cause but if a Director is elected by a voting group of stockholders, only the stockholders of that voting group may participate in the vote to remove him or her. A Director may be removed for cause by the Directors by vote of a majority of the Directors then in office but, if a Director is elected by a voting group of stockholders, only the Directors elected by that voting group may participate in the vote to remove him or her. A Director may be removed by the stockholders or the Directors only at a meeting called for the purpose of removing him or her, and the meeting notice must state that the purpose, or one of the purposes, of the meeting is removal of the Director.

Section 8. Regular and Annual Meetings.

(a) Regular meetings of the Board of Directors may be held at such times and places as shall from time to time be fixed by the Board of Directors, without notice of the date, time, place or purpose of the meeting.

(b) A meeting of the Board of Directors for the election of officers and the transaction of general business shall be held each year, at the place of and immediately after the final adjournment of the annual meeting of stockholders. No notice of such annual meeting need be given.

Section 9. Special Meetings. Special meetings of the Board of Directors may be called by the President, by the Secretary, by any two Directors, or by one Director in the event that there is only one Director.

Section 10. Notice. Special meetings of the Board must be preceded by at least two days' notice of the date, time and place of the meeting. The notice need not describe the purpose of the special meeting. All notices to directors shall conform to the requirements of Article II.

Section 11. Waiver of Notice. A Director may waive any notice before or after the date and time of the meeting. The waiver shall be in writing, signed by the Director entitled to the notice, or in the form of an electronic transmission by the Director to the Corporation, and filed with the minutes or corporate records. A Director's attendance at or participation in a meeting waives any required notice to him or her of the meeting unless the Director at the beginning of the meeting, or promptly upon his or her arrival, objects to holding the meeting or transacting business at the meeting and does not thereafter vote for or assent to action taken at the meeting.

Section 12. Quorum. A quorum of the Board of Directors consists of a majority of the Directors then in office, provided always that any number of Directors (whether one or more and whether or not constituting a quorum) constituting a majority of Directors present at any meeting or at any adjourned meeting may make any reasonable adjournment thereof.

Section 13. Action at Meeting. If a quorum is present when a vote is taken, the affirmative vote of a majority of Directors present is the act of the Board of Directors. A Director who is present at a meeting of the Board of Directors or a committee of the Board of Directors when corporate action is taken is considered to have assented to the action taken unless: (a) he or she objects at the beginning of the meeting, or promptly upon his or her arrival, to holding it or transacting business at the meeting;

(a) his or her dissent or abstention from the action taken is entered in the minutes of the meeting; or (c) he or she delivers written notice of his or her dissent or abstention to the presiding officer of the meeting before its adjournment or to the Corporation immediately after adjournment of the meeting. The right of dissent or abstention is not available to a Director who votes in favor of the action taken.

Section 14. Action Without Meeting. Any action required or permitted to be taken by the Directors may be taken without a meeting if the action is taken by the unanimous consent of the members of the Board of Directors. The action must be evidenced by one or more consents describing the action taken, in writing, signed by each Director, or delivered to the Corporation by electronic transmission, to the address specified by the Corporation for the purpose or, if no address has been specified, to the principal office of the Corporation, addressed to the Secretary or other officer or agent having custody of the records of proceedings of Directors, and included in the minutes or filed with the corporate records reflecting the action taken. Action taken under this Section is effective when the last Director signs or delivers the consent, unless the consent specifies a different effective date. A consent signed or delivered under this Section has the effect of a meeting vote and may be described as such in any document.

Section 15. Telephone Conference Meetings. The Board of Directors may permit any or all Directors to participate in a regular or special meeting by, or conduct the meeting through the use of, any means of communication by which all Directors participating may simultaneously hear each other during the meeting. A Director participating in a meeting by this means is considered to be present in person at the meeting.

Section 16. Committees. The Board of Directors may create one or more committees and appoint members of the Board of Directors to serve on them. Each committee may have one or more members, who serve at the pleasure of the Board of Directors. The creation of a committee and appointment of members to it must be approved by a majority of all the Directors in office when the action is taken. Article II and Sections 10 through 15 of this Article shall apply to committees and their members. To the extent specified by the Board of Directors, each committee may exercise the authority of the Board of Directors. A committee may not, however: (a) authorize distributions; (b) approve or propose to stockholders action that the DGCL requires be approved by stockholders; (c) change the number of the Board of Directors, remove Directors from office or fill vacancies on the Board of Directors; (d) amend the Certificate of Incorporation; (e) adopt, amend or repeal By-laws; or (f) authorize or approve reacquisition of shares, except according to a formula or method prescribed by the Board of Directors. The creation of, delegation of authority to, or action by a committee does not alone constitute compliance by a Director with the standards of conduct described in Section 18 of this Article.

Section 17. Compensation. The Board of Directors may fix the compensation of Directors.

Section 18. Standard of Conduct for Directors.

(a) A Director shall discharge his or her duties as a Director, including his or her duties as a member of a committee: (1) in good faith; (2) with the care that a person in a like position would reasonably believe appropriate under similar circumstances; and (3) in a manner the Director reasonably believes to be in the best interests of the Corporation. In determining what the Director reasonably believes to be in the best interests of the Corporation, a Director may consider the interests of the Corporation's employees, suppliers, creditors and customers, the economy of the state, the region and the nation, community and societal considerations, and the long-term and short-term interests of the Corporation and its stockholders, including the possibility that these interests may be best served by the continued independence of the Corporation.

(b) In discharging his or her duties, a Director who does not have knowledge that makes reliance unwarranted is entitled to rely on information, opinions, reports, or statements, including financial statements and other financial data, if prepared or presented by: (1) one or more officers or employees of the Corporation whom the Director reasonably believes to be reliable and competent with respect to the information, opinions, reports or statements presented; (2) legal counsel, public accountants, or other persons retained by the Corporation, as to matters involving skills or expertise the Director reasonably believes are matters (i) within the particular person's professional or expert competence or (ii) as to which the particular person merits confidence; or (3) a committee of the Board of Directors of which the Director is not a member if the Director reasonably believes the committee merits confidence.

(c) A Director is not liable for any action taken as a Director, or any failure to take any action, if he or she performed the duties of his or her office in compliance with this Section.

Section 19. Conflict of Interest.

(a) A conflict of interest transaction is a transaction with the Corporation in which a Director of the Corporation has a material direct or indirect interest. A conflict of interest transaction is not voidable by the Corporation solely because of the Director's interest in the transaction so long as any one of the following is true:

(b) the material facts of the transaction and the Director's interest were disclosed or known to the Board of Directors or a committee of the Board of Directors and the Board of Directors or committee authorized, approved, or ratified the transaction;

the material facts of the transaction and the Director's interest were disclosed or known to the stockholders entitled to vote and they authorized, approved, or ratified the transaction; or

the transaction was fair to the Corporation.

(c) For purposes of this Section, and without limiting the interests that may create conflict of interest transactions, a Director of the Corporation has an indirect interest in a transaction if: (1) another entity in which he or she has a material financial interest or in which he or she is a general partner is a party to the transaction; or (2) another entity of which he or she is a director, officer, or trustee or in which he or she holds another position is a party to the transaction and the transaction is or should be considered by the Board of Directors of the Corporation.

(d) For purposes of clause (1) of subsection (a), a conflict of interest transaction is authorized, approved, or ratified if it receives the affirmative vote of a majority of the Directors on the Board of Directors (or on the committee) who have no direct or indirect interest in the transaction, but a transaction may not be authorized, approved, or ratified under this Section by a single Director. If a majority of the Directors who have no direct or indirect interest in the transaction vote to authorize, approve, or ratify the transaction, a quorum is present for the purpose of taking action under this Section. The presence of, or a vote cast by, a Director with a direct or indirect interest in the transaction does not affect the validity of any action taken under clause (1) of subsection (a) if the transaction is otherwise authorized, approved, or ratified as provided in that subsection.

(e) For purposes of clause (2) of subsection (a), a conflict of interest transaction is authorized, approved, or ratified if it receives the vote of a majority of the shares entitled to be counted under this subsection. Shares owned by or voted under the control of a Director who has a direct or indirect interest in the transaction, and shares owned by or voted under the control of an entity described in clause (1) of subsection (b), may not be counted in a vote of stockholders to determine whether to authorize, approve, or ratify a conflict of interest transaction under clause (2) of subsection (a). The vote of those shares, however, shall be counted in determining whether the transaction is approved under other Sections of these By-laws. A majority of the shares, whether or not present, that are entitled to be counted in a vote on the transaction under this subsection constitutes a quorum for the purpose of taking action under this Section.

Section 20. Loans to Directors. The Corporation may not lend money to, or guarantee the obligation of, a Director of, the Corporation unless:

(a) the specific loan or guarantee is approved by a majority of the votes represented by the outstanding voting shares of all classes, voting as a single voting group, except the votes of shares owned by or voted under the control of the benefited Director; or (b) the Corporation's Board of Directors determines that the loan or guarantee benefits the Corporation and either approves the specific loan or guarantee or a general plan authorizing loans and guarantees. The fact that a loan or guarantee is made in violation of this Section shall not affect the borrower's liability on the loan.

**ARTICLE III
MANNER OF NOTICE**

All notices under these By-laws shall conform to the following requirements:

Section 1. Notice shall be in writing unless oral notice is reasonable under the circumstances. Notice by electronic transmission is written notice.

Section 2. Notice may be communicated in person; by telephone, voice mail, telegraph, teletype, or other electronic means; by mail; by electronic transmission; or by messenger or delivery service. If these forms of personal notice are impracticable, notice may be communicated by a newspaper of general circulation in the area where published; or by radio, television, or other form of public broadcast communication.

Section 3. Written notice, other than notice by electronic transmission, to any stockholder, if in a comprehensible form, is effective upon deposit in the United States mail, if mailed postpaid and correctly addressed to the stockholder's address shown in the Corporation's current record of stockholders.

Section 4. Written notice by electronic transmission, if in comprehensible form, is effective: (1) if by facsimile telecommunication, when directed to a number furnished by the stockholder or other recipient for the purpose; (2) if by electronic mail, when directed to an electronic mail address furnished by the stockholder or other recipient for the purpose; (3) if by a posting on an electronic network together with separate notice to the stockholder or other recipient of such specific posting, directed to an electronic mail address furnished by the stockholder or other recipient for the purpose, upon the later of (i) such posting and (ii) the giving of such separate notice; and (4) if by any other form of electronic transmission, when directed to the stockholder or other recipient in such manner as the stockholder or other recipient shall have specified to the Corporation. An affidavit of the Secretary or an Assistant Secretary of the Corporation, the transfer agent or other agent of the Corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Section 5. Except as provided in subsection (c), written notice, other than notice by electronic transmission, if in a comprehensible form, is effective at the earliest of the following:

Section 6. when received; (2) five days after its deposit in the United States mail, if mailed postpaid and correctly addressed; (3) on the date shown on the return receipt, if sent by registered or certified mail, return receipt requested; or if sent by messenger or delivery service, on the date shown on the return receipt signed by or on behalf of the addressee; or (4) on the date of publication if notice by publication is permitted.

Section 7. Oral notice is effective when communicated if communicated in a comprehensible manner.

**ARTICLE IV
OFFICERS**

Section 1. Enumeration. The Corporation shall have a President, a Treasurer, a Secretary and such other officers as may be appointed by the Board of Directors from time to time in accordance with these By-laws. The Board may appoint one of its members to the office of Chairman of the Board and from time to time define the powers and duties of that office notwithstanding any other provisions of these By-laws.

Section 2. Appointment. The officers shall be appointed by the Board of Directors. A duly appointed officer may appoint one or more officers or assistant officers if authorized by the Board of Directors. Each officer has the authority and shall perform the duties set forth in these By-laws or, to the extent consistent with these By-laws, the duties prescribed by the Board of Directors or by direction of an officer authorized by the Board of Directors to prescribe the duties of other officers.

Section 3. Qualification. The same individual may simultaneously hold more than one office in the Corporation.

Section 4. Tenure. Officers shall hold office until the first meeting of the Directors following the next annual meeting of stockholders after their appointment and until their respective successors are duly appointed, unless a shorter or longer term is specified in the vote appointing them.

Section 5. Resignation. An officer may resign at any time by delivering notice of the resignation to the Corporation. A resignation is effective when the notice is delivered unless the notice specifies a later effective date. If a resignation is made effective at a later date and the Corporation accepts the future effective date, the Board of Directors may fill the pending vacancy before the effective date if the Board of Directors provides that the successor shall not take office until the effective date. An officer's resignation shall not affect the Corporation's contract rights, if any, with the officer.

Section 6. Removal. The Board of Directors may remove any officer at any time with or without cause. The appointment of an officer shall not itself create contract rights. An officer's removal shall not affect the officer's contract rights, if any, with the Corporation.

Section 7. President. If there is no Chairman of the Board of Directors, the President when present shall preside at all meetings of the stockholders and of the Directors. He or she shall be the chief executive officer of the Corporation except as the Board of Directors may otherwise provide. The President shall perform such duties and have such powers additional to the foregoing as the Directors shall designate.

Section 8. Treasurer. The Treasurer shall, subject to the direction of the Directors, have general charge of the financial affairs of the Corporation and shall cause to be kept accurate books of accounts. He or she shall have custody of all funds, securities, and valuable documents of the Corporation, except as the Directors may otherwise provide. The Treasurer shall perform such duties and have such powers additional to the foregoing as the Directors may designate.

Section 9. Secretary. The Secretary shall have responsibility for preparing minutes of the Directors' and stockholders' meetings and for authenticating records of the Corporation. The Secretary shall perform such duties and have such powers additional to the foregoing as the Directors shall designate.

Section 10. Standards Of Conduct For Officers. An officer shall discharge his or her duties:

(a) in good faith; (b) with the care that a person in a like position would reasonably exercise under similar circumstances; and (c) in a manner the officer reasonably believes to be in the best interests of the Corporation. In discharging his or her duties, an officer who does not have knowledge that makes reliance unwarranted is entitled to rely on information, opinions, reports, or statements, including financial statements and other financial data, if prepared or presented by: (1) one or more officers or employees of the Corporation whom the officer reasonably believes to be reliable and competent with respect to the information, opinions, reports or statements presented; or (2) legal counsel, public accountants, or other persons retained by the Corporation as to matters involving skills or expertise the officer reasonably believes are matters (i) within the particular person's professional or expert competence or (ii) as to which the particular person merits confidence. An officer shall not be liable to the Corporation or its stockholders for any decision to take or not to take any action taken, or any failure to take any action, as an officer, if the duties of the officer are performed in compliance with this Section.

ARTICLE V
PROVISIONS RELATING TO SHARES AND SECURITIES

Section 1. Issuance and Consideration. The Board of Directors may issue the number of shares of each class or series authorized by the Certificate of Incorporation. The Board of Directors may authorize shares to be issued for consideration consisting of any tangible or intangible property or benefit to the Corporation, including cash, promissory notes, services performed, contracts for services to be performed, or other securities of the Corporation. Before the Corporation issues shares, the Board of Directors shall determine that the consideration received or to be received for shares to be issued is adequate. The Board of Directors shall determine the terms upon which the rights, options, or warrants for the purchase of shares or other securities of the Corporation are issued and the terms, including the consideration, for which the shares or other securities are to be issued.

Section 2. Stock Certificates. If shares are represented by certificates, at a minimum each stock certificate shall state on its face: (a) the name of the Corporation and that it is organized under the laws of the State of Delaware; (b) the name of the person to whom issued; and (c) the number and class of shares and the designation of the series, if any, the certificate represents. If different classes of shares or different series within a class are authorized, then the variations in rights, preferences and limitations applicable to each class and series, and the authority of the Board of Directors to determine variations for any future class or series, must be summarized on the front or back of each certificate. Alternatively, each certificate may state conspicuously on its front or back that the Corporation will furnish the stockholder this information on request in writing and without charge. Each stock certificate shall be signed, either manually or in facsimile, by the President or a Vice President and by the Treasurer or an Assistant Treasurer, or any two officers designated by the Board of Directors, and shall bear the corporate seal or its facsimile. If the person who signed, either manually or in facsimile, a stock certificate no longer holds office when the certificate is issued, the certificate shall be nevertheless valid.

Section 3. Uncertificated Shares. The Board of Directors may authorize the issue of some or all of the shares of any or all of the Corporation's classes or series without certificates. The authorization shall not affect shares already represented by certificates until they are surrendered to the Corporation. Within a reasonable time after the issue or transfer of shares without certificates, the Corporation shall send the stockholder a written statement of the information required by the DGCL to be on certificates.

Section 4. Record and Beneficial Owners. The Corporation shall be entitled to treat as the stockholder the person in whose name shares are registered in the records of the Corporation or, if the Board of Directors has established a procedure by which the beneficial owner of shares that are registered in the name of a nominee will be recognized by the Corporation as a stockholder, the beneficial owner of shares to the extent of the rights granted by a nominee certificate on file with the Corporation.

Section 5. Lost or Destroyed Certificates. The Board of Directors of the Corporation may, subject to the DGCL, determine the conditions upon which a new stock certificate may be issued in place of any certificate alleged to have been lost, destroyed, or wrongfully taken. The Board of Directors may, in its discretion, require the owner of such stock certificate, or his or her legal representative, to give a bond, sufficient in its opinion, with or without surety, to indemnify the Corporation against any loss or claim which may arise by reason of the issue of the new certificate.

Section 6. Transfer of Shares. Subject to any transfer restrictions then in force, the shares of stock of the Corporation shall be transferable only upon its books by the holders thereof in person or by their duly authorized attorneys or legal representatives. In the case of shares represented by certificates, such transfer shall be effected by delivery of the old certificate, together with a duly executed assignment and power to transfer endorsed thereon or attached thereto and with such proof of the authenticity of the signature and such proof of authority to make the transfer as the Corporation or its agents may reasonably require, to the person in charge of the stock and transfer books and ledgers or to such other person as the Board of Directors may designate, who shall thereupon cancel the old certificate and issue a new certificate.

Section 7. Voting of Securities owned by this Corporation. Subject always to the specific directions of the Board of Directors, (i) any shares or other securities issued by any other corporation or entity and owned or controlled by this Corporation may be voted in person at any meeting of security holders of such other corporation or entity by the President of this Corporation if he or she is present at such meeting, or in his or her absence by the Treasurer of this Corporation if he or she is present at such meeting, and (ii) whenever, in the judgment of the President, it is desirable for this Corporation to execute a proxy or written consent in respect to any shares or other securities issued by any other corporation or entity and owned by this Corporation, such proxy or consent shall be executed in the name of this Corporation by the President, without the necessity of any authorization by the Board of Directors, affixation of corporate seal or countersignature or attestation by another officer, provided that if the President is unable to execute such proxy or consent by reason of sickness, absence from the offices of this Corporation or other similar case, the Treasurer may execute such proxy or consent. Any person or persons designated in the manner above stated as the proxy or proxies of this Corporation shall have full right, power and authority to vote the shares or other securities issued by such other corporation or entity and owned by this Corporation.

ARTICLE VI CORPORATE RECORDS

Section 1. Records to be Kept.

(a) The Corporation shall keep as permanent records minutes of all meetings of its stockholders and Board of Directors, a record of all actions taken by the stockholders or Board of Directors without a meeting, and a record of all actions taken by a committee of the Board of Directors in place of the Board of Directors on behalf of the Corporation. The Corporation shall maintain appropriate accounting records. The Corporation or its agent shall maintain a record of its stockholders, in a form that permits preparation of a list of the names and addresses of all stockholders, in alphabetical order by class of shares showing the number and class of shares held by each. The Corporation shall maintain its records in written form or in another form capable of conversion into written form within a reasonable time.

(b) The Corporation shall keep within the State of Delaware a copy of the following records at its principal office or an office of its transfer agent or of its Secretary or Assistant Secretary or of its registered agent:

- (1) its Certificate of Incorporation and all amendments to them currently in effect;

- (2) its By-laws or restated By-laws and all amendments to them currently in effect;
- (3) resolutions adopted by its Board of Directors creating one or more classes or series of shares, and fixing their relative rights, preferences, and limitations, if shares issued pursuant to those resolutions are outstanding;
- (4) the minutes of all stockholders' meetings, and records of all action taken by stockholders without a meeting, for the past three years;
- (5) all written communications to stockholders generally within the past three years, including the financial statements furnished under the DGCL for the past three years;
- (6) a list of the names and business addresses of its current Directors and officers; and
- (7) its most recent annual report delivered to the Delaware Secretary of State.

Section 2. Inspection of Records by Stockholders.

(a) A stockholder is entitled to inspect and copy, during regular business hours at the office where they are maintained pursuant to Section 1(b) of this Article, copies of any of the records of the Corporation described in said Section, if he or she gives the Corporation written notice of his or her demand at least five business days before the date on which he or she wishes to inspect and copy.

(b) A stockholder is entitled to inspect and copy, during regular business hours at a reasonable location specified by the Corporation, any of the following records of the Corporation if the stockholder meets the requirements of subsection (c) and gives the Corporation written notice of his or her demand at least five business days before the date on which he or she wishes to inspect and copy:

- (1) excerpts from minutes reflecting action taken at any meeting of the Board of Directors, records of any action of a committee of the Board of Directors while acting in place of the Board of Directors on behalf of the Corporation, minutes of any meeting of the stockholders, and records of action taken by the stockholders or Board of Directors without a meeting, to the extent not subject to inspection under subsection (a) of this Section;
- (2) accounting records of the Corporation, but if the financial statements of the Corporation are audited by a certified public accountant, inspection shall be limited to the financial statements and the supporting schedules reasonably necessary to verify any line item on those statements; and
- (3) the record of stockholders described in Section 1(a) of this Article.

(c) A stockholder may inspect and copy the records described in subsection (b) only if:

- (1) his or her demand is made in good faith and for a proper purpose;

- (2) he or she describes with reasonable particularity his or her purpose and the records he or she desires to inspect;
- (3) the records are directly connected with his or her purpose; and
- (4) the Corporation shall not have determined in good faith that disclosure of the records sought would adversely affect the Corporation in the conduct of its business.

(d) For purposes of this Section, “stockholder” includes a beneficial owner whose shares are held in a voting trust or by a nominee on his or her behalf.

Section 3. Scope of Inspection Right.

(a) A stockholder’s agent or attorney has the same inspection and copying rights as the stockholder represented.

(b) The Corporation may, if reasonable, satisfy the right of a stockholder to copy records under Section 2 of this Article by furnishing to the stockholder copies by photocopy or other means chosen by the Corporation including copies furnished through an electronic transmission.

(c) The Corporation may impose a reasonable charge, covering the costs of labor, material, transmission and delivery, for copies of any documents provided to the stockholder. The charge may not exceed the estimated cost of production, reproduction, transmission or delivery of the records.

(d) The Corporation may comply, at its own expense, with a stockholder’s demand to inspect the record of stockholders under Section 2(b) (3) of this Article by providing the stockholder with a list of stockholders that was compiled no earlier than the date of the stockholder’s demand.

(e) The Corporation may impose reasonable restrictions on the use or distribution of records by the demanding stockholder.

Section 4. Inspection of Records by Directors. A Director is entitled to inspect and copy the books, records and documents of the Corporation at any reasonable time to the extent reasonably related to the performance of the Director’s duties as a Director, including duties as a member of a committee, but not for any other purpose or in any manner that would violate any duty to the Corporation.

ARTICLE VII INDEMNIFICATION

Section 1. Definitions. In this Article the following words shall have the following meanings unless the context requires otherwise:

(a) “Corporation”, shall mean Beta Bionics, Inc. and includes any domestic or foreign predecessor entity of the Corporation in a merger.

(b) “Director” or “officer”, an individual who is or was a Director or officer, respectively, of the Corporation or who, while a Director or officer of the Corporation, is or was serving at the Corporation’s request as a director, officer, partner, trustee, employee, or agent of another domestic or foreign corporation, partnership, joint venture, trust, employee benefit plan, or other entity. A Director or officer is considered to be serving an employee benefit plan at the Corporation’s request if his or her duties to the Corporation also impose duties on, or otherwise involve services by, him or her to the plan or to participants in or beneficiaries of the plan. “Director” or “officer” includes, unless the context requires otherwise, the estate or personal representative of a Director or officer.

(c) “Disinterested Director”, a Director who, at the time of a vote or selection referred to in Section 4 of this Article, is not (i) a party to the proceeding, or (ii) an individual having a familial, financial, professional, or employment relationship with the Director whose indemnification or advance for expenses is the subject of the decision being made, which relationship would, in the circumstances, reasonably be expected to exert an influence on the Director’s judgment when voting on the decision being made.

(d) “Expenses”, includes counsel fees.

(e) “Liability”, the obligation to pay a judgment, settlement, penalty, fine including an excise tax assessed with respect to an employee benefit plan, or reasonable expenses incurred with respect to a proceeding.

(f) “Party”, an individual who was, is, or is threatened to be made, a defendant or respondent in a proceeding.

(g) “Proceeding”, any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, arbitative, or investigative and whether formal or informal.

Section 2. Indemnification of Directors and Officers.

(a) Except as otherwise provided in this Section, the Corporation shall indemnify to the fullest extent permitted by law an individual who is a party to a proceeding because he or she is a Director or officer against liability incurred in the proceeding if: (1) (i) he or she conducted himself or herself in good faith; and (ii) he or she reasonably believed that his or her conduct was in the best interests of the Corporation or that his or her conduct was at least not opposed to the best interests of the Corporation; and (iii) in the case of any criminal proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful; or (2) he or she engaged in conduct for which he or she shall not be liable under a provision of the Certificate of Incorporation authorized by the DGCL.

(b) A Director’s or officer’s conduct with respect to an employee benefit plan for a purpose he or she reasonably believed to be in the interests of the participants in, and the beneficiaries of, the plan is conduct that satisfies the requirement that his or her conduct was at least not opposed to the best interests of the Corporation.

(c) The termination of a proceeding by judgment, order, settlement, or conviction, or upon a plea of nolo contendere or its equivalent, is not, of itself, determinative that the Director or officer did not meet the relevant standard of conduct described in this Section.

(d) Unless ordered by a court, the Corporation may not indemnify a Director or officer under this Section if his or her conduct did not satisfy the standards set forth in subsection (a) or subsection (b).

Section 3. Advance for Expenses. The Corporation shall, before final disposition of a proceeding, advance funds to pay for or reimburse the reasonable expenses incurred by a Director or officer who is a party to a proceeding because he or she is a Director or officer, if he or she delivers to the Corporation:

(a) a written affirmation of his or her good faith belief that he or she has met the relevant standard of conduct described in Section 2 of this Article or that the proceeding involves conduct for which liability has been eliminated under a provision of the Certificate of Incorporation as authorized by the DGCL; and

(b) his or her written undertaking to repay any funds advanced if he or she is not wholly successful, on the merits or otherwise, in the defense of such proceeding and it is ultimately determined pursuant to Section 4 of this Article or by a court of competent jurisdiction that he or she has not met the relevant standard of conduct described in Section 2 of this Article. Such undertaking must be an unlimited general obligation of the Director or officer but need not be secured and shall be accepted without reference to the financial ability of the Director or officer to make repayment.

Section 4. Determination of Indemnification. The determination of whether a Director or officer has met the relevant standard of conduct set forth in Section 2, which shall be made reasonably promptly after the Director or officer makes a claim for indemnification pursuant to this Article, shall be made:

(a) if there are two or more disinterested Directors, by the Board of Directors by a majority vote of all the disinterested Directors, a majority of whom shall for such purpose constitute a quorum, or by a majority of the members of a committee of two or more disinterested Directors appointed by vote;

(b) by special legal counsel (1) selected in the manner prescribed in clause (a); or (2) if there are fewer than two disinterested Directors, selected by the Board of Directors, in which selection Directors who do not qualify as disinterested Directors may participate; or

(c) by the stockholders, but shares owned by or voted under the control of a Director who at the time does not qualify as a disinterested Director may not be voted on the determination.

Section 5. Notification and Defense of Claim; Actions against the Corporation.

(a) Except to the extent otherwise required by law, the person asserting, or proposing to assert, the right to be indemnified, must notify the Corporation in writing as soon as practicable of any proceeding involving such person for which indemnity will or could be sought, but the failure to so notify shall not affect the Corporation's obligation to indemnify except to the extent the Corporation as a result loses substantive rights or defenses. With respect to any proceeding of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to such person. After notice from the Corporation to such person of its election so to assume such defense, the Corporation shall not be liable to such person for any legal or other expenses subsequently incurred by such person in connection with such proceeding other than as provided below in this subsection (a). Such person shall have the right to employ his or her own counsel in connection with such proceeding, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of such person unless (1) the employment of counsel by such person has been authorized by the Corporation,

(b) counsel to such person shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and such person in the conduct of the defense of such proceeding, or (3) the Corporation shall not in fact have employed counsel to assume the defense of such proceeding, in each of which cases the fees and expenses of counsel for such person shall be at the expense of the Corporation, except as otherwise expressly provided by this Article. The Corporation shall not be entitled, without the consent of such person, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for such person shall have reasonably made the conclusion provided for in clause (2) above.

(c) Notwithstanding anything to the contrary in this Article, except as set forth below in this subsection (b), the Corporation shall not indemnify or advance expenses to a Director or officer seeking indemnification or advancement in connection with a proceeding (or a part thereof) initiated by the Director or officer, unless the initiation thereof was approved by the Board of Directors of the Corporation. The right to indemnification or advancement of expenses granted by this Article shall be enforceable by a Director or officer in any court of competent jurisdiction if the Corporation denies a request for same, in whole or in part, or fails to make the determination provided for by Section 4 of this Article reasonably promptly after the Director or officer makes a claim. The expenses of a Director or officer incurred in connection with successfully establishing his or her right to indemnification or advancement of expenses, in whole or in part, in any such action shall also be paid by the Corporation.

Section 6. Insurance. The Corporation may purchase and maintain insurance on behalf of an individual who is a Director or officer of the Corporation, or who, while a Director or officer of the Corporation, serves at the Corporation's request as a director, officer, partner, trustee, employee, or agent of another domestic or foreign corporation, partnership, joint venture, trust, employee benefit plan, or other entity, against liability asserted against or incurred by him or her in that capacity or arising from his or her status as a Director or officer, whether or not the Corporation would have power to indemnify or advance expenses to him or her against the same liability under this Article.

Section 7. Application of this Article.

(a) The Corporation shall not be obligated to indemnify or advance expenses to a Director or officer of a predecessor of the Corporation, pertaining to conduct with respect to the predecessor, unless otherwise specifically provided.

(b) This Article shall not limit the Corporation's power to (1) pay or reimburse expenses incurred by a Director or an officer in connection with his or her appearance as a witness in a proceeding at a time when he or she is not a party or (2) indemnify, advance expenses to or provide or maintain insurance on behalf of an employee or agent.

(c) The indemnification and advancement of expenses provided by, or granted pursuant to, this Article shall not be considered exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled.

(d) Each person who is or becomes a Director or officer shall be deemed to have served or to have continued to serve in such capacity in reliance upon the indemnity provided for in this Article. All rights to indemnification under this Article shall be deemed to be provided by a contract between the Corporation and the person who serves as a Director or officer of the Corporation at any time while these By-laws and the relevant provisions of the DGCL are in effect. Any repeal or modification thereof shall not affect any rights or obligations then existing.

(e) If the laws of the State of Delaware are hereafter amended from time to time to increase the scope of permitted indemnification, indemnification hereunder shall be provided to the fullest extent permitted or required by any such amendment.

ARTICLE VIII FISCAL YEAR; OFFICES; SEAL

Section 1. The fiscal year of the Corporation shall be the year ending with December 31 in each year.

Section 2. The principal office of the Corporation shall be where the principal executive offices of the corporation are located, and shall be at such place, within or without the State of Delaware, as the Board of Directors may from time to time determine. The Corporation may also have offices at such other place or places within or without the State of Delaware as the Board of Directors may from time to time determine or the business of the corporation may require.

Section 3. The seal of the Corporation shall be in the form of a circle inscribed with the name of the Corporation, the year of its incorporation and the word "Delaware". To the extent not prohibited by law, a facsimile of the corporate seal may be affixed or reproduced.

ARTICLE IX AMENDMENTS

Section 1. The power to make, amend or repeal these By-laws shall be in the stockholders. If authorized by the Certificate of Incorporation, the Board of Directors may also make, amend or repeal these By-laws in whole or in part, except with respect to any provision thereof which by virtue of an express provision in the DGCL, the Certificate of Incorporation, or these By-laws, requires action by the stockholders.

Section 2. Not later than the time of giving notice of the meeting of stockholders next following the making, amending or repealing by the Board of Directors of any By-Law, notice stating the substance of the action taken by the Board of Directors shall be given to all stockholders entitled to vote on amending the By-laws. Any action taken by the Board of Directors with respect to the By-laws may be amended or repealed by the stockholders.

Section 3. Approval of an amendment to the By-laws that changes or deletes a quorum or voting requirement for action by stockholders must satisfy both the applicable quorum and voting requirements for action by stockholders with respect to amendment of these By-laws and also the particular quorum and voting requirements sought to be changed or deleted.

Section 4. A By-Law dealing with quorum or voting requirements for stockholders, including additional voting groups, may not be adopted, amended or repealed by the Board of Directors.

Section 5. A By-Law that fixes a greater or lesser quorum requirement for action by the Board of Directors, or a greater voting requirement, than provided for by the DGCL may be amended or repealed by the stockholders, or by the Board of Directors if authorized pursuant to subsection (a).

Section 6. If the Board of Directors is authorized to amend the By-laws, approval by the Board of Directors of an amendment to the By-laws that changes or deletes a quorum or voting requirement for action by the Board of Directors must satisfy both the applicable quorum and voting requirements for action by the Board of Directors with respect to amendment of the By- laws, and also the particular quorum and voting requirements sought to be changed or deleted.

BETA BIONICS, INC.
AMENDED AND RESTATED
2016 STOCK INCENTIVE PLAN

Adopted by the Board of Directors: August 30, 2024

Approved by the Stockholders: August 30, 2024

1. **Purposes of the Plan.** The purposes of this Stock Incentive Plan of Beta Bionics, Inc., a Delaware corporation (the “**Company**”) are to attract and retain the best available personnel; to provide additional incentive to Employees, Directors, and Consultants; and to promote the success of the Company’s business.

2. **Definitions.** As used herein, the following definitions shall apply:

2.1 “**Administrator**” means the Board of Directors or any committee appointed by the Board to administer the Plan.

2.2 “**Applicable Laws**” means the legal requirements relating to the administration of stock incentive plans, if any, under applicable provisions of federal and state securities laws, the corporate laws of Delaware, the rules of any applicable stock exchange or national market system, and the rules of any foreign jurisdiction applicable to Awards granted to residents of that jurisdiction.

2.3 “**Award**” means the grant of an Option, Restricted Stock, or other right or benefit under the Plan.

2.4 “**Award Agreement**” means the written agreement evidencing the grant of an Award executed by the Company and the Grantee, including any amendments thereto.

2.5 “**Board**” means the Board of Directors of the Company.

2.6 “**Cause**” shall have the same meaning as such term is expressly defined in the then-effective written agreement between the Grantee and the Company or a Related Entity with respect to the termination by the Company or a Related Entity of the Grantee’s Continuous Service (unless a different definition is specified in the Award Agreement). In the absence of such a then-effective written agreement or definition, “Cause” shall mean that such termination is based on, in the determination of the Administrator, the Grantee’s: (i) refusal or failure to act in accordance with any specific, lawful direction or order of the Company or Grantee’s employer; (ii) performance of any act or failure to perform any act in bad faith and to the material detriment of the Company or Grantee’s employer; (iii) dishonesty, intentional misconduct, or material breach of any agreement with the Company or Grantee’s employer; or

(iv) commission of embezzlement, misappropriation of trade secrets, or any felony involving dishonesty, breach of trust, or physical or emotional harm to any person. At least 14 calendar days before the termination of the Grantee’s Continuous Service under (i) above, the Company shall provide the Grantee with notice of the Company’s or such Related Entity’s intent to terminate, the reason therefor, and an opportunity for the Grantee to cure such defects in his or her service to the Company’s or such Related Entity’s satisfaction. During this 14-day (or longer) period, no Award issued to the Grantee under the Plan may be exercised or purchased.

2.7 “**Code**” means the Internal Revenue Code of 1986, as amended, including the applicable regulations.

2.8 “**Common Stock**” means the Company’s Class B Common Stock and no other class or series of stock.

2.9 “**Company**” means Beta Bionics, Inc., a Delaware corporation.

2.10 “**Consultant**” means any person (other than an Employee or a Director, solely with respect to rendering services in such person’s capacity as a Director) who is engaged by the Company or any Related Entity to render services to the Company or such Related Entity as an independent contractor.

2.11 “**Continuous Service**” means that the provision of services to the Company or a Related Entity in any capacity of Employee, Director, or Consultant is not interrupted or terminated. Continuous Service shall not be considered interrupted in the case of (i) any approved leave of absence; (ii) transfers among the Company and any Related Entity, in any capacity of Employee, Director, or Consultant; (iii) transfers to any successor to the Company’s business or assets in any Corporate Transaction or to any Parent, Subsidiary, or similar related entity of such successor, in any capacity of Employee, Director, or Consultant, to the extent determined by the Administrator; or (iv) any change in status as long as the individual remains in the service of the Company or a Related Entity in any capacity of Employee, Director, or Consultant (except as otherwise provided in the Award Agreement). An approved leave of absence shall include sick leave, military leave, or any other authorized personal leave. For purposes of Incentive Stock Options, no such leave may exceed 90 days, unless reemployment on expiration of such leave is guaranteed by statute or contract. The Administrator may, in its discretion, determine that the transfer of a Grantee to an entity that does not qualify as a Related Entity shall not terminate the Grantee’s Continuous Service.

2.12 “**Corporate Transaction**” means any of the following transactions to which the Company is a party:

(a) A merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated or to create a holding company that will be owned, directly or indirectly, by the persons who held the securities immediately before such transaction;

(b) The sale, transfer, or other disposition of all or substantially all of the assets of the Company (including the capital stock of the Company’s subsidiary corporations) in connection with the complete liquidation or dissolution of the Company;

(c) Any reverse merger in which the Company is the surviving entity but in which securities possessing more than 50 percent of the total combined voting power of the Company’s outstanding securities are transferred to persons different from those who held such securities immediately before such merger, but excluding any such transition if the Administrator determines that such transaction shall not be a Corporate Transaction; or

(d) Acquisition by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of SEC Rule 13d–3 under the Exchange Act, as defined below) of securities possessing more than 50 percent of the total combined voting power of the Company’s outstanding securities, but excluding any such transaction if (A) such transaction is a debt or equity financing transaction that is approved by the Board, (B) such transaction is a public offering, or (C) the Administrator determines that such transaction shall not be a Corporate Transaction.

2.13 “**Director**” means a member of the Board or the board of directors of any Related Entity.

2.14 “**Disability**” means that a Grantee would qualify for benefit payments under the long-term disability policy of the Company or the Related Entity to which the Grantee provides services regardless of whether the Grantee is covered by such policy, provided, however, that if no such policy is in effect, Disability shall mean that a Grantee is permanently unable to carry out the responsibilities and functions of the position held by the Grantee by reason of any medically determinable physical or mental impairment. A Grantee will not be considered to have incurred a Disability unless he or she furnishes proof of such impairment sufficient to satisfy the Administrator in its discretion.

2.15 “**Employee**” means any person, including an Officer or Director, who is an employee of the Company or any Related Entity. The payment of a director’s fee by the Company or a Related Entity shall not be sufficient to constitute “employment” by the Company.

2.16 “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

2.17 “**Fair Market Value**” means, as of any date, the value of Common Stock determined as follows:

(a) If there exists a public market for the Common Stock, the Fair Market Value shall be determined by the Administrator in accordance with applicable law and in a manner consistent with the requirements of §409A of the Code; or

(b) In the absence of an established market for the Common Stock of the type described in (i) above, the Fair Market Value shall be determined by the Administrator in good faith and in a manner consistent with the requirements of §409A of the Code.

2.18 “**Grantee**” means an Employee, Director, or Consultant who receives an Award under the Plan.

2.19 “**Incentive Stock Option**” means an Option intended to qualify as an incentive stock option within the meaning of §422 of the Code.

2.20 “**Nonqualified Stock Option**” means an Option not intended to qualify as an Incentive Stock Option.

2.21 “**Officer**” means a person who is an officer of the Company or a Related Entity within the meaning of §16 of the Exchange Act and the rules and regulations promulgated thereunder.

2.22 “**Option**” means an option to purchase Shares in accordance with an Award Agreement granted under the Plan.

2.23 “**Parent**” means a “parent corporation,” whether now or hereafter existing, as defined in §424(e) of the Code.

2.24 “**Plan**” means this Stock Incentive Plan.

2.25 “**Post-Termination Exercise Period**” means the applicable period specified in the Award Agreement commencing on the date of termination of the Grantee’s Continuous Service. The applicable Post-Termination Exercise Period will depend on the reason for the termination of Continuous Service.

2.26 “**Registration Date**” means the first to occur of (i) the closing of the first sale to the general public of (A) the Common Stock or (B) the same class of securities of a successor corporation (or its Parent) issued in a Corporate Transaction in exchange for or in substitution of the Common Stock, in accordance with a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended; or (ii) in the event of a Corporate Transaction, the date of the consummation of the Corporate Transaction if the same class of securities of the successor corporation (or its Parent) issuable in such Corporate Transaction shall have been sold to the general public in accordance with a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933, as amended, on or before the date of consummation of such Corporate Transaction.

2.27 “**Related Entity**” means any Parent, any Subsidiary, or any business, corporation, partnership, limited liability company, or other entity in which the Company, a Parent, or a Subsidiary holds a substantial ownership interest, directly or indirectly.

2.28 “**Restricted Stock**” means Shares issued under the Plan to the Grantee for such consideration, if any, and subject to such restrictions on transfer, rights of first refusal, repurchase provisions, forfeiture provisions, and other terms and conditions as established by the Administrator.

2.29 “**Share**” means a share of the Common Stock.

2.30 “**Subsidiary**” means a subsidiary corporation, whether now or hereafter existing, as defined in §424(f) of the Code.

3. **Stock Subject to the Plan.**

3.1 **Maximum Number of Shares.** Subject to the provisions of Section 11.1 below, the maximum aggregate number of Shares that may be issued in connection with all Awards (including Incentive Stock Options) is 12,145,954 Shares (which includes Shares issued under the Plan prior to the most recent date of amendment hereof in connection with Awards granted prior to the most recent date of amendment hereof). The Shares may be authorized but unissued, or reacquired Common Stock.

3.2 **Issued Shares Only.** Only Shares that actually have been issued under the Plan (after the most recent date of amendment hereof) in connection with an Award shall be counted against the maximum aggregate numbers above. Any Shares (covered by an Option or other Award under the Plan) that are forfeited or canceled, expire, are surrendered, or otherwise become unexercisable before the Shares have been issued under the Plan shall be deemed not to have been issued for purposes of determining the maximum aggregate number of Shares that may be issued under the Plan, and such unissued Shares shall become available for future grant under the Plan. Shares that have been issued under the Plan shall not be returned to the Plan and shall not become available for future issuance under the Plan.

4. **Administration of the Plan.**

4.1 **Plan Administrator.** With respect to grants of Awards to Employees, Directors, or Consultants, the Plan shall be administered by (i) the Board or (ii) a committee or subcommittee designated by the Board, which committee shall be constituted in such a manner as to satisfy Applicable Laws and shall consist of at least two individuals. Once appointed, the Administrator shall continue to serve in its designated capacity until otherwise directed by the Board. Any action of the Administrator with respect to the Plan shall be final, conclusive, and binding on all persons, including the Company, any Related Entity, any Grantee, and any other person claiming any rights under the Plan. The express grant of any specific power to the Administrator, a committee, or an Officer and the taking of any action by such Administrator, a committee, or an Officer shall not be construed as limiting any power or authority of the Administrator or the Board.

4.2 Powers of the Administrator. Subject to Applicable Laws and the provisions of the Plan (including any other powers given to the Administrator hereunder), and except as otherwise provided by the Board, the Administrator shall have the authority, in its sole discretion.

(a) To select the Employees, Directors, and Consultants to whom Awards may be granted from time to time hereunder;

(b) To determine whether and to what extent Awards are granted hereunder;

(c) To determine the number of Shares or the amount of other consideration to be covered by each Award granted hereunder;

(d) To approve forms of Award Agreements for use under the Plan;

(e) To determine the terms and conditions of any Award granted hereunder;

(f) For Grantees in foreign jurisdictions only, to establish different or additional terms, conditions, rules, or procedures to accommodate the applicable rules or laws of such jurisdictions and to afford Grantees favorable treatment under such rules or laws, provided, however, that any such term, condition, rule, or procedure that is inconsistent with the provisions of the Plan must be approved by the Board;

(g) To establish additional terms, conditions, rules, or procedures to accommodate the terms of any Corporate Transaction, Award exchange program, Award deferral program, or other such program, provided, however, that no Award shall be subject to any such additional terms, conditions, rules, or procedures that are inconsistent with the provisions of the Plan;

(h) To amend the terms of any outstanding Award granted under the Plan, provided, however, that any amendment that would adversely affect the Grantee's rights under an outstanding Award shall not be made without the Grantee's written consent, unless the Administrator determines that the amendment is necessary to comply with any Applicable Law or accounting standard or to avoid adverse accounting treatment;

(i) To define terms not otherwise defined in the Plan and to construe and interpret the terms of the Plan and Awards, including, without limitation, any notice of award or Award Agreement granted under the Plan;

(j) To prescribe, amend, and rescind rules and regulations relating to the Plan and Awards that are not inconsistent with the terms of the Plan; and

(k) To take such other action, not inconsistent with the terms of the Plan, as the Administrator deems appropriate.

4.3 Limitation of Liability. Each member of the Administrator, each member of the Board, and any Officer with authority to grant Awards or administer the Plan in any way shall be entitled to, in good faith, rely or act on any report or other information furnished to him or her by any Officer, Employee, Director, or Consultant of the Company or any Related Entity, the Company's accountants, or other professional retained by the Company to assist in the administration of the Plan. No member of the Administrator or the Board, nor any Officer or Employee of the Company acting on behalf of the Administrator, shall be personally liable for any action, determination, or interpretation taken or made in good faith with respect to the Plan, and all members of the Administrator and the Board, and any Officer or Employee of the Company acting on their behalf, shall, to the extent permitted by Applicable Law, be fully indemnified and protected by the Company with respect to any such action, determination, or interpretation.

5. **Eligibility.** Awards other than Incentive Stock Options may be granted to Employees, Directors, and Consultants. Incentive Stock Options may be granted only to Employees of the Company, a Parent, or a Subsidiary. Any Awards issued to an Employee, Director, or Consultant of a Related Entity must comply with the requirements of §409A of the Code. An Employee, Director, or Consultant who has been granted an Award may, if otherwise eligible, be granted additional Awards. Awards may be granted to such Employees, Directors, or Consultants who are residing in foreign jurisdictions, as the Administrator may determine from time to time.

6. **Terms and Conditions of Awards.**

6.1 **Type of Awards.** The Administrator is authorized under the Plan to award any type of arrangement to an Employee, Director, or Consultant that is not inconsistent with the provisions of the Plan and that by its terms involves or might involve the issuance of (i) Restricted Stock, (ii) an Option, or (iii) any other security with the value derived from the value of the Shares.

6.2 **Conditions of Award.** Subject to the terms of the Plan, the Administrator shall determine the provisions, terms, and conditions of each Award including, but not limited to, the Award vesting schedule, repurchase provisions, rights of first refusal, forfeiture provisions, form of payment (cash, Shares, or other consideration) on settlement of the Award, payment contingencies, and satisfaction of any performance criteria. The Administrator may impose such restrictions, conditions, and limitations that it determines are appropriate as to the timing and manner of exercise, sale, or transfer of any Awards or Shares issued under an Award, including, without limitation, restrictions under an insider trading policy, restrictions with respect to the use of a specific brokerage firm, restrictions during any period that the Administrator determines that the prospectus for such Award may not contain all required information, restrictions requested by the underwriter engaged in a public offering of the Company's securities, and clawback provisions. To the extent any terms in an Award Agreement (or any other agreement relating to the Award) conflict with the terms of this Plan, the terms of this Plan shall control.

6.3 **Acquisitions and Other Transactions.** The Administrator may issue Awards under the Plan in settlement, assumption, or substitution for outstanding obligations to grant future awards in connection with the Company or a Related Entity acquiring another entity, an interest in another entity, or an additional interest in a Related Entity whether by merger, stock purchase, asset purchase, or other form of transaction.

6.4 **Award Exchange Programs.** The Administrator may establish one or more programs under the Plan to permit selected Grantees to exchange an Award under the Plan for one or more other types of Awards under the Plan on such terms and conditions as determined by the Administrator from time to time.

6.5 **Separate Programs.** The Administrator may establish one or more separate programs under the Plan for the purpose of issuing particular forms of Awards to one or more classes of Grantees on such terms and conditions as determined by the Administrator from time to time.

6.6 Time of Granting Awards. The date of grant of an Award shall for all purposes be the date on which the Administrator makes the determination to grant such Award. Notice of the grant determination shall be given to each Employee, Director, or Consultant to whom an Award is so granted within a reasonable time after the date of such grant.

7. Consideration and Taxes.

7.1 Consideration. Subject to Applicable Laws, the consideration to be paid for the Shares to be issued on exercise or purchase of an Award, including the method of payment, shall be determined by the Administrator (and, in the case of an Incentive Stock Option, shall be determined at the time of grant). In addition to any other types of consideration that the Administrator may determine, the Administrator is authorized to accept as consideration for Shares issued under the Plan the following:

(a) Cash or its equivalent;

(b) Delivery of Grantee's promissory note with such recourse, interest, security, and redemption provisions as the Administrator determines as appropriate;

(c) With respect to Surrender of Shares, delivery of a properly executed form of attestation of ownership of Shares as the Administrator may require (or directing the Company to withhold Shares otherwise deliverable on exercise of the Award), which have a Fair Market Value on the date of exercise equal to the aggregate exercise price of the Shares as to which the Award shall be exercised, provided, however, that no such exercise of the Award shall be allowed if the exercise would result in an accounting compensation charge with respect to the Shares used to pay the exercise price, unless otherwise specifically approved by the Administrator;

(d) With respect to Options, if the exercise occurs on or after the Registration Date, payment through a broker-dealer sale and remittance procedure in accordance with which the Grantee (A) shall provide written instructions to a Company-designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company, out of the sale proceeds available on the settlement date, sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (B) shall provide written directives to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale transaction; or

(e) Any combination of the foregoing methods of payment.

7.2 Taxes. No Shares shall be delivered under the Plan to any Grantee or other person until such Grantee or other person has made arrangements acceptable to the Administrator for the satisfaction of any foreign, federal, state, or local income and employment tax withholding obligations, including, without limitation, obligations incident to the receipt of Shares or the disqualifying disposition of Shares received on exercise of an Incentive Stock Option. On exercise of an Award, the Company shall withhold or collect from the Grantee an amount sufficient to satisfy such tax obligations. If the Administrator allows the surrender or withholding of Shares to satisfy any tax withholding obligations, any such surrender or withholding shall be limited to the extent necessary to avoid a minimum statutory withholding (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes) that could be imposed on the transaction, and in any case in which it would not result in an additional accounting compensation charge to the Company, tax obligations in excess of the minimum statutory withholding amounts as determined by the Company.

8. *Terms and Conditions of Stock Option Awards.*

8.1 **Designation of Option.** An Option shall be designated as either an Incentive Stock Option or a Nonqualified Stock Option. However, notwithstanding such designation, to the extent that the aggregate Fair Market Value of Shares subject to Options designated as Incentive Stock Options that become exercisable for the first time by a Grantee during any calendar year (under all plans of the Company or any Parent or Subsidiary) exceeds \$100,000, such excess Options, to the extent of the Shares covered thereby in excess of the foregoing limitation, shall be treated as Nonqualified Stock Options. For this purpose, Incentive Stock Options shall be taken into account in the order in which they were granted, and the Fair Market Value of the Shares shall be determined as of the grant date of the relevant Option.

8.2 **Early Exercise.** The Award Agreement may, but need not, include a provision whereby the Grantee may elect at any time while an Employee, Director, or Consultant to exercise any part or all of the Option before full vesting of the Option. Any unvested Shares received in accordance with such exercise shall be subject to a repurchase right in favor of the Company or a Related Entity and to any other restriction that the Administrator determines to be appropriate.

8.3 **Term of Option.** The term of each Option shall be the term stated in the Award Agreement, provided, however, that the term shall be no more than 10 years from the date of grant thereof. However, in the case of an Incentive Stock Option granted to a Grantee who, at the time the Option is granted, owns stock representing more than 10 percent of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the Incentive Stock Option shall be 5 years from the date of grant thereof or such shorter term as may be provided in the Award Agreement.

8.4 **Transferability of Awards.** Nonqualified Stock Options shall be transferable by will, by the laws of descent and distribution, to a revocable trust, or (to the extent provided in the Award Agreement) in a manner consistent with Rule 701(b) under the Securities Act or any successor rule. Incentive Stock Options may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Grantee, only by the Grantee.

8.5 **Exercise Price.** The exercise price for an Option shall be as follows:

(a) In the case of an Incentive Stock Option:

(i) If granted to an Employee who at the time of the grant of such Incentive Stock Option owns stock representing more than 10 percent of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the per-Share exercise price shall be not less than 110 percent of the Fair Market Value per Share on the date of grant; or

(ii) If granted to any Employee other than an Employee described in the preceding paragraph, the per-Share exercise price shall be not less than 100 percent of the Fair Market Value per Share on the date of grant.

(b) In the case of a Nonqualified Stock Option granted to any person, the per- Share exercise price shall be not less than 100 percent of the Fair Market Value per Share on the date of grant.

(c) Notwithstanding the foregoing provisions of this Section 8, in the case of an Option issued in accordance with Section 6.3 above, the exercise price for the Option shall be determined in accordance with the principles of §§424(a) and 409A of the Code.

8.6 *Exercise of Option.*

(a) Procedure for Exercise; Rights as a Shareholder.

(i) Any Option granted hereunder shall be exercisable at such times and under such conditions as specified in the Award Agreement or later authorized by the Administrator under the terms of the Plan.

(ii) An Option shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Award Agreement by the person entitled to exercise the Option and full payment for the Shares with respect to which the Option is exercised, subject to the Grantee satisfying all other terms and conditions in the Plan or the Award Agreement. Until the issuance (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company) of the stock certificate evidencing such Shares, no right to vote or receive dividends or any other rights as a shareholder shall exist with respect to Shares subject to an Option, notwithstanding the exercise of the Option. No adjustment will be made for a dividend or other right for which the record date falls before the date the stock certificate is issued, except as provided in the Award Agreement or in Section 11.1 below.

(b) *Exercise of Option Following Termination of Continuous Service.* In the event of termination of a Grantee's Continuous Service (but not in the event of a Grantee's change of status from Employee, Director, or Consultant to any other status of Employee, Director, or Consultant), such Grantee may exercise the Option to the extent that the Grantee was entitled to exercise it at the date of such termination, or to such other extent as may be determined by the Administrator, during the periods set forth below. To the extent that the Grantee is not entitled to exercise the Option at the date of termination, or if the Grantee does not exercise the Option to the extent so entitled within the applicable period, the Option shall terminate.

(i) The Grantee's Award Agreement may provide that in the event of termination of the Grantee's Continuous Service for Cause, the Grantee's right to exercise the Option will terminate concurrently with the termination of Grantee's Continuous Service. The Grantee's Award Agreement may specify a definition of Cause applicable to such Option (which may or may not be the same as the definition of Cause in Section 2 above).

(ii) In the event of termination of a Grantee's Continuous Service as a result of his or her Disability, the Grantee may exercise the Option within six months from the date of such termination or such longer Post-Termination Exercise Period as may be set forth in the Award Agreement or subsequently approved by the Administrator in accordance with this Plan, provided, however, that if such Disability is not a "disability" as such term is defined in §422(e)(3) of the Code, in the case of an Incentive Stock Option, such Incentive Stock Option shall automatically convert to a Nonqualified Stock Option after three months following such termination.

(iii) In the event of a termination of the Grantee's Continuous Service as a result of his or her death, or in the event of the death of the Grantee during the applicable Post-Termination Exercise Period, the Grantee's estate or a person who acquired the right to exercise the Option by bequest or inheritance may exercise the Option within six months from the date of the Grantee's death or such longer Post-Termination Exercise Period as may be set forth in the Award Agreement or subsequently approved by the Administrator in accordance with this Plan.

(iv) In the event of termination of a Grantee's Continuous Service as a result of his or her transfer by the Company to an entity that is not a Related Entity or as a result of Grantee's employer ceasing to be a Related Entity, the Grantee may exercise the Option within 30 days from the date of such termination or such longer Post-Termination Exercise Period as may be set forth in the Award Agreement or subsequently approved by the Administrator in accordance with this Plan.

(v) In the event of termination of a Grantee's Continuous Service for any other reason, the Grantee may exercise the Option within 30 days from the date of such termination or such longer Post-Termination Exercise Period as may be set forth in the Award Agreement or subsequently approved by the Administrator in accordance with this Plan.

(c) **Change of Status.** In the event of a Grantee's change of status from Employee, Director, or Consultant to any other status of Employee, Director, or Consultant, the Administrator shall determine the extent to which the Award Agreement will continue to be exercisable and the extent to which the Option will continue to vest. In the event of a Grantee's change of status from Employee to Consultant, an Employee's Incentive Stock Option shall convert automatically to a Nonqualified Stock Option after 3 months following such change of status.

9. Terms and Conditions of Restricted Stock Awards.

9.1 **Repurchase Rights.** The Award Agreement may grant to the Company the right to repurchase Shares on termination of the Grantee's Continuous Service, in which case the Award Agreement shall provide that:

(a) The consideration payable for the Shares on exercise of such repurchase right shall be made by check or by cancellation of indebtedness;

(b) The amount of such consideration shall be equal to the lesser of (A) the Fair Market Value of each Share on the date of repurchase and (B) the original purchase price paid by Grantee for each such Share; and

(c) The right to repurchase Shares at the original purchase price in accordance with Section 9.1(b)(B) shall lapse at such times and under such conditions as determined by the Administrator under the terms of the Plan and specified in the Award Agreement.

9.2 **Purchase Price.** In the case of the sale of Shares granted to any person, the per-Share purchase price shall be not less than 100 percent of the Fair Market Value per Share on the date of grant.

10. Conditions on Issuance of Awards or Shares.

10.1 Notwithstanding any other provision in the Plan or any Award Agreement, Awards shall not be granted and Shares shall not be issued in accordance with any Award unless the issuance and delivery of such Award or Shares comply with all Applicable Laws and are approved by any regulatory body as may be required, and such issuance and delivery shall be further subject to the approval of counsel for the Company with respect to such compliance. The Company reserves the right to restrict the delivery of Shares pursuant to any Award until all requirements of this section are satisfied as determined by the Company, in its sole discretion.

10.2 As a condition to the issuance of Shares in accordance with any Award, the Company may require the person receiving such Shares to represent and warrant at the time of such issuance that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any Applicable Law.

10.3 As a condition to the issuance of Shares in connection with any Award, the Grantee agrees to comply with any applicable policies or procedures adopted by the Company regarding its stock (including, but not limited to, insider trader restrictions and pre-clearance procedures) that, in the opinion of counsel for the Company, are necessary or desirable for compliance with any Applicable Law.

10.4 As a condition to the grant of any Award, the Grantee agrees to forfeit all Awards granted to the Grantee and to repay any gain realized and any benefit obtained from all such Awards under the following circumstances: (i) any circumstances requiring a clawback (or required to be covered in a clawback policy) under any Applicable Law, or (ii) any circumstances set forth in a clawback or similar policy that is approved by the Administrator and applies generally to a class of Employees, Consultants, and/or Directors that includes the Grantee, including any such policy that may be approved after the date the Award was granted or exercised. The manner of repaying an amount subject to this clawback provision shall be set forth in the applicable policy or determined by the Administrator in its sole discretion.

11. *Adjustments on Changes in Capitalization or Corporate Transaction.*

11.1 ***Adjustments on Changes in Capitalization.*** Subject to any required action by the shareholders of the Company, the number of Shares that have been authorized for issuance under the Plan but as to which no Awards have yet been granted or that have been returned to the Plan, any limits on the maximum number of Shares that may be issued to any Grantee or as a specific type of Award, the number of Shares covered by each outstanding Award, the exercise or purchase price of each such outstanding Award, and any other terms that the Administrator determines require adjustment shall be proportionately adjusted for (i) any increase or decrease in the number of issued Shares resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Shares, or similar transaction affecting the Shares; (ii) any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company; or, (iii) as the Administrator may determine in its discretion, any other transaction with respect to Common Stock to which §424(a) of the Code applies or a similar transaction, provided, however, that conversion of any convertible securities of the Company shall not be deemed to have been “effected without receipt of consideration.” Such adjustment shall be made by the Administrator, and its determination shall be final, binding, and conclusive. Except as the Administrator determines, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason hereof shall be made with respect to, the number or price of Shares subject to an Award.

11.2 ***Termination of Award in Event of Corporate Transaction.*** In the event of a Corporate Transaction, all Awards shall be subject to the agreement governing the Corporate Transaction, which need not treat Awards identically and which shall treat all Awards as follows:

(a) For Options, all Options shall be treated in accordance with one or more of the following approaches:

(i) The assumption of the Option (or portion) by the successor corporation or Parent thereof in connection with the Corporate Transaction.

(ii) The substitution of the Option (or portion) by the successor corporation or Parent thereof in connection with the Corporate Transaction, in which case the Option (or portion that has been substituted) will terminate on the consummation of the Corporate Transaction.

(iii) The Company shall provide the Grantee with written notice of the Corporate Transaction and an exercise period for the Option of not less than five full business days preceding the closing date of the Corporate Transaction, unless (1) a shorter period is required to permit a timely closing of the Corporate Transaction and (2) such shorter period still offers the Grantee a reasonable opportunity to exercise the Option. Any exercise of the Option during such period shall be contingent on the closing of the Corporate Transaction. Any portion of the Option that is unexercised as of the closing of the Corporate Transaction shall be terminated and shall cease to be exercisable, subject to the consummation of the Corporate Transaction.

(iv) The Company or successor, or its Affiliate, shall terminate the Option (or portion) and pay the Grantee an amount equal to the excess of (1) the Fair Market Value of the vested Shares subject to the Option (as of the effective date of the Corporate Transaction) over (2) the aggregate exercise price for such Shares, provided, however, that if the exercise price exceeds the Fair Market Value, the Option may be terminated without any payment. The payment shall be made in the same form—that is, cash, securities of the surviving corporation or its Affiliate, or other property with a Fair Market Value equal to the required amount—that is being paid to the Company's shareholders in the Corporate Transaction, except as otherwise approved by the Administrator. If any portion of the consideration received by the Company's shareholders in accordance with the Corporate Transaction will be paid on a contingent or delayed basis, the Administrator may, subject to §409A of the Code, either subject the payment to the same timing and conditions that apply to the shareholders' consideration or determine the Fair Market Value of the Shares as of the time of the Corporate Transaction on the basis of the Administrator's good faith estimate of the present value of the probable future payment of such consideration. Any termination of the Option and any payment for such Option shall be contingent on the consummation of the Corporate Transaction.

(b) For Awards subject to a repurchase right (including Restricted Stock Awards and Options with early exercise), the Award shall be (A) assumed by the successor corporation or Parent thereof in connection with the Corporate Transaction, (B) substituted by the successor corporation or Parent thereof in connection with the Corporate Transaction, or (C) repurchased, in which case the vesting of the Award (or portion that has been substituted) shall terminate as of the consummation of the Corporate Transaction (or such other date selected by the Administrator), and the repurchase right may be exercised before the Corporate Transaction, subject to the consummation of the Corporate Transaction.

(c) For all other types of Awards, the Award shall terminate as of the consummation of the Corporate Transaction in the manner set forth in the agreement governing the Corporate Transaction or as determined by the Administrator in its sole discretion.

11.3 Acceleration of Award in Event of Corporate Transaction. Except as provided otherwise in an individual Award Agreement, in the event of a Corporate Transaction, each Award that is at the time outstanding under the Plan shall automatically become fully vested and exercisable and be released from any restrictions on transfer (other than transfer restrictions applicable to Options) and repurchase or forfeiture rights, immediately before the specified effective date of the Corporate Transaction, for all of the Shares at the time represented by such Award if the Award is not assumed or substituted by the successor corporation or the Parent thereof in connection with the Corporate Transaction. For the purposes of accelerating the vesting and the release of restrictions applicable to Awards under this subsection (but not for purposes of termination of such Awards), the Award shall be considered substituted if, in connection with the Corporate Transaction, the Award is replaced with a comparable Award with respect to shares of capital stock of the successor corporation or Parent thereof or is replaced with a cash incentive program of the successor corporation or Parent thereof that preserves the compensation element of such Award existing at the time of the Corporate Transaction and provides for subsequent payout in accordance with the same vesting schedule applicable to such Award. The Administrator shall make the determination of Award comparability above, and its determination shall be final, binding, and conclusive. An individual Award Agreement may provide acceleration of vesting or exercisability of an Award in the event of any Corporate Transaction, provided, however, that (i) such acceleration shall be conditioned on the definition of a Corporate Transaction in this Plan, which shall control over any different definition in an Award Agreement or employment agreement; (ii) such acceleration shall not occur if the Award is either assumed by the successor corporation or Parent thereof or replaced with a comparable Award with respect to shares of the capital stock of the successor corporation or Parent thereof; and (iii) unless the shareholder approval requirements of §280G of the Code and the regulations thereunder are satisfied, such acceleration shall be limited so that no Grantee receives any benefit hereunder that constitutes an “excess parachute payment” under §280G, as determined by the Company’s accountants in their sole discretion, taking into account the aggregate value of all compensation payments or benefits to be paid or provided to the Grantee in connection with such Corporate Transaction under any other plan, agreement, or arrangement with the Company. Only the Administrator may waive the requirements of this Section.

12. Effective Date and Term of Plan. The Plan shall become effective on the earlier to occur of its adoption by the Board or its approval by the shareholders of the Company, which dates are listed on Exhibit A. It shall continue in effect for a term of 10 years unless sooner terminated by the Board. Subject to Section 18 below and Applicable Laws, Awards may be granted under the Plan at and after the time it becomes effective.

13. Amendment, Suspension, or Termination of the Plan.

13.1 The Board may at any time amend, suspend, or terminate the Plan. To the extent necessary to comply with Applicable Laws, the Company shall obtain shareholder approval of any Plan amendment in such a manner and to such a degree as required.

13.2 No Award may be granted during any suspension of the Plan or after termination of the Plan.

13.3 Any amendment, suspension, or termination of the Plan (including termination of the Plan under Section 12 above) shall not affect Awards already granted, and such Awards shall remain in full force and effect as if the Plan had not been amended, suspended, or terminated, unless (i) mutually agreed otherwise between the Grantee and the Administrator, which agreement must be in writing and signed by the Grantee and the Company; (ii) the Administrator determines that the amendment, suspension, or termination is necessary to comply with any Applicable Law or to avoid adverse accounting treatment; or (iii) the Administrator determines that the amendment, suspension, or termination is not reasonably likely to diminish the benefits provided under such Awards or any such diminishment has been or will be reasonably compensated.

14. Reservation of Shares.

14.1 The Company, during the term of the Plan, shall at all times reserve and keep available such number of Shares as will be sufficient to satisfy the requirements of the Plan.

14.2 The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

15. **No Effect on Terms of Employment or Consulting Relationship.** The Plan shall not confer on any Grantee any right with respect to the Grantee's Continuous Service, nor shall it interfere in any way with his or her right or the Company's right to terminate the Grantee's Continuous Service at any time, with or without cause, and with or without notice.

16. **Not an ERISA Plan or Deferred Compensation Plan.** The Plan is not a "Retirement Plan" or "Welfare Plan" under the Employee Retirement Income Security Act of 1974, as amended. The Plan is not a deferred compensation plan and is not intended to provide for the deferral of compensation under §409A of the Code. Except as specifically provided in a retirement or other benefit plan of the Company or a Related Entity, Awards shall not be deemed compensation for purposes of computing benefits or contributions under any retirement plan or deferred compensation plan of the Company or a Related Entity and shall not affect any benefits under any other benefit plan of any kind or any benefit plan subsequently instituted under which the availability or amount of benefits is related to level of compensation.

17. **Shareholder Approval.** Continuance of the Plan shall be subject to approval by the shareholders of the Company within 12 months before or after the date the Plan is adopted. Such shareholder approval shall be obtained in the degree and manner required under Applicable Laws. Any Award that is granted or exercised before shareholder approval is obtained shall be rescinded if shareholder approval is not obtained within the time prescribed, and Shares issued on the exercise of any such Award shall not be counted in determining whether shareholder approval is obtained.

18. **Tax Treatment.** Notwithstanding any other provision of the Plan, although the Administrator shall use its best efforts to avoid the imposition of taxation, penalties, and interest under §409A of the Code and other provisions of the Code, the tax treatment of Awards under the Plan shall not be, and is not, warranted or guaranteed. Although the Company or its agents may provide information regarding tax consequence to Grantees for the convenience of Grantees and their tax advisors, the Company and its advisors cannot give Grantees tax advice, and no Grantee may rely on such information or any other information from the Company or its advisors regarding the tax consequences of Awards. All Grantees are advised to consult with their own tax consultants in connection with the purchase or disposition of Shares in accordance with an Award. Neither the Company, the Administrator, the Board, nor any of their agents or designees shall be held liable for any taxes, penalties, or other monetary amounts owed by a Grantee, beneficiary, or other person as a result of any exercise, purchase, or payment under the Plan or the administration of the Plan. For example, the Administrator will in good faith determine the Fair Market Value of its Common Stock in accordance with the requirements of §409A and grant Options at or above such Fair Market Value on the date of grant so that the Options are exempt from §409A, but there is no guarantee that the Internal Revenue Service will agree with the Administrator's determination, and if any taxing authority challenges the Fair Market Value determination and finds that an Option is subject to §409A, the Grantee shall not make any claim against the Administrator, the Board, the Company, or any valuation firm engaged by the Company.

19. **Information to Grantee.** During the term of any Option granted under the Plan, the Company shall provide or otherwise make available to each Grantee a copy of such financial statements as it generally provides to its shareholders, at least annually, provided, however, that the foregoing shall not apply to the extent that the Company complies with Rule 701 of the Securities Act with respect to the Plan; and provided further that for purposes of determining compliance, any registered domestic partner shall be considered a “family member,” as that term is defined in Rule 701.

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BETA BIONICS, INC. AMENDED AND RESTATED 2016 STOCK INCENTIVE PLAN
STOCK OPTION AGREEMENT

This Stock Option Agreement (the “Option Agreement”) between Beta Bionics, Inc., a Delaware corporation (the “Company”), and the Grantee named in the Notice of Stock Option Award below (the “Notice”), is effective as of the Date of Award and sets forth the terms and conditions governing the Award Number set forth in the Notice.

A. NOTICE OF STOCK OPTION AWARD

1. Grant of Option.

Grantee: ###PARTICIPANT_NAME###

The Company grants to you an option (the “Option”) to purchase the Shares of the Company’s Common Stock at the Exercise Price as follows:

Award Number	###EMPLOYEE_GRANT_NUMBER###
Date of Award	###GRANT_DATE###
Vesting Commencement Date	###ALTERNATIVE_VEST_BASE_DATE###
Exercise Price per Share	###GRANT_PRICE###
Total Number of Shares (“Shares”)	###TOTAL_AWARDS###
Total Exercise Price	###TOTAL_EXERCISE_PRICE###
Type of Option (check one)	###DICTIONARY_AWARD_NAME###

2. Vesting Schedule.

The Shares subject to the Option may be exercised, in whole or in part, after they become vested in accordance with the vesting schedule below, and unvested Shares may not be exercised, except as otherwise set forth in this Option Agreement and the Plan. Subject to the Grantee’s Continuous Service through the applicable vesting date, the Option will vest in accordance with the following schedule:

###VEST_SCHEDULE_DESCRIPTION###

3. *Termination of the Option.*

This Option shall terminate on ####EXPIRY_DATE### (the “Expiration Date”), unless terminated sooner as set forth below. Notwithstanding any provision of this Option Agreement to the contrary, if the Grantee holds more than 10 percent of the voting power of all classes of stock of the Company as of the Date of Award set forth above, the Expiration Date of any Incentive Stock Option issued to the Grantee shall be 5 years after the Date of Award.

If the Grantee’s Continuous Service terminates for any reason, the Option shall terminate, to the extent the Option has not been exercised, on completion of the applicable period set forth below (the “Post-Termination Exercise Period”), except as provided in Section 6 of this Option Agreement. If the Grantee’s Continuous Service terminates as a result of his or her Disability, the Grantee may, to the extent the Option had vested on the date of such termination (the “Termination Date”), exercise the Option for 6 months after the Termination Date. If Grantee’s Continuous Service terminates as a result of his or her death, the Grantee’s successor in interest may, to the extent the Option had vested on the date of the Termination Date, exercise the Option for 6 months after the Termination Date.

If the Grantee’s Continuous Service is terminated for Cause, the Grantee’s right to exercise the Option shall terminate on the Termination Date, except as otherwise determined by the Administrator in its sole discretion.

If the Grantee’s Continuous Service terminates for any other reason, the Grantee may, to the extent the Option had vested on the Termination Date, exercise the Option 6 months after the Termination Date. In no event shall the Option be exercised later than the Expiration Date. To the extent that the Grantee is not entitled to exercise the Option on the Termination Date and to the extent the Grantee does not exercise the Option within the applicable Post-Termination Exercise Period, the Option shall terminate. The Grantee shall have no right to exercise any portion of the unvested Shares, except as otherwise determined by the Administrator in its sole discretion.

B. TERMS AND CONDITIONS OF OPTION

1. *Terms of Option.*

This Option is granted under the Beta Bionics Amended and Restated 2016 Stock Incentive Plan, as amended (the “Plan”), and is subject to the terms and conditions of the Plan and this Option Agreement (including both the Notice and the following Terms and Conditions). Both the Plan and the Option Agreement contain important terms and restrictions covering this Option. The Plan is incorporated into this Option Agreement by reference in its entirety. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Option Agreement.

If designated in the Notice as an Incentive Stock Option, the Option is intended to qualify as an Incentive Stock Option as defined in §422 of the Code. However, to the extent that the Option exceeds the \$100,000 limit in §422, such excess Option shall be treated as a Nonqualified Stock Option.

The Exercise Price designated in the Notice must not be less than the Fair Market Value on the Date of Award. The Exercise Price is intended to be at least the Fair Market Value on the Date of Award, but if it is subsequently determined that the Exercise Price was less than the actual Fair Market Value on the Date of Award, the parties agree to work in good faith and in compliance with Applicable Laws to adjust the Exercise Price to the extent possible so that it is no less than the Fair Market Value on the Date of Award.

The Fair Market Value has been determined by the Board of Directors, and the Company believes the valuation is in good faith compliance with the requirements of §422 of the Code (so that the Option, if designated as an ISO, will qualify as an ISO) and §409A of the Code (so that the Option will be exempt from §409A). The Grantee understands, however, that there is no guarantee that the Internal Revenue Service ("IRS") will agree with the Fair Market Value determination, and it is possible that the Internal Revenue Service could successfully assert that the Fair Market Value on the Date of Award is greater than the value determined by the Board of Directors. If the Internal Revenue Service were to succeed in a determination that the Fair Market Value on the Date of Award is greater than the Exercise Price, the Option, if designated as an ISO, would no longer qualify as an ISO, and the Option would no longer be exempt from §409A and would likely violate §409A. Any additional taxes, interest, and penalties due would be payable by the Grantee, and the Company has no obligation to reimburse the Grantee for that tax liability. The Grantee assumes all responsibility for such potential tax liability.

2. Exercise of Option.

- (a) *Right to Exercise.* The Option shall be exercisable during its term to the extent it has vested in accordance with the Vesting Schedule set out in the Notice. The Option shall be subject to the provisions of Section 11 of the Plan relating to the exercisability or termination of the Option in the event of a Corporate Transaction. The Option may not be exercised if the issuance of the Shares subject to the Option at the time of such exercise would constitute a violation of any Applicable Laws and any applicable provision of the Plan and the Option Agreement. No partial exercise of the Option may be for less than the lesser of 5 percent of the total number of Shares subject to the Option or the remaining number of Shares subject to the Option. In no event shall the Company issue fractional Shares.
- (b) *Method of Exercise.* Any exercise of the Option shall occur at the principal office of the Company. To exercise the Option, the Grantee and, if applicable, Grantee's spouse must do the following:
 - (i) Complete and sign the Exercise Notice (attached as Exhibit A);

- (ii) Deliver the Exercise Notice and full payment of the Exercise Price (in a manner authorized by Section 4 below) either in person, by certified mail, or by any other method approved by the Administrator; and
- (iii) Make arrangements acceptable to the Company for satisfaction of any applicable taxes as described in Section 2(d) below.
- (c) *Exercise Date.* Any exercise of the Option shall be deemed effective on the date that the Company has received a fully executed Exercise Notice accompanied by the full Exercise Price. The Shares shall be considered transferred on such exercise date.
- (d) *Taxes.* No Shares will be delivered to the Grantee or other person in accordance with the exercise of the Option until the Grantee or other person has made arrangements acceptable to the Company for the satisfaction of all applicable income tax, employment tax, and social security tax withholding obligations. On exercise of the Option, the Company or the Grantee's employer may offset or withhold (from any amount owed by the Company or the Grantee's employer to the Grantee) or collect from the Grantee or other person an amount sufficient to satisfy such tax withholding obligations. In the case of an Incentive Stock Option, the Grantee also agrees, as partial consideration for the designation of the Option as an Incentive Stock Option, to notify the Company in writing within 30 days of any disposition of any shares acquired by exercise of the Option if such disposition occurs within 2 years from the Award Date or within 1 year from the date that the Shares were transferred to the Grantee. If the Company is required to satisfy any federal, state, or local income or employment tax withholding obligations as a result of such an early disposition, the Grantee agrees to satisfy the amount of such withholding in a manner prescribed by the Company.
- (e) *Certificate.* Except as otherwise provided in this Option Agreement or the Plan, as soon as practicable after the Grantee has satisfied all of the obligations of this Section, the Company will prepare a certificate representing the Shares purchased by the Grantee in the names set forth in the Exercise Notice. If required by the Option Agreement or any attachments, the Shares will be held in escrow.

3. *Grantee's Representations.*

- (a) The Grantee understands that neither the Option nor the Shares exercisable in accordance with the Option have been registered under the Securities Act of 1933, as amended, or any other United States securities laws.
- (b) The Grantee represents that the person who signs the spousal consent for this Option Agreement, as well as any Exercise Notice, is the Grantee's spouse or domestic partner. If no one has signed the spousal consent, the Grantee represents that he or she has no spouse or domestic partner.

4. Method of Payment. Payment of the Exercise Price shall be made by any of the following, or a combination thereof, at the election of the Grantee, provided, however, that such exercise method does not then violate any Applicable Law:

- (a) Cash or its equivalent;
- (b) Surrender of Shares, in a manner acceptable to the Administrator, which have a Fair Market Value on the date of exercise equal to the aggregate Exercise Price of the Shares as to which the Option is being exercised (but only to the extent that such use of Shares would not result in an accounting compensation charge with respect to the Shares used to pay the exercise price); or
- (c) If the exercise occurs on or after the Registration Date, payment through any cashless exercise program that may be established by the Company or a Company-designated brokerage firm under the Plan;

5. Restrictions on Exercise. The Option may not be exercised until such time as the Plan has been approved by the shareholders of the Company. If the Grantee is an employee of the Company or a Related Entity and is not exempt from the overtime requirements under either federal or state wage and hour law, Grantee may not exercise any Shares during the 6-month period following the Date of Award, except as authorized by Grantee's employer in its sole discretion.

The Option may be exercised before the time that the Plan has been approved by the shareholders of the Company, provided, however, that all Shares issued on any such exercise shall be rescinded if shareholder approval is not obtained within the time prescribed, and Shares issued on any such exercise shall not be counted in determining whether shareholder approval is obtained.

6. Terminations, Leaves, and Changes in Continuous Service.

- (a) *Changes in Continuous Service.* In the event of the Grantee's change in status from Employee, Director, or Consultant to any other status as Employee, Director, or Consultant, the Option shall remain in effect and shall continue to vest, except that if the Grantee changes from an Employee to a Consultant or Director or from an Employee whose customary employment is 20 hours or more per week to an Employee whose customary employment is fewer than 20 hours per week, the Administrator may, in its discretion, cease the vesting of the Option as of such change in status.

An Incentive Stock Option shall cease to be treated as an Incentive Stock Option following a change in status to the extent required by the Code.

- (b) *Leaves of Absence.* During any leave of absence authorized by the Grantee's employer, the Option shall remain in effect, and the vesting of the Option shall cease after the leave of absence exceeds a period of 90 days, unless continued vesting is required by applicable law. Vesting of the Option shall resume on the Grantee's termination of the leave of absence and return to service to the Company or a Related Entity. If the Option is an Incentive Stock Option and the leave of absence does not satisfy the applicable provisions of the Code, the Grantee must exercise the Incentive Stock Option within the time period required by the Code, or the Option shall cease to be treated as an Incentive Stock Option.
- (c) *Transfers and Reorganizations.* If a transfer of the Grantee or any spinoff, sale, transaction, or other change in the Grantee's employer does not interrupt the Grantee's Continuous Service, the Option shall remain in effect and shall continue to vest, except to the extent otherwise determined by the Administrator in its sole discretion. If a transfer of the Grantee or any spinoff, sale, transaction, or other change in the Grantee's employer results in a termination of the Grantee's Continuous Service, the Grantee's Continuous Service shall be deemed terminated on the date of such transfer, transaction, or change, except to the extent otherwise determined by the Administrator in its sole discretion.
- (d) *Disability of Grantee.* If the Option is an Incentive Stock Option and the Grantee's employment terminates as a result of a Disability that does not qualify as a "disability" under the applicable provisions of the Code, the Grantee must exercise the Incentive Stock Option within the time period required by the Code, or the Option shall cease to be treated as an Incentive Stock Option.
- (e) *Post-Termination Death of Grantee.* In the event of the Grantee's death during the Post-Termination Exercise Period, the Grantee's estate, or a person who acquired the right to exercise the Option by bequest or inheritance, may exercise the Option, but only to the extent the Grantee could exercise the Option on the Termination Date, within the Post-Termination Exercise Period set forth in the Notice applicable if the Grantee's Continuous Service had terminated as a result of his or her death, except that such Post-Termination Exercise Period shall commence on the date of death rather than termination. The Option may not be exercised later than the Expiration Date. If the Option is not exercised to the extent so entitled within the time specified herein, the Option shall terminate.

7. Transferability of Option. The Option, if an Incentive Stock Option, may not be transferred in any manner other than by will or by the laws of descent and distribution and may be exercised during the lifetime of the Grantee only by the Grantee. The Option, if a Nonqualified Stock Option, may be transferred by will, by the laws of descent and distribution, and to the extent and in the manner authorized by the Administrator, to members of the Grantee's immediate family (as determined by the Administrator) or under a domestic relations order. The terms of the Option shall be binding on any executors, administrators, heirs, successors, and assigns of the Grantee.

8. Company's Right of First Refusal. Neither the Grantee nor a transferee (either being sometimes referred to herein as the "Holder") shall sell, pledge, encumber, or otherwise transfer (including transfers by operation of law) any Shares or any right or interest therein without first complying with the provisions of this Section or obtaining the prior written consent of the Company.

- (a) *Transfer Notice.* Prior to any proposed transfer of the Shares, the Holder shall provide the Company with written notice (the "Transfer Notice") describing fully the proposed transfer, including: (i) the name and address of the proposed transferee; (ii) the number of Shares to be transferred (the "Offered Shares"); and (iii) the bona fide cash price or other consideration for which the Holder proposes to transfer the Shares, and the terms thereof. The Transfer Notice must be signed by both the Holder and the proposed transferee and must constitute a bona fide and binding commitment of the Holder and the proposed transferee for the transfer of the Transfer Shares subject only to the Right of First Refusal.
- (b) *Exercise of Right of First Refusal.* At any time during the 60-day period after receipt of the Transfer Notice (the "Option Period"), the Company shall have the right to purchase (the "Right of First Refusal") all, but not less than all, of the Offered Shares at a price determined by subsection (c) below, which Right of First Refusal shall be exercised by written notice (the "First Refusal Exercise Notice") to the Holder.
- (c) *Payment Terms.* The purchase price for the Offered Shares shall be the price stated in the Transfer Notice. In the event the Transfer Notice provides for payment in consideration other than cash, the Company (or its assign(s) as provided in Section 8(d) below) shall have the right to pay for the Offered Shares by the cash equivalent value of the consideration described in the Transfer Notice as determined by the Administrator in good faith. The Company (or its assign(s)) shall pay the purchase price for the Offered Shares to the Holder by cash, check, cancellation of any indebtedness to the Company, any consideration stated in the Transfer Notice, or a combination thereof, within 15 days after delivery of the First Refusal Exercise Notice or in the manner and at the times set forth in the Transfer Notice. On payment for the Offered Shares to the Holder or into escrow for the benefit of the Holder, the Company (or its assign(s)) shall become the legal and beneficial owner of the Offered Shares and all rights and interest therein or related thereto, and the Company shall have the right to transfer the Offered Shares to its own name or its assigns without further action by the Holder.
- (d) *Assignment.* Whenever the Company has the right to purchase Shares under this Right of First Refusal, the Company may designate or assign one or more employees, officers, directors, or shareholders of the Company or other persons or organizations to exercise all or a part of the Company's Right of First Refusal.

- (e) *Holder's Right to Transfer.* If the Company (or its assign(s)) does not elect to exercise the Right of First Refusal within the Option Period or such earlier time in which the Company (or its assign(s)) notifies the Holder that it will not exercise the Right of First Refusal, then the Holder may transfer the Shares on the terms and conditions stated in the Transfer Notice, provided that the transfer is made within 90 days of the expiration of the Option Period, the transfer complies with all Applicable Laws, and the transferee agrees in writing (in a form approved by the Administrator) that the Shares shall be held subject to the provisions of this Option Agreement, including this Right of First Refusal. No transfer of the Offered Shares following that 90-day period and no transfer in accordance with terms that are different than the terms stated in the Transfer Notice (including the name of the proposed transferee) and no transfer by the proposed transferee shall be permitted without a new written Transfer Notice prepared and submitted in accordance with the requirements of this Right of First Refusal.
- (f) *Exception for Certain Family Transfers.* The transfer of any or all of the Shares during the Grantee's lifetime or on the Grantee's death by will or intestacy to the Grantee's Immediate Family or a trust for the benefit of the Grantee or the Grantee's Immediate Family shall be exempt from the provisions of this Right of First Refusal (a "Permitted Transfer"). In a Permitted Transfer, the transferee shall agree in writing (in a form approved by the Administrator) to receive and hold the Shares so transferred subject to the provisions of this Option Agreement, and there shall be no further transfer of such Shares except in accordance with the terms of this Option Agreement, including this Right of First Refusal, and the Grantee shall retain full control with respect to the voting rights of such Shares for as long as the Grantee is alive. "Immediate Family" as used herein shall mean spouse, domestic partner (as determined by the Administrator), child, lineal descendant or antecedent, father, mother, brother, or sister, and the lineal descendants of such individuals.
- (g) *Termination of Right of First Refusal.* The provisions of this Right of First Refusal shall terminate as to all Shares on the Registration Date.
- (h) *Additional Shares or Substituted Securities.* In the event of any transaction described in Section 11(a) of the Plan, any new, substituted, or additional securities or other property that by reason of any such transaction is distributed with respect to the Shares shall be immediately subject to the Right of First Refusal, but only to the extent the Shares are at the time covered by such right.
- (i) *Corporate Transaction.* Immediately before the consummation of a Corporate Transaction, the Right of First Refusal shall automatically lapse in its entirety, except to the extent this Option Agreement is assumed by the successor corporation (or its Parent) in connection with such Corporate Transaction, in which case the Right of First Refusal shall apply to the new capital stock or other property received in exchange for the Shares in consummation of the Corporate Transaction, but only to the extent the Shares are at the time covered by such right.

The Grantee acknowledges and agrees that the Shares are subject to a right of first refusal (“Right of First Refusal”) as set forth in the Bylaws of the Company and that, except in compliance with such right of first refusal, neither the Grantee nor a transferee (either being sometimes referred to herein as the “Holder”) shall sell, pledge, encumber, or otherwise transfer any Shares or any right or interest therein.

9. Lock-up Agreement. The Grantee, if requested by the Company and the lead underwriter of any public offering of the Common Stock or other securities of the Company (the “Lead Underwriter”), hereby irrevocably agrees not to sell, contract to sell, grant any option to purchase, transfer the economic risk of ownership in, make any short sale of, pledge, or otherwise transfer or dispose of any interest in any Common Stock or any securities convertible into or exchangeable or exercisable for, or any other rights to purchase or acquire, Common Stock (except Common Stock included in such public offering or acquired on the public market after such offering or as authorized in writing by the Company and the Lead Underwriter) during the period following the effective date of a registration statement of the Company filed under the Securities Act of 1933, as amended, as the Lead Underwriter shall specify, which shall not exceed 180 days (plus any additional period as may be reasonably requested by the Company or the Lead Underwriter to accommodate regulatory restrictions on (a) the publication or other distribution of research reports and (b) analyst recommendations and opinions, including, but not limited to, the restrictions contained in NASD Rule 2711(f)(4) or NYSE Rule 472(f)(4), or any successor provisions or amendments thereto). The Grantee further agrees that the Company may impose stop-transfer instructions with respect to such Common Stock until the end of such period. The Grantee agrees to sign such documents as may be requested by the Lead Underwriter to effect the foregoing and, if requested by the Company or the Lead Underwriter, to provide such information as may be required by the Company or Lead Underwriter in connection with the completion of the public offering. The Company and the Grantee acknowledge that each Lead Underwriter of a public offering of the Company’s stock, during the period of such offering and for the 180-day period thereafter, is an intended beneficiary of this Section.

10. Stop-Transfer Notices.

- (a) In order to ensure compliance with the restrictions on transfer set forth in this Option Agreement or the Plan, the Company may issue appropriate stop-transfer instructions to its transfer agent, if any, and if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

- (b) *Refusal to Transfer.* The Company shall not be required (a) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of this Option Agreement or (b) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares have been so transferred.

11. Clawbacks. Grantee irrevocably agrees that this Option is conditioned on Grantee's obligation to repay any amount received or benefit obtained from the Option (including proceeds from the sale of the Shares or amounts received on the termination of the Option pursuant to a Corporate Transaction) under the following circumstances: (a) any circumstances requiring a clawback (or required to be covered in a clawback policy) under any Applicable Law; or (b) any circumstances set forth in a clawback or similar policy that is approved by the Administrator and applies generally to a class of Employees, Consultants, or Directors that includes the Grantee, including any such policy that may be approved after the date the Option is granted or exercised. The manner of repaying an amount subject to this clawback provision shall be set forth in the applicable policy or determined by the Administrator in its sole discretion.

12. Tax Consequences. Set forth below is a brief summary, as of the date of this Option Agreement, of some of the federal tax consequences of exercise of the Option and disposition of the Shares. This summary is necessarily incomplete, and the tax laws and regulations are subject to change. The Grantee should consult his or her own tax adviser before exercising the option or disposing of the Shares. The Company and its advisors cannot give Grantee tax advice, and the Grantee may not rely on the information in this Section or any other information from the Company or its advisors regarding the tax consequences of Awards.

- (a) *Exercise of Incentive Stock Option.* If the Option qualifies as an Incentive Stock Option, there will be no regular federal income tax liability on the exercise of the Option, although the excess, if any, of the Fair Market Value of the Shares on the date of exercise over the Exercise Price will be treated as income for purposes of the alternative minimum tax for federal tax purposes and may subject the Grantee to the alternative minimum tax in the year of exercise. The option will lose its ISO treatment if it is exercised later than (i) the date that is 3 months after termination of the Grantee's employment with the Company or, (ii) in the event of Disability, the date that is 1 year after termination of employment. In the event of the Grantee's death, the option would be eligible for ISO treatment only if the Grantee dies while employed by the Company or within the 3-month period after the Grantee's employment terminates.
- (b) *Exercise of Nonqualified Stock Option.* On exercise of a Nonqualified Stock Option, the Grantee will be treated as having received compensation income (taxable at ordinary income tax rates) equal to the excess, if any, of the Fair Market Value of the Shares on the date of exercise over the Exercise Price. If the Grantee is an Employee or a former Employee, the Company will be required to withhold from the Grantee's compensation or collect from the Grantee and pay to the applicable taxing authorities an amount in cash equal to a percentage of this compensation income at the time of exercise and may refuse to honor the exercise and refuse to deliver Shares if such withholding amounts are not delivered at the time of exercise.

- (c) *Disposition of Shares.* In the case of a Nonqualified Stock Option, if Shares are held for more than 1 year, any gain realized on disposition of the Shares will be treated as long-term capital gain for federal income tax purposes. In the case of an Incentive Stock Option, if Shares transferred in accordance with the Option are held for more than 1 year after receipt of the Shares and are disposed of more than 2 years after the Date of Award, any gain realized on disposition of the Shares will also be treated as long-term capital gain for federal income tax purposes. If Shares purchased under an Incentive Stock Option are disposed of before the expiration of such 1-year or 2-year periods, any gain realized on such disposition will be treated as compensation income (taxable at ordinary income rates) to the extent of the difference between the Exercise Price and the lesser of (i) the Fair Market Value of the Shares on the date of exercise or (ii) the sale price of the Shares. Any additional gain will be treated as capital gain for federal income tax purposes.

13. Restrictive Legends. On exercise of the Option, the Grantee understands and agrees that the Company shall cause the legends set forth below, or legends substantially equivalent thereto, to be placed on any certificate(s) evidencing ownership of the Shares, together with any other legends that may be required by the Company or by state or federal securities laws:

- (a) *Securities Law Restrictions:*

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") OR ANY STATE SECURITIES LAWS AND MAY NOT BE OFFERED, SOLD, OR OTHERWISE TRANSFERRED, PLEDGED, OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT OR, IN THE OPINION OF COUNSEL SATISFACTORY TO THE ISSUER OF THESE SECURITIES, SUCH OFFER, SALE, TRANSFER, PLEDGE, OR HYPOTHECATION IS IN COMPLIANCE THEREWITH.

- (b) *Option Agreement Restrictions:*

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO A LOCK-UP AGREEMENT, CERTAIN RESTRICTIONS ON TRANSFER AND A RIGHT OF FIRST REFUSAL HELD BY THE ISSUER OR ITS ASSIGNEE(S), AS SET FORTH IN THE OPTION AGREEMENT BETWEEN THE ISSUER AND THE ORIGINAL HOLDER OF THESE SHARES, A COPY OF WHICH MAY BE OBTAINED AT THE PRINCIPAL OFFICE OF THE ISSUER. SUCH LOCK-UP AGREEMENT, TRANSFER RESTRICTIONS AND RIGHT OF FIRST REFUSAL ARE BINDING ON TRANSFEREES OF THESE SHARES.

- (c) *Removal of Legend.* If, in the opinion of the Company and its counsel (in their sole discretion), any of the legends on a certificate representing the Shares is no longer required, the Grantee shall be entitled to exchange such certificate for a new certificate representing the Shares without such legend.

14. Notices. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given on personal delivery, on deposit in the United States mail by certified mail (if the parties are within the United States), or on deposit for delivery by a mail courier service, with postage and fees prepaid, addressed as follows: (a) to the Company at the then-current address of the Company's headquarters, or (b) to the Grantee or any subsequent Holder at the last address on record with the Company. Grantee and any subsequent Holder shall be obligated to notify the Company in writing of any change in address.

15. Electronic Delivery of Documents. Grantee consents to electronic delivery of any documents relating to this Option and the Plan, any documents that are required to be delivered to the Company's shareholders or option holders, and any disclosures required by Applicable Laws. This consent may be withdrawn at any time on written notice to the Company.

16. Interpretation, Modification, and Enforcement of Option Agreement.

- (a) *Entire Agreement, Choice of Law.* The Plan and the Option Agreement constitute the entire agreement with respect to this Option and supersede all prior or contemporaneous agreements and representations of the Company and the Grantee with respect to this Option (including, but not limited to, any prior notices or option agreements with the same Award Number and any references to this Option in an offer letter or employment agreement). The Plan and Option Agreement are to be construed in accordance with and governed by the internal laws of the State of Delaware, without giving effect to any choice-of-law rule that would cause the application of the laws of any other jurisdiction.
- (b) *Assignment, Binding Effect.* The Company may assign any of its rights under the Option Agreement to single or multiple assignees, and the Plan and Option Agreement shall be binding on and shall inure to the benefit of the successors, heirs, executors, administrators, permitted transferees, and permitted assigns of the parties.
- (c) *Captions, Decisions of Administrator.* The captions used in the Plan and Option Agreement are inserted for convenience and shall not be deemed a part of the agreement for construction or interpretation. The parties agree to accept as final and binding all decisions and interpretations of the Administrator on any issues arising under the Plan or this Option.
- (d) *Modification, Waiver, No Third Party Rights.* The Option Agreement may not be modified adversely to the Grantee's interest except in a writing signed by the Company and the Grantee, unless the Administrator determines that the amendment is necessary to comply with any Applicable Law or to avoid adverse accounting treatment. The Option will be subject to any modifications to the Plan that are made in accordance with the terms

of the Plan. No waiver of any right in the Option Agreement shall be effective unless in writing. Nothing in the Plan and Option Agreement (except as expressly provided therein) is intended to confer any rights or remedies on any persons other than the parties.

- (e) *Enforceability.* Should any provision of the Plan or Option Agreement be determined by a court of law to be illegal or unenforceable, such provision shall be enforced to the fullest extent allowed by law and the other provisions shall nevertheless remain effective and shall remain enforceable.
- (f) *Further Assurances.* The parties agree to execute such further instruments and to take such further action as may be reasonably necessary to carry out the purposes and intent of the Plan and Option Agreement.

17. No Rights as Shareholder Prior to Exercise. Until the stock certificate evidencing such Shares is issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a shareholder shall exist with respect to the Shares, notwithstanding the exercise of the Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date the stock certificate is issued, except as provided in Section 11(a) of the Plan. The Grantee shall enjoy rights as a shareholder until such time as the Grantee disposes of the Shares or the Company (or its assign(s)) exercises the Right of First Refusal.

18. No Rights to Partial Vesting, Future Awards, or Continuous Service. The Grantee acknowledges and agrees as follows:

- (a) The Grantee's right to any Shares subject to the Option shall vest, if at all, only as set forth in the vesting schedule in the Notice, and Grantee shall not have any rights at all with respect to Shares before they have vested, except as otherwise provided in this Option Agreement. If Grantee's Continuous Service is terminated, with or without cause, before any vesting date or event, Grantee shall not be entitled to any vesting of any portion of the Shares that would have vested on the vesting date or event, except as otherwise provided in this Option Agreement.
- (b) Nothing in the Option Agreement or the Plan (including, but not limited to, the Administrator's past history of granting Awards under the Plan) shall confer on the Grantee any right with respect to future awards.
- (c) Except as otherwise provided in a written agreement signed by an authorized officer of the Company (or any Related Entity for which Grantee is providing services), both the Grantee and the Company have the right to terminate Grantee's Continuous Service at will, with or without cause, and at any time, with or without notice, and nothing in the Option Agreement or the Plan shall confer on the Grantee any right with respect to the continuation of Grantee's Continuous Service.

19. Acknowledgment. By signing this Option Agreement, the Grantee acknowledges that he or she has received a copy of the Plan and this Option Agreement, represents that he or she has reviewed the Plan and this Option Agreement in their entirety, acknowledges that he or she has had an opportunity to obtain the advice of counsel before executing this Option Agreement, and accepts the Option subject to all of the terms and provisions of the Plan and this Option Agreement. This Option Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

Offered by:

Date: ###GRANT_DATE###

Beta Bionics, Inc., a Delaware corporation

By:

Name:

Accepted by:

Date: ###ACCEPTANCE_DATE###

Name: ###PARTICIPANT_NAME###

Address:

###HOME_ADDRESS###

4. **Taxes.** I understand that I may suffer adverse tax consequences as a result of my purchase or disposition of the Shares. The Company advises me to consult with my own tax consultants in connection with the purchase or disposition of the Shares, and I have done so to the extent I consider advisable. I am not relying on the Company for any tax advice.

5. Risk of Investment. I am aware that my purchase of the Shares is a speculative investment that has limited liquidity and may be completely lost. I am willing and able to take the risk of a complete loss of my investment.

6. Investment Representations. I understand that the Shares have not been registered under the Securities Act of 1933 in reliance on a specific exemption therefrom and that the exemption depends on, among other things, the bona fide nature of my investment representations below. On the basis of this understanding, I make the following representations to the Company, and the Company will rely on these representations unless the Shares have been registered under the Securities Act at the time of exercise:

- (a) I am aware of the Company's business affairs and financial condition and have acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Shares.
- (b) I am acquiring and will hold the Shares for investment for my own account only and not with a view to, or for resale in connection with, any "distribution" of the Shares within the meaning of the Securities Act.
- (c) I understand that the Shares must be held indefinitely unless they are subsequently registered under the Securities Act or unless I obtain an opinion of counsel satisfactory to the Company that registration is not required. I further understand that the Company is under no obligation to register the Shares.
- (d) I understand that the Shares, which were acquired in a nonpublic offering, are considered "restricted securities" under the Securities Act, and that the Securities and Exchange Commission has adopted Rules 144 and 701 under the Securities Act, which permit limited public resale of "restricted securities" subject to the satisfaction of certain conditions. These conditions may include, but are not limited to, the following: that certain current public information about the Company is available, that the sale occur after a particular holding period, that the sale be made through an unsolicited broker's transaction, that the amount of securities being sold during any 3-month period not exceed specific limits, and that certain forms published by the Securities and Exchange Commission have been timely filed. I understand that these conditions have not been satisfied and that the Company is under no obligation to satisfy these conditions.
- (e) I agree not to sell or otherwise dispose of the Shares except in compliance with Rule 144 under the Securities Act and any other applicable rule under the Securities Act, the Securities Exchange Act of 1934, or any other Applicable Law, and in compliance with any applicable policies or procedures adopted by the Company (including, but not limited to, insider trader restrictions and pre-clearance procedures) that, in the opinion of counsel for the Company, are necessary or desirable for compliance with any Applicable Law.

7. Exercise Date. The effective date of this exercise shall be as set forth in Section 2(c) of the Option Agreement.

8. Acknowledgment. By signing this Exercise Notice, I acknowledge that I have received, read, and understood this Exercise Notice, the Plan, and the Option Agreement and agree to be bound by their terms. This Exercise Notice may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

Submitted by:

Date: _____

[Signature of Grantee]

[Typed name]

[Grantee's address]

Accepted by: Date:

Date: _____

[NAME OF COMPANY],

[state of incorporation] corporation

By: _____

[Signature]

Name: _____

[Typed name]

Its: _____

[Title]

[Company's address]

CONSENT OF SPOUSE OR DOMESTIC PARTNER

I, __[name of spouse or domestic partner]__, spouse or domestic partner of the Grantee, have read and hereby approve the foregoing Exercise Notice. In consideration of the Company's granting my spouse or domestic partner the right to purchase the Shares as set forth in the Exercise Notice, I agree that any community property or similar interest that I may have in the Shares shall be bound irrevocably by the Exercise Notice, the Option Agreement, and the Plan. I hereby appoint my spouse or domestic partner as my attorney-in-fact with respect to any amendment or exercise of any rights with respect to the Option.

Date: _____

[Typed name].

[Signature of spouse or domestic partner]



**STANDARD INDUSTRIAL/COMMERCIAL SINGLE-TENANT LEASE – NET
(DO NOT USE THIS FORM FOR MULTI-TENANT BUILDINGS)**

1. Basic Provisions (“Basic Provisions”).

1.1 Parties. This Lease (“**Lease**”), dated for reference purposes only February 3, 2020, is made by and between Pacific Industrial Partners, LLC (“**Lessor**”) and Beta Bionics, Inc. (“**Lessee**”), (collectively the “**Parties**,” or individually a “**Party**”).

1.2 Premises: That certain real property, including all improvements therein or to be provided by Lessor under the terms of this Lease, commonly known as (street address, city, state, zip): 11 Hughes, Irvine, CA 92618 (“**Premises**”). The Premises are located in the County of Orange, and are generally described as (describe briefly the nature of the property and, if applicable, the “**Project**,” if the property is located within a Project): an approximately 50,020 square foot building situated on 129,702 square feet of land. (See also Paragraph 2)

1.3 Term: 7 years and 0 months (“**Original Term**”) commencing June 1, 2020 (“**Commencement Date**”) and ending May 31, 2027 (“**Expiration Date**”). (See also Paragraph 3)

1.4 Early Possession: If the Premises are available Lessee may have non-exclusive possession of the Premises commencing April 1, 2020 (“**Early Possession Date**”). (See also Paragraphs 3.2 and 3.3)

1.5 Base Rent: \$37,515 per month (“**Base Rent**”), payable on the 1st day of each month commencing June 1, 2020. (See also Paragraph 4)

☒ If this box is checked, there are provisions in this Lease for the Base Rent to be adjusted. See Paragraph 51.

1.6 Base Rent and Other Monies Paid Upon Execution:

- (a) Base Rent: \$37,515 for the period June 1, 2020 - June 31, 2020.
- (b) Security Deposit: \$63,525 (“**Security Deposit**”). (See also Paragraph 5)
- (c) Association Fees: N/A for the period _____.
- (d) Other: N/A for _____.
- (e) Total Due Upon Execution of this Lease: \$101,040.

1.7 Agreed Use: General office, manufacturing, testing related to the distribution and storage of medical devices. (See also Paragraph 6)

1.8 Insuring Party. Lessor is the “**Insuring Party**” unless otherwise stated herein. (See also Paragraph 8)

1.9 Real Estate Brokers. (See also Paragraph 15 and 25)

(a) **Representation:** Each Party acknowledges receiving a Disclosure Regarding Real Estate Agency Relationship, confirms and consents to the following agency relationships in this lease with the following real estate brokers (“**Broker(s)**”) and/or their agents (“**Agent(s)**”):

Lessor’s Brokerage Firm CBRE License No. 00409987 is the broker of (check one): ☐ the Lessor; or ☒ both the Lessee and Lessor (dual agent).

Lessor’s Agent Jeff Carr License No. 01009600 is (check one): ☐ the Lessor’s Agent (salesperson or broker associate); or ☒ both the Lessee’s Agent and the Lessor’s Agent (dual agent).

Lessee’s Brokerage Firm CBRE License No. 00409987 is the broker of (check one): ☐ the Lessee; or ☒ both the Lessee and Lessor (dual agent).

Lessee’s Agent Jeff Carr License No. 01009600 is (check one): ☐ the Lessee’s Agent (salesperson or broker associate); or ☒ both the Lessee’s Agent and the Lessor’s Agent (dual agent).

(b) **Payment to Brokers.** Upon execution and delivery of this Lease by both Parties, Lessor shall pay to the Brokers the brokerage fee agreed to in a separate written agreement.

/s/ RN

/s/ AM
INITIALS

/s/ERD

INITIALS

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1.11 Attachments. Attached hereto are the following, all of which constitute a part of this Lease:

☒ an Addendum consisting of Paragraphs 51 through 60;

☒ a plot plan depicting the Premises; **Exhibit A, “Premises A”**

☐ a current set of the Rules and Regulations;

☐ a Work Letter;

☒ other(specify): Exhibit B (Signage Criteria), Exhibit C (Move-Out Conditions), Exhibit D (Demolition Plan and Space Plan) & Exhibit E (estimated monthly base NNN charges).

2. Premises.

2.1 Letting. Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, the Premises, for the term, at the rental, and upon all of the terms, covenants and conditions set forth in this Lease. While the approximate square footage of the Premises may have been used in the marketing of the Premises for purposes of comparison, the Base Rent stated herein is NOT tied to square footage and is not subject to adjustment should the actual size be determined to be different. **NOTE: Lessee is advised to verify the actual size prior to executing this Lease.**

2.2 Condition. Lessor shall deliver the Premises to Lessee broom clean and free of debris on the Commencement Date or the Early Possession Date, whichever first occurs (“**Start Date**”), and, so long as the required service contracts described in Paragraph 7.1(b) below are obtained by Lessee and in effect within thirty days following the Start Date, warrants that the existing electrical, plumbing, fire sprinkler, lighting, heating, ventilating and air conditioning systems (“**HVAC**”), loading doors, sump pumps, if any, and all other such elements in the Premises, other than those constructed by Lessee, shall be in good operating condition on said date, that the structural elements of the roof, bearing walls and foundation of any buildings on the Premises (the “**Building**”) shall be free of material defects, and that the Premises do not contain hazardous levels of any mold or fungi defined as toxic under applicable state or federal law. If a non-compliance with said warranty exists as of the Start Date, or if one of such systems or elements should malfunction or fail within the appropriate warranty period, Lessor shall, as Lessor’s sole obligation with respect to such matter, except as otherwise provided in this Lease, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, malfunction or failure, rectify same at Lessor’s expense. The warranty periods shall be as follows: (i) 6 months as to the HVAC systems, and (ii) 30 days as to the remaining systems and other elements of the Building. If Lessee does not give Lessor the required notice within the appropriate warranty period, correction of any such non-compliance, malfunction or failure shall be the obligation of Lessee at Lessee’s sole cost and expense. Lessor also warrants, that unless otherwise specified in writing, Lessor is unaware of (i) any recorded Notices of Default affecting the Premise; (ii) any delinquent amounts due under any loan secured by the Premises; and (iii) any bankruptcy proceeding affecting the Premises.

2.3 Compliance. Lessor warrants that to the best of its knowledge the improvements on the Premises comply with the building codes, applicable laws, covenants or restrictions of record, regulations, and ordinances (“**Applicable Requirements**”) that were in effect at the time that each Improvement, or portion thereof, was constructed. Said warranty does not apply to the use to which Lessee will put the Premises, modifications which may be required by the Americans with Disabilities Act or any similar laws as a result of Lessee’s use (see Paragraph 49), or to any Alterations or Utility installations (as defined in Paragraph 7.3(a)) made or to be made by Lessee. **NOTE: Lessee is responsible for determining whether or not the Applicable Requirements, and especially the zoning, are appropriate for Lessee’s intended use, and acknowledges that past uses of the Premises may no longer be allowed.** If the Premises do not comply with said warranty, Lessor shall, except as otherwise provided, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, rectify the same at Lessor’s expense. If Lessee **or the appropriate governmental agency** does not give Lessor written notice of a non-compliance with this warranty within 6 months following the Start Date, correction of that non-compliance shall be the obligation of Lessee at Lessee’s sole cost and expense. If the Applicable Requirements are hereafter changed so as to require during the term of this Lease the construction of an addition to or an alteration of the Premises and/or Building, the remediation of any Hazardous Substance, or the reinforcement or other physical modification of the Unit, Premises and/or Building (“**Capital Expenditure**”), Lessor and Lessee shall allocate the cost of such work as follows:

(a) Subject to Paragraph 2.3(c) below, if such Capital Expenditures are required as a result of the specific and unique use of the Premises by Lessee as compared with uses by tenants in general, Lessee shall be fully responsible for the cost thereof, provided, however, that if such Capital Expenditure is required during the last 2 years of this Lease and the cost thereof exceeds 6 months’ Base Rent, Lessee may Instead terminate this Lease unless Lessor notifies Lessee, in writing, within 10 days after receipt of Lessee’s termination notice that Lessor has elected to pay the difference between the actual cost thereof and an amount equal to 6 months’ Base Rent. If Lessee elects termination, Lessee shall, **as soon as reasonably practicable**, cease the use of the Premises which requires such Capital Expenditure and deliver to Lessor written notice specifying a termination date at least 90 days thereafter. Such termination date shall, however, in no event be earlier than the last day that Lessee could legally utilize the Premises without commencing such Capital Expenditure.

/s/ RN

/s/ AM

INITIALS

/s/ERD

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(b) if such Capital Expenditure is not the result of the specific and unique use of the Premises by Lessee (such as, governmentally mandated seismic modifications), then Lessor shall pay for such Capital Expenditure and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease or any extension thereof, on the date that on which the Base Rent is due, an amount equal to 1/144th of the portion of such costs reasonably attributable to the Premises. Lessee shall pay interest on the balance but may prepay its obligation at any time. If, however, such Capital Expenditure is required during the last **12 months** of this Lease or if Lessor reasonably determines that it is not economically feasible to pay its share thereof, Lessor shall have the option to terminate this Lease upon 90 days prior written notice to Lessee unless Lessee notifies Lessor, in writing, within 10 days after receipt of Lessor's termination notice that Lessee will pay for such Capital Expenditure. If Lessor does not elect to terminate, and fails to tender its share of any such Capital Expenditure, Lessee may advance such funds and deduct same, with Interest, from Rent until Lessor's share of such costs have been fully paid. If Lessee is unable to finance Lessor's share, or if the balance of the Rent due and payable for the remainder of this Lease is not sufficient to fully reimburse Lessee on an offset basis, Lessee shall have the right to terminate this Lease upon 30 days written notice to Lessor.

(c) Notwithstanding the above, the provisions concerning Capital Expenditures are intended to apply only to non-voluntary, unexpected, and new Applicable Requirements. If the Capital Expenditures are instead triggered by Lessee as a result of an actual or proposed change in use, change in intensity of use, or modification to the Premises then, and in that event, Lessee shall either: (i) **as soon as reasonably practicable**, cease such changed use or intensity of use and/or take such other steps as may be necessary to eliminate the requirement for such Capital Expenditure, or (ii) complete such Capital Expenditure at its own expense. Lessee shall not, however, have any right to terminate this Lease.

2.4 Acknowledgements. Lessee acknowledges that: (a) it has been given an opportunity to inspect and measure the Premises, (b) it has been advised by Lessor and/or Brokers to satisfy itself with respect to the size and condition of the Premises (including but not limited to the electrical, HVAC and fire sprinkler systems, security, environmental aspects, and compliance with Applicable Requirements and the Americans with Disabilities Act), and their suitability for Lessee's Intended use, (c) Lessee has made such investigation as it deems necessary with reference to such matters and assumes all responsibility therefor as the same relate to its occupancy of the Premises, (d) It is not relying on any representation as to the size of the Premises made by Brokers or Lessor, (e) the square footage of the Premises was not material to Lessee's decision to lease the Premises and pay the Rent stated herein, and (f) neither Lessor, Lessor's agents, nor Brokers have made any oral or written representations or warranties with respect to said matters other than as set forth in this Lease. In addition, Lessor acknowledges that: (i) Brokers have made no representations, promises or warranties concerning Lessee's ability to honor the Lease or suitability to occupy the Premises, and (ii) it is Lessor's sole responsibility to investigate the financial capability and/or suitability of all proposed tenants.

3. Term.

3.1 Term. The Commencement Date, Expiration Date and Original Term of this Lease are as specified In Paragraph 1.3.

3.2 Early Possession. Any provision herein granting Lessee Early Possession of the Premises is subject to and conditioned upon the Premises being available for such possession prior to the Commencement Date. Any grant of Early Possession only conveys a non-exclusive right to occupy the Premises. If Lessee totally or partially occupies the Premises prior to the Commencement Date, the obligation to pay Base Rent shall be abated for the period of such Early Possession. All other terms of this Lease (including but not limited to the obligations to pay Real Property Taxes and insurance premiums and to maintain the Premises) shall be in effect during such period. Any such Early Possession shall not affect the Expiration Date.

3.3 Delay In Possession. Lessor agrees to use Its best commercially reasonable efforts to deliver possession of the Premises to Lessee by the Commencement Date. If, despite said efforts, Lessor is unable to deliver possession by such date, Lessor shall not be subject to any liability therefor, nor shall such failure affect the validity of this Lease or change the Expiration Date. Lessee shall not, however, be obligated to pay Rent or perform its other obligations until Lessor delivers possession of the Premises and any period of rent abatement that Lessee would otherwise have enjoyed shall run from the date of delivery of possession and continue for a period equal to what Lessee would otherwise have enjoyed under the terms hereof, but minus any days of delay caused by the acts or omissions of Lessee. If possession is not delivered within 60 days after the Commencement Date, as the same may be extended under the terms of any Work Letter executed by Parties, Lessee may, at its option, by notice in writing within 10 days after the end of such 60 day period, cancel this Lease, in which event the Parties shall be discharged from all obligations hereunder. If such written notice is not received by Lessor within said 10 day period, Lessee's right to cancel shall terminate. If possession of the Premises is not delivered within 120 days after the Commencement Date, this Lease shall terminate unless other agreements are reached between Lessor and Lessee, in writing.

/s/ RN

/s/ AM
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/s/ERD

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3.4 Lessee Compliance. Lessor shall not be required to tender possession of the Premises to Lessee until Lessee complies with its obligation to provide evidence of insurance (Paragraph 8.5). Pending delivery of such evidence, Lessee shall be required to perform all of its obligations under this Lease from and after the Start Date, including the payment of Rent, notwithstanding Lessor's election to withhold possession pending receipt of such evidence of insurance. Further, if Lessee is required to perform any other conditions prior to or concurrent with the Start Date, the Start Date shall occur but Lessor may elect to withhold possession until such conditions are satisfied.

4. Rent.

4.1 Rent Defined. All monetary obligations of Lessee to Lessor under the terms of this Lease (except for the Security Deposit) are deemed to be rent ("**Rent**").

4.2 Payment. Lessee shall cause payment of Rent to be received by Lessor in lawful money of the United States, without offset or deduction (except as specifically permitted in this Lease), on or before the day on which it is due. All monetary amounts shall be rounded to the nearest whole dollar. In the event that any invoice prepared by Lessor is inaccurate such inaccuracy shall not constitute a waiver and Lessee shall be obligated to pay the amount set forth in this Lease. Rent for any period during the term hereof which is for less than one full calendar month shall be prorated based upon the actual number of days of said month. Payment of Rent shall be made to Lessor at its address stated herein or to such other persons or place as Lessor may from time to time designate in writing. Acceptance of a payment which is less than the amount then due shall not be a waiver of Lessor's rights to the balance of such Rent, regardless of Lessor's endorsement of any check so stating. In the event that any check, draft, or other instrument of payment given by Lessee to Lessor is dishonored for any reason, Lessee agrees to pay to Lessor the sum of \$25 in addition to any Late Charge and Lessor, at its option, may require all future Rent be paid by cashier's check. Payments will be applied first to accrued late charges and attorney's fees, second to accrued interest, then to Base Rent, Insurance and Real Property Taxes, and any remaining amount to any other outstanding charges or costs.

5. Security Deposit. See Addendum Paragraph #53 Lessee shall deposit with Lessor upon execution hereof the Security Deposit as security for Lessee's faithful performance of its obligations under this Lease. If Lessee fails to pay Rent, or otherwise Defaults under this Lease, Lessor may use, apply or retain all or any portion of said Security Deposit for the payment of any amount already due Lessor, for Rents which will be due in the future, and/or to reimburse or compensate Lessor for any liability, expense, loss or damage which Lessor may suffer or incur by reason thereof. If Lessor uses or applies all or any portion of the Security Deposit, Lessee shall within 10 days after written request therefor deposit monies with Lessor sufficient to restore said Security Deposit to the full amount required by this Lease. Should the Agreed Use be amended to accommodate a material change in the business of Lessee or to accommodate a sublessee or assignee, Lessor shall have the right to increase the Security Deposit to the extent necessary, in Lessor's reasonable judgment, to account for any increased wear and tear that the Premises may suffer as a result thereof. If a change in control of Lessee occurs during this Lease and following such change the financial condition of Lessee is, in Lessor's reasonable judgment, significantly reduced, Lessee shall deposit such additional monies with Lessor as shall be sufficient to cause the Security Deposit to be at a commercially reasonable level based on such change in financial condition. Lessor shall not be required to keep the Security Deposit separate from its general accounts. Within 90 days after the expiration or termination of this Lease, Lessor shall return that portion of the Security Deposit not used or applied by Lessor. Lessor shall upon written request provide Lessee with an accounting showing how that portion of the Security Deposit that was not returned was applied. No part of the Security Deposit shall be considered to be held in trust, to bear interest or to be prepayment for any monies to be paid by Lessee under this Lease. THE SECURITY DEPOSIT SHALL NOT BE USED BY LESSEE IN LIEU OF PAYMENT OF THE LAST MONTH'S RENT.

6. Use.

6.1 Use. Lessee shall use and occupy the Premises only for the Agreed Use, and for no other purpose. Lessee shall not use or permit the use of the Premises in a manner that is unlawful, creates damage, waste or a nuisance, or that disturbs occupants of or causes damage to neighboring premises or properties. Other than guide, signal and seeing eye dogs, Lessee shall not keep or allow in the Premises any pets, animals, birds, fish, or reptiles. Lessor shall not unreasonably withhold or delay its consent to any written request for a modification of the Agreed Use, so long as the same will not impair the structural integrity of the improvements on the premises or the mechanical or electrical systems therein, and/or is not significantly more burdensome to the Premises. If Lessor elects to withhold consent, Lessor shall within 7 days after such request give written notification of same, which notice shall include an explanation of Lessor's objections to the change in the Agreed Use.

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6.2 Hazardous Substances.

(a) **Reportable Uses Require Consent.** The term “**Hazardous Substance**” as used in this Lease shall mean any product, substance, or waste whose presence, use, manufacture, disposal, transportation, or release, either by itself or in combination with other materials expected to be on the Premises, is either: (i) potentially injurious to the public health, safety or welfare, the environment or the Premises, (ii) regulated or monitored by any governmental authority, or (iii) a basis for potential liability of Lessor to any governmental agency or third party under any applicable statute or common law theory. Hazardous Substances shall include, but not be limited to, hydrocarbons, petroleum, gasoline, and/or crude oil or any products, by-products or fractions thereof. Lessee shall not engage in any activity in or on the Premises which constitutes a Reportable Use of Hazardous Substances without the express prior written consent of Lessor and timely compliance (at Lessee’s expense) with all Applicable Requirements. “**Reportable Use**” shall mean (i) the installation or use of any above or below ground storage tank, (ii) the generation, possession, storage, use, transportation, or disposal of a Hazardous Substance that requires a permit from, or with respect to which a report, notice, registration or business plan is required to be filed with, any governmental authority, and/or (iii) the presence at the Premises of a Hazardous Substance with respect to which any Applicable Requirements requires that a notice be given to persons entering or occupying the Premises or neighboring properties. Notwithstanding the foregoing, Lessee may use any ordinary and customary materials reasonably required to be used in the normal course of the Agreed Use, ordinary office supplies (copier toner, liquid paper, glue, etc.) and common household cleaning materials, so long as such use is in compliance with all Applicable Requirements, is not a Reportable Use, and does not expose the Premises or neighboring property to any meaningful risk of contamination or damage or expose Lessor to any liability therefor. In addition, Lessor may condition its consent to any Reportable Use upon receiving such additional assurances as Lessor reasonably deems necessary to protect itself, the public, the Premises and/or the environment against damage, contamination, injury and/or liability, including, but not limited to, the installation (and removal on or before Lease expiration or termination) of protective modifications (such as concrete encasements) and/or increasing the Security Deposit.

(b) **Duty to Inform Lessor.** If Lessee knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the Premises, other than as previously consented to by Lessor, Lessee shall, as soon as reasonably practicable, give written notice of such fact to Lessor, and provide Lessor with a copy of any report, notice, claim or other documentation which it has concerning the presence of such Hazardous Substance.

(c) **Lessee Remediation.** Lessee shall not cause or permit any Hazardous Substance to be spilled or released in, on, under, or about the Premises (including through the plumbing or sanitary sewer system) and shall promptly, at Lessee’s expense, comply with all Applicable Requirements and take all investigatory and/or remedial action reasonably recommended, whether or not formally ordered or required, for the cleanup of any contamination of, and for the maintenance, security and/or monitoring of the Premises or neighboring properties, that was caused or materially contributed to by Lessee, or pertaining to or involving any Hazardous Substance brought onto the Premises during the term of this Lease, by or for Lessee, or any third party.

(d) **Lessee Indemnification.** Except to the extent caused by the negligence or misconduct of Lessor, Lessee shall indemnify, defend and hold Lessor, its agents, employees, lenders and ground lessor, if any, harmless from and against any and all loss of rents and/or damages, liabilities, judgments, claims, expenses, penalties, and attorneys’ and consultants’ fees arising out of or involving any Hazardous Substance brought onto the Premises by or for Lessee, or any third party (provided, however, that Lessee shall have no liability under this Lease with respect to underground migration of any Hazardous Substance under the Premises from adjacent properties not caused or contributed to by Lessee). Lessee’s obligations shall include, but not be limited to, the effects of any contamination or injury to person, property or the environment created or suffered by Lessee, and the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease. No termination, cancellation or release agreement entered into by Lessor and Lessee shall release Lessee from its obligations under this Lease with respect to Hazardous Substances, unless specifically so agreed by Lessor in writing at the time of such agreement.

(e) **Lessor Indemnification.** Except as otherwise provided in paragraph 8.7, Lessor and its successors and assigns shall indemnify, defend, reimburse and hold Lessee, its employees and lenders, harmless from and against any and all environmental damages, including the cost of remediation, which result from Hazardous Substances which existed on the Premises prior to Lessee’s occupancy or which are caused by the negligence or misconduct of Lessor, its agents or employees. Lessor’s obligations, as and when required by the Applicable Requirements, shall include, but not be limited to, the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease.

(f) **Investigations and Remediations.** Lessor shall retain the responsibility and pay for any investigations or remediation measures required by governmental entities having jurisdiction with respect to the existence of Hazardous Substances on the Premises prior to Lessee’s occupancy, unless such remediation measure is required as a result of Lessee’s use (including “**Alterations**”, as defined in paragraph 7.3(a) below) of the Premises, in which event Lessee shall be responsible for such payment. Lessee shall cooperate fully in any such activities at the request of Lessor, including allowing Lessor and Lessor’s agents to have reasonable access to the Premises at reasonable times in order to carry out Lessor’s investigative and remedial responsibilities.

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(g) **Lessor Termination Option.** If a Hazardous Substance Condition (see Paragraph 9.1(e)) occurs during the term of this Lease, unless Lessee is legally responsible therefor (in which case Lessee shall make the investigation and remediation thereof required by the Applicable Requirements and this Lease shall continue in full force and effect, but subject to Lessor's rights under Paragraph 6.2(d) and Paragraph 13), Lessor may, at Lessor's option, either (i) investigate and remediate such Hazardous Substance Condition, if required, as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) if the estimated cost to remediate such condition exceeds 12 times the then monthly Base Rent or \$100,000, whichever is greater, give written notice to Lessee, within 30 days after receipt by Lessor of knowledge of the occurrence of such Hazardous Substance Condition, of Lessor's desire to terminate this Lease as of the date 60 days following the date of such notice. In the event Lessor elects to give a termination notice, Lessee may, within 10 days thereafter, give written notice to Lessor of Lessee's commitment to pay the amount by which the cost of the remediation of such Hazardous Substance Condition exceeds an amount equal to 12 times the then monthly Base Rent or \$100,000, whichever is greater. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days following such commitment. In such event, this Lease shall continue in full force and effect, and Lessor shall proceed to make such remediation as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the required funds or assurance thereof within the time provided, this Lease shall terminate as of the date specified in Lessor's notice of termination.

6.3 Lessee's Compliance with Applicable Requirements. Except as otherwise provided in this Lease, Lessee shall, at Lessee's sole expense, fully, diligently and in a timely manner, materially comply with all Applicable Requirements, the requirements of any applicable fire insurance underwriter or rating bureau, and the recommendations of Lessor's engineers and/or consultants which relate in any manner to the Premises, without regard to whether said Applicable Requirements are now in effect or become effective after the Start Date. Lessee shall, within 10 days after receipt of Lessor's written request, provide Lessor with copies of all permits and other documents, and other information evidencing Lessee's compliance with any Applicable Requirements specified by Lessor, and shall immediately upon receipt, notify Lessor in writing (with copies of any documents involved) of any threatened or actual claim, notice, citation, warning, complaint or report pertaining to or involving the failure of Lessee or the Premises to comply with any Applicable Requirements. Likewise, Lessee shall immediately give written notice to Lessor of: (i) any water damage to the Premises and any suspected seepage, pooling, dampness or other condition conducive to the production of mold; or (ii) any mustiness or other odors that might indicate the presence of mold in the Premises. In addition, Lessee shall provide copies of all relevant material safety data sheets (MSDS) to Lessor within 10 days of the receipt of a written request therefor. In addition, Lessee shall provide Lessor with copies of its business license, certificate of occupancy and/or any similar document within 10 days of the receipt of a written request therefor.

6.4 Inspection; Compliance. Lessor and Lessor's "Lender" (as defined in Paragraph 30) and consultants authorized by Lessor shall have the right to enter into Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable notice, for the purpose of inspecting and/or testing the condition of the Premises and/or for verifying compliance by Lessee with this Lease. The cost of any such inspections shall be paid by Lessor, unless a violation of Applicable Requirements, or a Hazardous Substance Condition (see paragraph 9.1) is found to exist or be imminent, or the inspection is requested or ordered by a governmental authority. In such case, Lessee shall upon request reimburse Lessor for the cost of such inspection, so long as such Inspection is reasonably related to the violation or contamination. In addition, Lessee shall provide copies of all relevant material safety data sheets (MSDS) to Lessor within 10 days of the receipt of a written request therefor. Lessee acknowledges that any failure on its part to allow such inspections or testing will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, should the Lessee fail to allow such inspections and/or testing in a timely fashion the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or \$100, whichever is greater for the remainder to the Lease. The Parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to allow such inspection and/or testing. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to such failure nor prevent the exercise of any of the other rights and remedies granted hereunder.

7. Maintenance; Repairs; Utility Installations; Trade Fixtures and Alterations. See Addendum Paragraph #54

7.1 Lessee's Obligations.

(a) **In General.** Subject to the provisions of Paragraph 2.2 (Condition), 2.3 (Compliance), 6.3 (Lessee's Compliance with Applicable Requirements), 7.2 (Lessor's Obligations), 9 (Damage or Destruction), and 14 (Condemnation), Lessee shall, at Lessee's sole expense, keep the Premises, Utility Installations (intended for Lessee's exclusive use, no matter where located), and Alterations in good order, condition and repair (whether or not the portion of the Premises requiring repairs, or the means of repairing the same, are reasonably or readily accessible to Lessee, and whether or not the need for such repairs occurs as a result of Lessee's use, any prior use, the elements or the age of such portion of the Premises), including, but not limited to, all equipment or facilities, such as plumbing, HVAC equipment, electrical, lighting facilities, boilers, pressure vessels, fire protection system, fixtures, walls (Interior and exterior), foundations, ceilings, roofs, roof drainage systems, floors, windows, doors, plate glass, skylights, landscaping, driveways, parking lots, fences, retaining walls, signs, sidewalks and parkways located in, on, or adjacent to the Premises. Lessee, in keeping the Premises in good order, condition and repair, shall exercise and perform good maintenance practices, specifically including the procurement and maintenance of the service contracts required by Paragraph 7.1(b) below. Lessee's obligations shall include restorations, replacements or renewals when necessary to keep the Premises and all improvements thereon or a part thereof in good order, condition and state of repair. Lessee shall, during the term of this Lease, keep the exterior appearance of the Building in a first-class condition (including, e.g. graffiti removal) consistent with the exterior appearance of other similar facilities of comparable age and size in the vicinity, including, when necessary, the exterior repainting of the Building.

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(b) **Service Contracts.** Lessee shall, at Lessee's sole expense, procure and maintain contracts, with copies to Lessor, in customary form and substance for, and with contractors specializing and experienced in the maintenance of the following equipment and improvements, if any, if and when installed on the Premises: (i) HVAC equipment, (ii) boiler, and pressure vessels, (iii) fire extinguishing systems, including fire alarm and/or smoke detection, (iv) landscaping and irrigation systems, (v) roof covering and drains, and (vi) clarifiers. However, Lessor reserves the right, upon notice to Lessee, to procure and maintain any or all of such service contracts, and Lessee shall reimburse Lessor, upon demand, for the cost thereof.

(c) **Failure to Perform.** If Lessee fails to perform Lessee's obligations under this Paragraph 7.1, Lessor may enter upon the Premises after 10 days' prior written notice to Lessee (except in the case of an emergency, in which case no notice shall be required), perform such obligations on Lessee's behalf, and put the Premises in good order, condition and repair, and Lessee shall promptly pay to Lessor a sum equal to 115% of the cost thereof.

(d) **Replacement.** Subject to Lessee's indemnification of Lessor as set forth in Paragraph 8.7 below, and without relieving Lessee of liability resulting from Lessee's failure to exercise and perform good maintenance practices, if an item described in Paragraph 7.1(b) cannot be repaired other than at a cost which is in excess of 50% of the cost of replacing such item, then such item shall be replaced by Lessor, and the cost thereof shall be prorated between the Parties and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease, on the date on which Base Rent is due, an amount equal to the product of multiplying the cost of such replacement by a fraction, the numerator of which is one, and the denominator of which is 144 (ie. 1/144th of the cost per month). Lessee shall pay Interest on the unamortized balance but may prepay its obligation at any time.

7.2 Lessor's Obligations. Subject to the provisions of Paragraphs 2.2 (Condition), 2.3 (Compliance), 9 (Damage or Destruction) and 14 (Condemnation), it is intended by the Parties hereto that Lessor have no obligation, in any manner whatsoever, to repair and maintain the Premises, or the equipment therein, all of which obligations are intended to be that of the Lessee. It is the intention of the Parties that the terms of this Lease govern the respective obligations of the Parties as to maintenance and repair of the Premises.

7.3 Utility Installations; Trade Fixtures; Alterations.

(a) **Definitions.** The term "**Utility Installations**" refers to all floor and window coverings, air and/or vacuum lines, power panels, electrical distribution, security and fire protection systems, communication cabling, lighting fixtures, HVAC equipment, plumbing, and fencing in or on the Premises. The term "**Trade Fixtures**" shall mean Lessee's machinery and equipment that can be removed without doing material damage to the Premises. The term "**Alterations**" shall mean any modification of the improvements, other than Utility Installations or Trade Fixtures, whether by addition or deletion. "**Lessee Owned Alterations and/or Utility Installations**" are defined as Alterations and/or Utility Installations made by Lessee that are not yet owned by Lessor pursuant to Paragraph 7.4(a).

(b) **Consent.** Lessee shall not make any Alterations or Utility Installations to the Premises without Lessor's prior written consent. Lessee may, however, make non-structural Alterations or Utility Installations to the interior of the Premises (excluding the roof) without such consent but upon notice to Lessor, as long as they are not visible from the outside, do not involve puncturing, relocating or removing the roof or any existing walls, will not affect the electrical, plumbing, HVAC, and/or life safety systems, do not trigger the requirement for additional modifications and/or improvements to the Premises resulting from Applicable Requirements, such as compliance with Title 24, and the cumulative cost thereof during this Lease as extended does not exceed a sum equal to **\$150,000** in any one year. Notwithstanding the foregoing, Lessee shall not make or permit any roof penetrations and/or install anything on the roof without the prior written approval of Lessor. Lessor may, as a precondition to granting such approval, require Lessee to utilize a contractor chosen and/or approved by Lessor. Any Alterations or Utility Installations that Lessee shall desire to make and which require the consent of the Lessor shall be presented to Lessor in written form with detailed plans. Consent shall be deemed conditioned upon Lessee's: (i) acquiring all applicable governmental permits, (ii) furnishing Lessor with copies of both the permits and the plans and specifications prior to commencement of the work, and (iii) compliance with all conditions of said permits and other Applicable Requirements in a prompt and expeditious manner. Any Alterations or Utility Installations shall be performed in a workmanlike manner with good and sufficient materials. Lessee shall promptly upon completion furnish Lessor with as-built plans and specifications. For work which costs an amount in excess of one month's Base Rent, Lessor may condition its consent upon Lessee providing a lien and completion bond in an amount equal to 150% of the estimated cost of such Alteration or Utility Installation and/or upon Lessee's posting an additional Security Deposit with Lessor.

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(c) **Liens; Bonds.** Lessee shall pay, when due, all claims for labor or materials furnished or alleged to have been furnished to or for Lessee at or for use on the Premises, which claims are or may be secured by any mechanic's or materialmen's lien against the Premises or any interest therein. Lessee shall give Lessor not less than 10 days notice prior to the commencement of any work in, on or about the Premises, and Lessor shall have the right to post notices of non-responsibility. If Lessee shall contest the validity of any such lien, claim or demand, then Lessee shall, at its sole expense defend and protect itself, Lessor and the Premises against the same and shall pay and satisfy any such adverse judgment that may be rendered thereon before the enforcement thereof. If Lessor shall require, Lessee shall furnish a surety bond in an amount equal to 150% of the amount of such contested lien, claim or demand, indemnifying Lessor against liability for the same. If Lessor elects to participate in any such action, Lessee shall pay Lessor's attorneys' fees and costs.

7.4 Ownership; Removal; Surrender; and Restoration.

(a) **Ownership.** Subject to Lessor's right to require removal or elect ownership as hereinafter provided, all Alterations and Utility Installations made by Lessee shall be the property of Lessee, but considered a part of the Premises. Lessor may, at any time, elect in writing to be the owner of all or any specified part of the Lessee Owned Alterations and Utility Installations. Unless otherwise instructed per paragraph 7.4(b) hereof, all Lessee Owned Alterations and Utility Installations shall, at the expiration or termination of this Lease, become the property of Lessor and be surrendered by Lessee with the Premises.

(b) **Removal.** Lessor may impose, as a condition to its consent to any and all utility installations, the requirement that, with respect to alterations or utility installations consisting of non-general office improvements, Lessee shall, at Lessee's sole expense, remove any alterations or utility installations upon the expiration or any early termination of the Term; provided that Lessee is notified of such requirement at the time of consent to such alteration or utility installation. Lessor may require the removal at any time of all or any part of any Lessee Owned Alterations or Utility Installations made without the required consent.

(c) **Surrender; Restoration.** Lessee shall surrender the Premises by the Expiration Date or any earlier termination date, with all of the improvements, parts and surfaces thereof broom clean and free of debris, and in good operating order, condition and state of repair, ordinary wear and tear excepted. "Ordinary wear and tear" shall not include any damage or deterioration that would have been prevented by good maintenance practice. Notwithstanding the foregoing and the provisions of Paragraph 7.1(a), if the Lessee occupies the Premises for 12 months or less, then Lessee shall surrender the Premises in the same condition as delivered to Lessee on the Start Date with NO allowance for ordinary wear and tear. Lessee shall repair any damage occasioned by the installation, maintenance or removal of Trade Fixtures, Lessee owned Alterations and/or Utility Installations, furnishings, and equipment as well as the removal of any storage tank installed by or for Lessee. Lessee shall also remove from the Premises any and all Hazardous Substances brought onto the Premises by or for Lessee, or any third party (except Hazardous Substances which were deposited via underground migration from areas outside of the Premises) to the level specified in Applicable Requirements. Trade Fixtures shall remain the property of Lessee and shall be removed by Lessee. Any personal property of Lessee not removed on or before the Expiration Date or any earlier termination date shall be deemed to have been abandoned by Lessee and may be disposed of or retained by Lessor as Lessor may desire. The failure by Lessee to timely vacate the Premises pursuant to this Paragraph 7.4(c) without the express written consent of Lessor shall constitute a holdover under the provisions of Paragraph 26 below.

8. Insurance; Indemnity.

8.1 Payment For Insurance. Lessee shall pay for all insurance required under Paragraph 8 except to the extent of the cost attributable to liability insurance carried by Lessor under Paragraph 8.2(b) in excess of \$2,000,000 per occurrence. Premiums for policy periods commencing prior to or extending beyond the Lease term shall be prorated to correspond to the Lease term. Payment shall be made by Lessee to Lessor within 10 days following receipt of an invoice.

8.2 Liability Insurance.

(a) **Carried by Lessee.** Lessee shall obtain and keep in force a Commercial General Liability policy of insurance protecting Lessee and Lessor as an additional insured against claims for bodily injury, personal injury and property damage based upon or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount not less than \$1,000,000 per occurrence with an annual aggregate of not less than \$2,000,000. Lessee shall add Lessor as an additional insured by means of an endorsement at least as broad as the Insurance Service Organization's "Additional Insured-Managers or Lessors of Premises" Endorsement. The policy shall not contain any intra-insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an "**Insured contract**" for the performance of Lessee's Indemnity obligations under this Lease. The limits of said insurance shall not, however, limit the liability of Lessee nor relieve Lessee of any obligation hereunder. Lessee shall provide an endorsement on its liability policy(ies) which provides that its insurance shall be primary to and not contributory with any similar insurance carried by Lessor, whose insurance shall be considered excess insurance only.

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(b) **Carried by Lessor.** Lessor shall maintain liability insurance as described in Paragraph 8.2(a), in addition to, and not in lieu of, the insurance required to be maintained by Lessee. Lessee shall not be named as an additional insured therein.

8.3 Property Insurance—Building, Improvements and Rental Value.

(a) **Building and Improvements.** The Insuring Party shall obtain and keep in force a policy or policies in the name of Lessor, with loss payable to Lessor, any ground-lessor, and to any Lender insuring loss or damage to the Premises. The amount of such insurance shall be equal to the full insurable replacement cost of the Premises, as the same shall exist from time to time, or the amount required by any Lender, but in no event more than the commercially reasonable and available insurable value thereof. Lessee Owned Alterations and Utility Installations, Trade Fixtures, and Lessee's personal property shall be insured by Lessee not by Lessor. If the coverage is available and commercially appropriate, such policy or policies shall insure against all risks of direct physical loss or damage (except the perils of flood and/or earthquake unless required by a Lender), including coverage for debris removal and the enforcement of any Applicable Requirements requiring the upgrading, demolition, reconstruction or replacement of any portion of the Premises as the result of a covered loss. Said policy or policies shall also contain an agreed valuation provision in lieu of any coinsurance clause, waiver of subrogation, and inflation guard protection causing an increase in the annual property insurance coverage amount by a factor of not less than the adjusted U.S. Department of Labor Consumer Price Index for All Urban Consumers for the city nearest to where the Premises are located. If such insurance coverage has a deductible clause, the deductible amount shall not exceed \$10,000 per occurrence, and Lessee shall be liable for such deductible amount in the event of an Insured Loss.

(b) **Rental Value.** The Insuring Party shall obtain and keep in force a policy or policies in the name of Lessor with loss payable to Lessor and any Lender, insuring the loss of the full Rent for one year with an extended period of indemnity for an additional 180 days ("Rental Value insurance"). Said insurance shall contain an agreed valuation provision in lieu of any coinsurance clause, and the amount of coverage shall be adjusted annually to reflect the projected Rent otherwise payable by Lessee, for the next 12 month period. Lessee shall be liable for any deductible amount in the event of such loss.

(c) **Adjacent Premises.** If the Premises are part of a larger building, or of a group of buildings owned by Lessor which are adjacent to the Premises, the Lessee shall pay for any increase in the premiums for the property insurance of such building or buildings if said increase is caused by Lessee's acts, omissions, use or occupancy of the Premises.

8.4 Lessee's Property; Business Interruption Insurance; Worker's Compensation Insurance.

(a) **Property Damage.** Lessee shall obtain and maintain insurance coverage on all of Lessee's personal property, Trade Fixtures, and Lessee Owned Alterations and Utility Installations. Such insurance shall be full replacement cost coverage with a deductible of not to exceed \$1,000 per occurrence. The proceeds from any such Insurance shall be used by Lessee for the replacement of personal property, Trade Fixtures and Lessee Owned Alterations and Utility Installations.

(b) **Business Interruption.** Lessee shall obtain and maintain loss of income and extra expense insurance in amounts as will reimburse Lessee for direct or indirect loss of earnings attributable to all perils commonly insured against by prudent lessees in the business of Lessee or attributable to prevention of access to the Premises as a result of such perils.

(c) **Worker's Compensation Insurance.** Lessee shall obtain and maintain Worker's Compensation Insurance in such amount as may be required by Applicable Requirements. Such policy shall include a 'Waiver of Subrogation' endorsement. Lessee shall provide Lessor with a copy of such endorsement along with the certificate of insurance or copy of the policy required by paragraph 8.5.

(d) **No Representation of Adequate Coverage.** Lessor makes no representation that the limits or forms of coverage of insurance specified herein are adequate to cover Lessee's property, business operations or obligations under this Lease.

8.5 Insurance Policies. Insurance required herein shall be by companies maintaining during the policy term a "General Policyholders Rating" of at least A-, VII, as set forth in the most current issue of "Best's Insurance Guide", or such other rating as may be required by a Lender. Lessee shall not do or permit to be done anything which invalidates the required insurance policies. Lessee shall, prior to the Start Date, deliver to Lessor certified copies of policies of such insurance or certificates with copies of the required endorsements evidencing the existence and amounts of the required insurance. No such policy shall be cancelable or subject to modification except after 30 days prior written notice to Lessor. Lessee shall, at least 10 days prior to the expiration of such policies, furnish Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof, or Lessor may increase his liability insurance coverage and charge the cost thereof to Lessee, which amount shall be payable by Lessee to Lessor upon demand. Such policies shall be for a term of at least one year, or the length of the remaining term of this Lease, whichever is less. If either Party shall fail to procure and maintain the insurance required to be carried by it, the other Party may, but shall not be required to, procure and maintain the same.

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8.6 Waiver of Subrogation. Without affecting any other rights or remedies, Lessee and Lessor each hereby release and relieve the other, and waive their entire right to recover damages against the other, for loss of or damage to its property arising out of or incident to the perils required to be Insured against herein. The effect of such releases and waivers is not limited by the amount of insurance carried or required, or by any deductibles applicable hereto. The Parties agree to have their respective property damage insurance carriers waive any right to subrogation that such companies may have against Lessor or Lessee, as the case may be, so long as the Insurance is not invalidated thereby.

8.7 Indemnity. Except for Lessor's gross negligence or misconduct, Lessee shall indemnify, protect, defend and hold harmless the Premises, Lessor and its agents, Lessor's master or ground lessor, partners and Lenders, from and against any and all claims, loss of rents and/or damages, liens, judgments, penalties, attorneys' fees, expenses and/or liabilities arising out of, involving, or in connection with, a Breach of the Lease by Lessee and/or the use and/or occupancy of the Premises and/or Project by Lessee and/or by Lessee's employees, contractors or invitees. If any action or proceeding is brought against Lessor by reason of any of the foregoing matters, Lessee shall upon notice defend the same at Lessee's expense by counsel reasonably satisfactory to Lessor and Lessor shall cooperate with Lessee in such defense. Lessor need not have first paid any such claim in order to be defended or indemnified.

8.8 Exemption of Lessor and Its Agents from Liability. Notwithstanding the negligence or breach of this Lease by Lessor or its agents, neither Lessor nor its agents shall be liable under any circumstances for: (i) injury or damage to the person or goods, wares, merchandise or other property of Lessee, Lessee's employees, contractors, invitees, customers, or any other person in or about the Premises, whether such damage or injury is caused by or results from fire, steam, electricity, gas, water or rain, indoor air quality, the presence of mold or from the breakage, leakage, obstruction or other defects of pipes, fire sprinklers, wires, appliances, plumbing, HVAC or lighting fixtures, or from any other cause, whether the said injury or damage results from conditions arising upon the Premises or upon other portions of the building of which the Premises are a part, or from other sources or places, (ii) any damages arising from any act or neglect of any other tenant of Lessor or from the failure of Lessor or its agents to enforce the provisions of any other lease in the Project, or (iii) injury to Lessee's business or for any loss of income or profit therefrom. Instead, it is intended that Lessee's sole recourse in the event of such damages or injury be to file a claim on the insurance policy(ies) that Lessee is required to maintain pursuant to the provisions of paragraph 8.

8.9 Failure to Provide Insurance. Lessee acknowledges that any failure on its part to obtain or maintain the Insurance required herein will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, for any month or portion thereof that Lessee does not maintain the required insurance and/or does not provide Lessor with the required binders or certificates evidencing the existence of the required insurance, the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or \$100, whichever is greater. The parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to maintain the required insurance. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to the failure to maintain such insurance, prevent the exercise of any of the other rights and remedies granted hereunder, nor relieve Lessee of its obligation to maintain the insurance specified in this Lease.

9. Damage or Destruction.

9.1 Definitions.

(a) **"Premises Partial Damage"** shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations, which can reasonably be repaired in 6 months or less from the date of the damage or destruction. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(b) **"Premises Total Destruction"** shall mean damage or destruction to the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which cannot reasonably be repaired in 6 months or less from the date of the damage or destruction. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(c) **"Insured Loss"** shall mean damage or destruction to improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which was caused by an event required to be covered by the insurance described in Paragraph 8.3(a), irrespective of any deductible amounts or coverage limits involved.

(d) **"Replacement Cost"** shall mean the cost to repair or rebuild the improvements owned by Lessor at the time of the occurrence to their condition existing immediately prior thereto, including demolition, debris removal and upgrading required by the operation of Applicable Requirements, and without deduction for depreciation.

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(e) “**Hazardous Substance Condition**” shall mean the occurrence or discovery of a condition involving the presence of, or a contamination by, a Hazardous Substance, in, on, or under the Premises which requires restoration.

9.2 Partial Damage—Insured Loss. If a Premises Partial Damage that is an Insured Loss occurs, then Lessor shall, at Lessor’s expense, repair such damage (but not Lessee’s Trade Fixtures or Lessee Owned Alterations and Utility Installations) as soon as reasonably possible and this Lease shall continue in full force and effect; provided, however, that Lessee shall, at Lessor’s election, make the repair of any damage or destruction the total cost to repair of which is \$10,000 or less, and, in such event, Lessor shall make any applicable Insurance proceeds available to Lessee on a reasonable basis for that purpose. Notwithstanding the foregoing, if the required insurance was not in force or the insurance proceeds are not sufficient to effect such repair, the Insuring Party shall promptly contribute the shortage in proceeds (except as to the deductible which is Lessee’s responsibility) as and when required to complete said repairs. In the event, however, such shortage was due to the fact that, by reason of the unique nature of the improvements, full replacement cost insurance coverage was not commercially reasonable and available, Lessor shall have no obligation to pay for the shortage in insurance proceeds or to fully restore the unique aspects of the Premises unless Lessee provides Lessor with the funds to cover same, or adequate assurance thereof, within 10 days following receipt of written notice of such shortage and request therefor. If Lessor receives said funds or adequate assurance thereof within said 10 day period, the party responsible for making the repairs shall complete them as soon as reasonably possible and this Lease shall remain in full force and effect. If such funds or assurance are not received, Lessor may nevertheless elect by written notice to Lessee within 10 days thereafter to: (i) make such restoration and repair as is commercially reasonable with Lessor paying any shortage in proceeds, in which case this Lease shall remain in full force and effect, or (ii) have this Lease terminate 30 days thereafter. Lessee shall not be entitled to reimbursement of any funds contributed by Lessee to repair any such damage or destruction. Premises Partial Damage due to flood or earthquake shall be subject to Paragraph 9.3, notwithstanding that there may be some insurance coverage, but the net proceeds of any such insurance shall be made available for the repairs if made by either Party.

9.3 Partial Damage—Uninsured Loss. If a Premises Partial Damage that is not an Insured Loss occurs, unless caused by a negligent or willful act of Lessee (in which event Lessee shall make the repairs at Lessee’s expense), Lessor may either: (i) repair such damage as soon as reasonably possible at Lessor’s expense, in which event this Lease shall continue in full force and effect, or (ii) terminate this Lease by giving written notice to Lessee within 30 days after receipt by Lessor of knowledge of the occurrence of such damage. Such termination shall be effective 60 days following the date of such notice. In the event Lessor elects to terminate this Lease, Lessee shall have the right within 10 days after receipt of the termination notice to give written notice to Lessor of Lessee’s commitment to pay for the repair of such damage without reimbursement from Lessor. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days after making such commitment. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such repairs as soon as reasonably possible after the required funds are available. If Lessee does not make the required commitment, this Lease shall terminate as of the date specified in the termination notice.

9.4 Total Destruction. Notwithstanding any other provision hereof, if a Premises Total Destruction occurs, this Lease shall terminate 60 days following such Destruction. If the damage or destruction was caused by the gross negligence or willful misconduct of Lessee, Lessor shall have the right to recover Lessor’s damages from Lessee, except as provided in Paragraph 8.6.

9.5 Damage Near End of Term. If at any time during the last 6 months of this Lease there is damage for which the cost to repair exceeds one month’s Base Rent, whether or not an Insured Loss, Lessor may terminate this Lease effective 60 days following the date of occurrence of such damage by giving a written termination notice to Lessee within 30 days after the date of occurrence of such damage. Notwithstanding the foregoing, if Lessee at that time has an exercisable option to extend this Lease or to purchase the Premises, then Lessee may preserve this Lease by, (a) exercising such option and (b) providing Lessor with any shortage in insurance proceeds (or adequate assurance thereof) needed to make the repairs on or before the earlier of (i) the date which is 10 days after Lessee’s receipt of Lessor’s written notice purporting to terminate this Lease, or (ii) the day prior to the date upon which such option expires. If Lessee duly exercises such option during such period and provides Lessor with funds (or adequate assurance thereof) to cover any shortage in insurance proceeds, Lessor shall, at Lessor’s commercially reasonable expense, repair such damage as soon as reasonably possible and this Lease shall continue in full force and effect. If Lessee fails to exercise such option and provide such funds or assurance during such period, then this Lease shall terminate on the date specified in the termination notice and Lessee’s option shall be extinguished.

9.6 Abatement of Rent; Lessee’s Remedies.

(a) **Abatement.** In the event of Premises Partial Damage or Premises Total Destruction or a Hazardous Substance Condition for which Lessee is not responsible under this Lease, the Rent payable by Lessee for the period required for the repair, remediation or restoration of such damage shall be abated in proportion to the degree to which Lessee’s use of the Premises is impaired. All other obligations of Lessee hereunder shall be performed by Lessee, and Lessor shall have no liability for any such damage, destruction, remediation, repair or restoration except as provided herein.

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(b) **Remedies.** If Lessor is obligated to repair or restore the Premises and does not commence, in a substantial and meaningful way, such repair or restoration within 90 days after such obligation shall accrue, Lessee may, at any time prior to the commencement of such repair or restoration, give written notice to Lessor and to any Lenders of which Lessee has actual notice, of Lessee's election to terminate this Lease on a date not less than 60 days following the giving of such notice. If Lessee gives such notice and such repair or restoration is not commenced within 30 days thereafter, this Lease shall terminate as of the date specified in said notice. If the repair or restoration is commenced within such 30 days, this Lease shall continue in full force and effect. "Commence" shall mean either the unconditional authorization of the preparation of the required plans, or the beginning of the actual work on the Premises, whichever first occurs.

9.7 Termination; Advance Payments. Upon termination of this Lease pursuant to Paragraph 6.2(g) or Paragraph 9, an equitable adjustment shall be made concerning advance Base Rent and any other advance payments made by Lessee to Lessor. Lessor shall, in addition, return to Lessee so much of Lessee's Security Deposit as has not been, or is not then required to be, used by Lessor.

10. Real Property Taxes.

10.1 Definition. As used herein, the term "Real Property Taxes" shall include any form of assessment; real estate, general, special, ordinary or extraordinary, or rental levy or tax (other than inheritance, personal income or estate taxes); improvement bond; and/or license fee imposed upon or levied against any legal or equitable interest of Lessor in the Premises or the Project, Lessor's right to other income therefrom, and/or Lessor's business of leasing, by any authority having the direct or indirect power to tax and where the funds are generated with reference to the Building address. Real Property Taxes shall also include any tax, fee, levy, assessment or charge, or any increase therein: (i) imposed by reason of events occurring during the term of this Lease, including but not limited to, a change in the ownership of the Premises, and (ii) levied or assessed on machinery or equipment provided by Lessor to Lessee pursuant to this Lease.

10.2 Payment of Taxes. In addition to Base Rent, Lessee shall pay to Lessor an amount equal to the Real Property Tax installment due at least 20 days prior to the applicable delinquency date. If any such installment shall cover any period of time prior to or after the expiration or termination of this Lease, Lessee's share of such installment shall be prorated. In the event Lessee incurs a late charge on any Rent payment, Lessor may estimate the current Real Property Taxes, and require that such taxes be paid in advance to Lessor by Lessee monthly in advance with the payment of the Base Rent. Such monthly payments shall be an amount equal to the amount of the estimated installment of taxes divided by the number of months remaining before the month in which said installment becomes delinquent. When the actual amount of the applicable tax bill is known, the amount of such equal monthly advance payments shall be adjusted as required to provide the funds needed to pay the applicable taxes. If the amount collected by Lessor is insufficient to pay such Real Property Taxes when due, Lessee shall pay Lessor, upon demand, such additional sum as is necessary. Advance payments may be intermingled with other moneys of Lessor and shall not bear interest. In the event of a Breach by Lessee in the performance of its obligations under this Lease, then any such advance payments may be treated by Lessor as an additional Security Deposit.

10.3 Joint Assessment. If the Premises are not separately assessed, Lessee's liability shall be an equitable proportion of the Real Property Taxes for all of the land and improvements included within the tax parcel assessed, such proportion to be conclusively determined by Lessor from the respective valuations assigned in the assessor's work sheets or such other information as may be reasonably available.

10.4 Personal Property Taxes. Lessee shall pay, prior to delinquency, all taxes assessed against and levied upon Lessee Owned Alterations, Utility Installations, Trade Fixtures, furnishings, equipment and all personal property of Lessee. When possible, Lessee shall cause its Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lessor. If any of Lessee's said property shall be assessed with Lessor's real property, Lessee shall pay Lessor the taxes attributable to Lessee's property within 10 days after receipt of a written statement setting forth the taxes applicable to Lessee's property.

11. Utilities and Services. Lessee shall pay for all water, gas, heat, light, power, telephone, trash disposal and other utilities and services supplied to the Premises, together with any taxes thereon. If any such services are not separately metered or billed to Lessee, Lessee shall pay a reasonable proportion, to be determined by Lessor, of all charges jointly metered or billed. There shall be no abatement of rent and Lessor shall not be liable in any respect whatsoever for the inadequacy, stoppage, interruption or discontinuance of any utility or service due to riot, strike, labor dispute, breakdown, accident, repair or other cause beyond Lessor's reasonable control or in cooperation with governmental request or directions.

Within fifteen days of Lessor's written request, Lessee agrees to deliver to Lessor such information, documents and/or authorization as Lessor needs in order for Lessor to comply with new or existing Applicable Requirements relating to commercial building energy usage, ratings, and/or the reporting thereof.

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12. Assignment and Subletting. See Addendum Paragraph #55

12.1 Lessor's Consent Required.

(a) Lessee shall not voluntarily or by operation of law assign, transfer, mortgage or encumber (collectively, “**assign or assignment**”) or sublet all or any part of Lessee's interest in this Lease or in the Premises without Lessor's prior written consent.

(b) Unless Lessee is a corporation and its stock is publicly traded on a national stock exchange, a change in the control of Lessee shall constitute an assignment requiring consent. The transfer, on a cumulative basis, of **50%** or more of the voting control of Lessee shall constitute a change in control for this purpose.

(c) The involvement of Lessee or its assets in any transaction, or series of transactions (by way of merger, sale, acquisition, financing, transfer, leveraged buy-out or otherwise), whether or not a formal assignment or hypothecation of this Lease or Lessee's assets occurs, which results or will result in a reduction of the Net Worth of Lessee by an amount greater than 25% of such Net Worth as it was represented at the time of the execution of this Lease or at the time of the most recent assignment to which Lessor has consented, or as it exists immediately prior to said transaction or transactions constituting such reduction, whichever was or is greater, shall be considered an assignment of this Lease to which Lessor may withhold its consent. “**Net Worth of Lessee**” shall mean the net worth of Lessee (excluding any guarantors) established under generally accepted accounting principles.

(d) An assignment or subletting without consent shall, at Lessor's option, be a Default curable after notice per Paragraph 13.1(d), or a noncurable Breach without the necessity of any notice and grace period. If Lessor elects to treat such unapproved assignment or subletting as a noncurable Breach, Lessor may either: (i) terminate this Lease, or (ii) upon 30 days written notice, increase the monthly Base Rent to 110% of the Base Rent then in effect. Further, in the event of such Breach and rental adjustment, (i) the purchase price of any option to purchase the Premises held by Lessee shall be subject to similar adjustment to 110% of the price previously in effect, and (ii) all fixed and non-fixed rental adjustments scheduled during the remainder of the Lease term shall be increased to 110% of the scheduled adjusted rent.

(e) Lessee's remedy for any breach of Paragraph 12.1 by Lessor shall be limited to compensatory damages and/or injunctive relief.

(f) Lessor may reasonably withhold consent to a proposed assignment or subletting if Lessee is in Default at the time consent is requested.

(g) Notwithstanding the foregoing, allowing a de minimis portion of the Premises, ie. 20 square feet or less, to be used by a third party vendor in connection with the installation of a vending machine or payphone shall not constitute a subletting.

12.2 Terms and Conditions Applicable to Assignment and Subletting.

(a) Regardless of Lessor's consent, no assignment or subletting shall: (i) be effective without the express written assumption by such assignee or sublessee of the obligations of Lessee under this Lease, (ii) release Lessee of any obligations hereunder, or (iii) alter the primary liability of Lessee for the payment of Rent or for the performance of any other obligations to be performed by Lessee.

(b) Lessor may accept Rent or performance of Lessee's obligations from any person other than Lessee pending approval or disapproval of an assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of Rent or performance shall constitute a waiver or estoppel of Lessor's right to exercise its remedies for Lessee's Default or Breach.

(c) Lessor's consent to any assignment or subletting shall not constitute a consent to any subsequent assignment or subletting.

(d) In the event of any Default or Breach by Lessee, Lessor may proceed directly against Lessee, any Guarantors or anyone else responsible for the performance of Lessee's obligations under this Lease, including any assignee or sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefor to Lessor, or any security held by Lessor.

(e) Each request for consent to an assignment or subletting shall be in writing, accompanied by information relevant to Lessor's determination as to the financial and operational responsibility and appropriateness of the proposed assignee or sublessee, including but not limited to the intended use and/or required modification of the Premises, if any, together with a fee of \$500 as consideration for Lessor's considering and processing said request. Lessee agrees to provide Lessor with such other or additional information and/or documentation as may be reasonably requested. (See also Paragraph 36)

(f) Any assignee of, or sublessee under, this Lease shall, by reason of accepting such assignment, entering into such sublease, or entering into possession of the Premises or any portion thereof, be deemed to have assumed and agreed to conform and comply with each and every term, covenant, condition and obligation herein to be observed or performed by Lessee during the term of said assignment or sublease, other than such obligations as are contrary to or inconsistent with provisions of an assignment or sublease to which Lessor has specifically consented to in writing.

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(g) Lessor's consent to any assignment or subletting shall not transfer to the assignee or sublessee any Option granted to the original Lessee by this Lease unless such transfer is specifically consented to by Lessor in writing. (See Paragraph 39.2)

12.3 Additional Terms and Conditions Applicable to Subletting. The following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be deemed included in all subleases under this Lease whether or not expressly incorporated therein:

(a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all Rent payable on any sublease, and Lessor may collect such Rent and apply same toward Lessee's obligations under this Lease; provided, however, that until a Breach shall occur in the performance of Lessee's obligations, Lessee may collect said Rent. In the event that the amount collected by Lessor exceeds Lessee's then outstanding obligations any such excess shall be refunded to Lessee. Lessor shall not, by reason of the foregoing or any assignment of such sublease, nor by reason of the collection of Rent, be deemed liable to the sublessee for any failure of Lessee to perform and comply with any of Lessee's obligations to such sublessee. Lessee hereby irrevocably authorizes and directs any such sublessee, upon receipt of a written notice from Lessor stating that a Breach exists in the performance of Lessee's obligations under this Lease, to pay to Lessor all Rent due and to become due under the sublease. Sublessee shall rely upon any such notice from Lessor and shall pay all Rents to Lessor without any obligation or right to inquire as to whether such Breach exists, notwithstanding any claim from Lessee to the contrary.

(b) In the event of a Breach by Lessee, Lessor may, at its option, require sublessee to attorn to Lessor, in which event Lessor shall undertake the obligations of the sublessor under such sublease from the time of the exercise of said option to the expiration of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to such sublessor or for any prior Defaults or Breaches of such sublessor.

(c) Any matter requiring the consent of the sublessor under a sublease shall also require the consent of Lessor.

(d) No sublessee shall further assign or sublet all or any part of the Premises without Lessor's prior written consent.

(e) Lessor shall deliver a copy of any notice of Default or Breach by Lessee to the sublessee, who shall have the right to cure the Default of Lessee within the grace period, if any, specified in such notice. The sublessee shall have a right of reimbursement and offset from and against Lessee for any such Defaults cured by the sublessee.

13. Default; Breach; Remedies.

13.1 Default; Breach. A "**Default**" is defined as a failure by the Lessee to comply with or perform any of the terms, covenants, conditions or Rules and Regulations under this Lease. A "**Breach**" is defined as the occurrence of one or more of the following Defaults, and the failure of Lessee to cure such Default within any applicable grace period:

(a) The abandonment of the Premises; or the vacating of the Premises without providing a commercially reasonable level of security, or where the coverage of the property insurance described in Paragraph 8.3 is jeopardized as a result thereof, or without providing reasonable assurances to minimize potential vandalism.

(b) The failure of Lessee to make any payment of Rent or any Security Deposit required to be made by Lessee hereunder, whether to Lessor or to a third party, when due, to provide reasonable evidence of insurance or surety bond, or to fulfill any obligation under this Lease which endangers or threatens life or property, where such failure continues for a period of 3 business days following written notice to Lessee. THE ACCEPTANCE BY LESSOR OF A PARTIAL PAYMENT OF RENT OR SECURITY DEPOSIT SHALL NOT CONSTITUTE A WAIVER OF ANY OF LESSOR'S RIGHTS, INCLUDING LESSOR'S RIGHT TO RECOVER POSSESSION OF THE PREMISES.

(c) The failure of Lessee to allow Lessor and/or its agents access to the Premises or the commission of waste, act or acts constituting public or private nuisance, and/or an illegal activity on the Premises by Lessee, where such actions continue for a period of 3 business days following written notice to Lessee. In the event that Lessee commits waste, a nuisance or an illegal activity a second time then, the Lessor may elect to treat such conduct as a non-curable Breach rather than a Default.

(d) The failure by Lessee to provide (i) reasonable written evidence of compliance with Applicable Requirements, (ii) the service contracts, (iii) the rescission of an unauthorized assignment or subletting, (iv) an Estoppel Certificate or financial statements, (v) a requested subordination, (vi) evidence concerning any guaranty and/or Guarantor, (vii) any document requested under Paragraph 42, (viii) material safety data sheets (MSDS), or (ix) any other documentation or information which Lessor may reasonably require of Lessee under the terms of this Lease, where any such failure continues for a period of **10 business** days following written notice to Lessee.

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(e) A Default by Lessee as to the terms, covenants, conditions or provisions of this Lease, or of the rules adopted under Paragraph 40 hereof, other than those described in subparagraphs 13.1(a), (b), (c) or (d), above, where such Default continues for a period of 30 days after written notice; provided, however, that if the nature of Lessee's Default is such that more than 30 days are reasonably required for its cure, then it shall not be deemed to be a Breach if Lessee commences such cure within said 30 day period and thereafter diligently prosecutes such cure to completion.

(f) The occurrence of any of the following events: (i) the making of any general arrangement or assignment for the benefit of creditors; (ii) becoming a "**debtor**" as defined in 11 U.S.C. § 101 or any successor statute thereto (unless, in the case of a petition filed against Lessee, the same is dismissed within 60 days); (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within 30 days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where such seizure is not discharged within 30 days; provided, however, in the event that any provision of this subparagraph is contrary to any applicable law, such provision shall be of no force or effect, and not affect the validity of the remaining provisions.

(g) The discovery that any financial statement of Lessee or of any Guarantor given to Lessor was materially false.

(h) If the performance of Lessee's obligations under this Lease is guaranteed: (i) the death of a Guarantor, (ii) the termination of a Guarantor's liability with respect to this Lease other than in accordance with the terms of such guaranty, (iii) a Guarantor's becoming insolvent or the subject of a bankruptcy filing, (iv) a Guarantor's refusal to honor the guaranty, or (v) a Guarantor's breach of its guaranty obligation on an anticipatory basis, and Lessee's failure, within 60 days following written notice of any such event, to provide written alternative assurance or security, which, when coupled with the then existing resources of Lessee, equals or exceeds the combined financial resources of Lessee and the Guarantors that existed at the time of execution of this Lease.

13.2 Remedies. If Lessee fails to perform any of its affirmative duties or obligations, within 10 days after written notice (or in case of an emergency, without notice), Lessor may, at its option, perform such duty or obligation on Lessee's behalf, including but not limited to the obtaining of reasonably required bonds, insurance policies, or governmental licenses, permits or approvals. Lessee shall pay to Lessor an amount equal to 115% of the costs and expenses incurred by Lessor in such performance upon receipt of an invoice therefor. In the event of a Breach, Lessor may, with or without further notice or demand, and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such Breach:

(a) Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease shall terminate and Lessee shall immediately surrender possession to Lessor. In such event Lessor shall be entitled to recover from Lessee: (i) the unpaid Rent which had been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) the worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the Lessee proves could be reasonably avoided; and (iv) any other amount necessary to compensate Lessor for all the detriment proximately caused by the Lessee's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to the cost of recovering possession of the Premises, expenses of reletting, including necessary renovation and alteration of the Premises, reasonable attorneys' fees, and that portion of any leasing commission paid by Lessor in connection with this Lease applicable to the unexpired term of this Lease. The worth at the time of award of the amount referred to in provision (iii) of the immediately preceding sentence shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of the District within which the Premises are located at the time of award plus one percent. Efforts by Lessor to mitigate damages caused by Lessee's Breach of this Lease shall not waive Lessor's right to recover any damages to which Lessor is otherwise entitled. If termination of this Lease is obtained through the provisional remedy of unlawful detainer, Lessor shall have the right to recover in such proceeding any unpaid Rent and damages as are recoverable therein, or Lessor may reserve the right to recover all or any part thereof in a separate suit. If a notice and grace period required under Paragraph 13.1 was not previously given, a notice to pay rent or quit, or to perform or quit given to Lessee under the unlawful detainer statute shall also constitute the notice required by Paragraph 13.1. In such case, the applicable grace period required by Paragraph 13.1 and the unlawful detainer statute shall run concurrently, and the failure of Lessee to cure the Default within the greater of the two such grace periods shall constitute both an unlawful detainer and a Breach of this Lease entitling Lessor to the remedies provided for in this Lease and/or by said statute.

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(b) Continue the Lease and Lessee's right to possession and recover the Rent as it becomes due, in which event Lessee may sublet or assign, subject only to reasonable limitations. Acts of maintenance, efforts to relet, and/or the appointment of a receiver to protect the Lessor's interests, shall not constitute a termination of the Lessee's right to possession.

(c) Pursue any other remedy now or hereafter available under the laws or judicial decisions of the state wherein the Premises are located. The expiration or termination of this Lease and/or the termination of Lessee's right to possession shall not relieve Lessee from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the term hereof or by reason of Lessee's occupancy of the Premises.

13.3 Inducement Recapture. Any agreement for free or abated rent or other charges, the cost of tenant improvements for Lessee paid for or performed by Lessor, or for the giving or paying by Lessor to or for Lessee of any cash or other bonus, inducement or consideration for Lessee's entering into this Lease, all of which concessions are hereinafter referred to as "**Inducement Provisions**," shall be deemed conditioned upon Lessee's full and faithful performance of all of the terms, covenants and conditions of this Lease. Upon Breach of this Lease by Lessee, any such Inducement Provision shall automatically be deemed deleted from this Lease and of no further force or effect, and any rent, other charge, bonus, Inducement or consideration theretofore abated, given or paid by Lessor under such an Inducement Provision shall be immediately due and payable by Lessee to Lessor, notwithstanding any subsequent cure of said Breach by Lessee. The acceptance by Lessor of rent or the cure of the Breach which initiated the operation of this paragraph shall not be deemed a waiver by Lessor of the provisions of this paragraph unless specifically so stated in writing by Lessor at the time of such acceptance.

13.4 Late Charges. Lessee hereby acknowledges that late payment by Lessee of Rent will cause Lessor to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Lessor by any Lender. Accordingly, if any Rent shall not be received by Lessor within 5 days after such amount shall be due, then, without any requirement for notice to Lessee, Lessee shall immediately pay to Lessor a one-time late charge equal to 10% of each such overdue amount or \$100, whichever is greater. The Parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of such late payment. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's Default or Breach with respect to such overdue amount, nor prevent the exercise of any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, whether or not collected, for 3 consecutive installments of Base Rent, then notwithstanding any provision of this Lease to the contrary, Base Rent shall, at Lessor's option, become due and payable quarterly in advance.

13.5 Interest. Any monetary payment due Lessor hereunder, other than late charges, not received by Lessor, when due shall bear interest from the 31st day after it was due. The interest ("**Interest**") charged shall be computed at the rate of 10% per annum but shall not exceed the maximum rate allowed by law. Interest is payable in addition to the potential late charge provided for in Paragraph 13.4.

13.6 Breach by Lessor.

(a) **Notice of Breach.** Lessor shall not be deemed in breach of this Lease unless Lessor fails within a reasonable time to perform an obligation required to be performed by Lessor. For purposes of this Paragraph, a reasonable time shall in no event be less than 30 days after receipt by Lessor, and any Lender whose name and address shall have been furnished to Lessee in writing for such purpose, of written notice specifying wherein such obligation of Lessor has not been performed; provided, however, that if the nature of Lessor's obligation is such that more than 30 days are reasonably required for its performance, then Lessor shall not be in breach if performance is commenced within such 30 day period and thereafter diligently pursued to completion.

(b) **Performance by Lessee on Behalf of Lessor.** In the event that neither Lessor nor Lender cures said breach within 30 days after receipt of said notice, or if having commenced said cure they do not diligently pursue it to completion, then Lessee may elect to cure said breach at Lessee's expense and offset from Rent the actual and reasonable cost to perform such cure, provided, however, that such offset shall not exceed an amount equal to the greater of two month's Base Rent or the Security Deposit, reserving Lessee's right to seek reimbursement from Lessor for any such expense in excess of such offset. Lessee shall document the cost of said cure and supply said documentation to Lessor.

14. Condemnation. If the Premises or any portion thereof are taken under the power of eminent domain or sold under the threat of the exercise of said power (collectively "**Condemnation**"), this Lease shall terminate as to the part taken as of the date the condemning authority takes title or possession, whichever first occurs. If more than 10% of the Building, or more than 25% of that portion of the Premises not occupied by any building, is taken by Condemnation, Lessee may, at Lessee's option, to be exercised in writing within 10 days after Lessor shall have given Lessee written notice of such taking (or in the absence of such notice, within 10 days after the condemning authority shall have taken possession) terminate this Lease as of the date the condemning authority takes such possession. If Lessee does not terminate this Lease in accordance with the foregoing, this Lease shall remain in full force and effect as to the portion of the Premises remaining, except that the Base Rent shall be reduced in proportion to the reduction in utility of the Premises caused by such Condemnation. Condemnation awards and/or payments shall be the property of Lessor, whether such award shall be made as compensation for diminution in value of the leasehold, the value of the part taken, or for severance damages; provided, however, that Lessee shall be entitled to any compensation paid by the condemnor for Lessee's relocation expenses, loss of business goodwill and/or Trade Fixtures, without regard to whether or not this Lease is terminated pursuant to the provisions of this Paragraph. All Alterations and Utility Installations made to the Premises by Lessee, for purposes of Condemnation only, shall be considered the property of the Lessee and Lessee shall be entitled to any and all compensation which is payable therefor. In the event that this Lease is not terminated by reason of the Condemnation, Lessor shall repair any damage to the Premises caused by such Condemnation.

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15. Brokerage Fees.

15.1 Representations and Indemnities of Broker Relationships. Lessee and Lessor each represent and warrant to the other that it has had no dealings with any person, firm, broker, agent or finder (other than the Brokers and Agents, if any) in connection with this Lease, and that no one other than said named Brokers and Agents is entitled to any commission or finder's fee in connection herewith. Lessee and Lessor do each hereby agree to indemnify, protect, defend and hold the other harmless from and against liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings or actions of the indemnifying Party, including any costs, expenses, attorneys' fees reasonably incurred with respect thereto.

16. Estoppel Certificates.

(a) Each Party (as "**Responding Party**") shall within 10 business days after written notice from the other Party (the "**Requesting Party**") execute, acknowledge and deliver to the Requesting Party a statement in writing in form similar to the then most current "**Estoppel Certificate**" form published BY AIR CRE, plus such additional information, confirmation and/or statements as may be reasonably requested by the Requesting Party.

(b) If the Responding Party shall fail to execute or deliver the Estoppel Certificate within such 10 day period, the Requesting Party may execute an Estoppel Certificate stating that: (i) the Lease is in full force and effect without modification except as may be represented by the Requesting Party, (ii) there are no uncured defaults in the Requesting Party's performance, and (iii) if Lessor is the Requesting Party, not more than one month's rent has been paid in advance. Prospective purchasers and encumbrancers may rely upon the Requesting Party's Estoppel Certificate, and the Responding Party shall be estopped from denying the truth of the facts contained in said Certificate. In addition, Lessee acknowledges that any failure on its part to provide such an Estoppel Certificate will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, should the Lessee fail to execute and/or deliver a requested Estoppel Certificate in a timely fashion the monthly Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or \$100, whichever is greater for remainder of the Lease. The Parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to provide the Estoppel Certificate. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to the failure to provide the Estoppel Certificate nor prevent the exercise of any of the other rights and remedies granted hereunder.

(c) If Lessor desires to finance, refinance, or sell the Premises, or any part thereof, Lessee and all Guarantors shall within 10 days after written notice from Lessor deliver to any potential lender or purchaser designated by Lessor such financial statements as may be reasonably required by such lender or purchaser, including but not limited to Lessee's financial statements for the past 3 years. All such financial statements shall be received by Lessor and such lender or purchaser in confidence and shall be used only for the purposes herein set forth.

17. Definition of Lessor. The term "**Lessor**" as used herein shall mean the owner or owners at the time in question of the fee title to the Premises, or, if this is a sublease, of the Lessee's interest in the prior lease. In the event of a transfer of Lessor's title or interest in the Premises or this Lease, Lessor shall deliver to the transferee or assignee (in cash or by credit) any unused Security Deposit held by Lessor. Upon such transfer or assignment and delivery of the Security Deposit, as aforesaid, the prior Lessor shall be relieved of all liability with respect to the obligations and/or covenants under this Lease thereafter to be performed by the Lessor. Subject to the foregoing, the obligations and/or covenants in this Lease to be performed by the Lessor shall be binding only upon the Lessor as hereinabove defined.

18. Severability. The invalidity of any provision of this Lease, as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.

19. Days. Unless otherwise specifically indicated to the contrary, the word "**days**" as used in this Lease shall mean and refer to calendar days.

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20. Limitation on Liability. The obligations of Lessor under this Lease shall not constitute personal obligations of Lessor, or its partners, members, directors, officers or shareholders, and Lessee shall look to the Premises, **including insurance**, and to no other assets of Lessor, for the satisfaction of any liability of Lessor with respect to this Lease, and shall not seek recourse against Lessor's partners, members, directors, officers or shareholders, or any of their personal assets for such satisfaction.

21. Time of Essence. Time is of the essence with respect to the performance of all obligations to be performed or observed by the Parties under this Lease.

22. No Prior or Other Agreements; Broker Disclaimer. This Lease contains all agreements between the Parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective. Lessor and Lessee each represents and warrants to the Brokers that it has made, and is relying solely upon, its own investigation as to the nature, quality, character and financial responsibility of the other Party to this Lease and as to the use, nature, quality and character of the Premises. Brokers have no responsibility with respect thereto or with respect to any default or breach hereof by either Party.

23. Notices.

23.1 Notice Requirements. All notices required or permitted by this Lease or applicable law shall be in writing and may be delivered in person (by hand or by courier) or may be sent by regular, certified or registered mail or U.S. Postal Service Express Mail, **or other reputable overnight carrier such as UPS or Federal Express** with postage prepaid, or by facsimile transmission, or by email, and shall be deemed sufficiently given if served in a manner specified in this Paragraph 23. The addresses noted adjacent to a Party's signature on this Lease shall be that Party's address for delivery or mailing of notices. Either Party may by written notice to the other specify a different address for notice, except that upon Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for notice. A copy of all notices to Lessor shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate in writing.

23.2 Date of Notice. Any notice sent by registered or certified mail, return receipt requested, shall be deemed given on the date of delivery shown on the receipt card, or if no delivery date is shown, the postmark thereon. If sent by regular mail the notice shall be deemed given 72 hours after the same is addressed as required herein and mailed with postage prepaid. Notices delivered by United States Express Mail or overnight courier that guarantees next day delivery shall be deemed given 24 hours after delivery of the same to the Postal Service or courier. Notices delivered by hand, or transmitted by facsimile transmission or by email shall be deemed delivered upon actual receipt. If notice is received on a Saturday, Sunday or legal holiday, it shall be deemed received on the next business day.

23.3 Options. Notwithstanding the foregoing, in order to exercise any Options (see paragraph 39), the Notice must be sent by Certified Mail (return receipt requested), Express Mail (signature required), courier (signature required) or some other methodology that provides a receipt establishing the date the notice was received by the Lessor.

24. Waivers.

(a) No waiver by Lessor of the Default or Breach of any term, covenant or condition hereof by Lessee, shall be deemed a waiver of any other term, covenant or condition hereof, or of any subsequent Default or Breach by Lessee of the same or of any other term, covenant or condition hereof. Lessor's consent to, or approval of, any act shall not be deemed to render unnecessary the obtaining of Lessor's consent to, or approval of, any subsequent or similar act by Lessee, or be construed as the basis of an estoppel to enforce the provision or provisions of this Lease requiring such consent.

(b) The acceptance of Rent by Lessor shall not be a waiver of any Default or Breach by Lessee. Any payment by Lessee may be accepted by Lessor on account of monies or damages due Lessor, notwithstanding any qualifying statements or conditions made by Lessee in connection therewith, which such statements and/or conditions shall be of no force or effect whatsoever unless specifically agreed to in writing by Lessor at or before the time of deposit of such payment.

(c) THE PARTIES AGREE THAT THE TERMS OF THIS LEASE SHALL GOVERN WITH REGARD TO ALL MATTERS RELATED THERETO AND HEREBY WAIVE THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE TO THE EXTENT THAT SUCH STATUTE IS INCONSISTENT WITH THIS LEASE.

25. Disclosures Regarding The Nature of a Real Estate Agency Relationship.

(a) When entering into a discussion with a real estate agent regarding a real estate transaction, a Lessor or Lessee should from the outset understand what type of agency relationship or representation it has with the agent or agents in the transaction. Lessor and Lessee acknowledge being advised by the Brokers in this transaction, as follows:

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(i) **Lessor's Agent.** A Lessor's agent under a listing agreement with the Lessor acts as the agent for the Lessor only. A Lessor's agent or subagent has the following affirmative obligations: **To the Lessor:** A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessor. **To the Lessee and the Lessor:** (a) Diligent exercise of reasonable skills and care in performance of the agent's duties. (b) A duty of honest and fair dealing and good faith. (c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential Information obtained from the other Party which does not involve the affirmative duties set forth above.

(ii) **Lessee's Agent.** An agent can agree to act as agent for the Lessee only. In these situations, the agent is not the Lessor's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the Lessor. An agent acting only for a Lessee has the following affirmative obligations. **To the Lessee:** A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessee. **To the Lessee and the Lessor:** (a) Diligent exercise of reasonable skills and care in performance of the agent's duties. (b) A duty of honest and fair dealing and good faith. (c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(iii) **Agent Representing Both Lessor and Lessee.** A real estate agent, either acting directly or through one or more associate licenses, can legally be the agent of both the Lessor and the Lessee in a transaction, but only with the knowledge and consent of both the Lessor and the Lessee. In a dual agency situation, the agent has the following affirmative obligations to both the Lessor and the Lessee: (a) A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either Lessor or the Lessee. (b) Other duties to the Lessor and the Lessee as stated above in subparagraphs (i) or (ii). In representing both Lessor and Lessee, the agent may not, without the express permission of the respective Party, disclose to the other Party confidential information, including, but not limited to, facts relating to either Lessee's or Lessor's financial position, motivations, bargaining position, or other personal information that may impact rent, including Lessor's willingness to accept a rent less than the listing rent or Lessee's willingness to pay rent greater than the rent offered. The above duties of the agent in a real estate transaction do not relieve a Lessor or Lessee from the responsibility to protect their own interests. Lessor and Lessee should carefully read all agreements to assure that they adequately express their understanding of the transaction. A real estate agent is a person qualified to advise about real estate. If legal or tax advice is desired, consult a competent professional. Both Lessor and Lessee should strongly consider obtaining tax advice from a competent professional because the federal and state tax consequences of a transaction can be complex and subject to change.

(b) Brokers have no responsibility with respect to any default or breach hereof by either Party. The Parties agree that no lawsuit or other legal proceeding involving any breach of duty, error or omission relating to this Lease may be brought against Broker more than one year after the Start Date and that the liability (including court costs and attorneys' fees), of any Broker with respect to any such lawsuit and/or legal proceeding shall not exceed the fee received by such Broker pursuant to this Lease; provided, however, that the foregoing limitation on each Broker's liability shall not be applicable to any gross negligence or willful misconduct of such Broker.

(c) Lessor and Lessee agree to identify to Brokers as "Confidential" any communication or information given Brokers that is considered by such Party to be confidential.

26. No Right To Holdover. Lessee has no right to retain possession of the Premises or any part thereof beyond the expiration or termination of this Lease. In the event that Lessee holds over, **for the thirty (30) days following the expiration of the initial term the last base rent shall apply**, then the Base Rent shall be increased to 150% of the Base Rent applicable immediately preceding the expiration or termination. Holdover Base Rent shall be calculated on monthly basis. Nothing contained herein shall be construed as consent by Lessor to any holding over by Lessee.

27. Cumulative Remedies. No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.

28. Covenants and Conditions; Construction of Agreement. All provisions of this Lease to be observed or performed by Lessee are both covenants and conditions. In construing this Lease, all headings and titles are for the convenience of the Parties only and shall not be considered a part of this Lease. Whenever required by the context, the singular shall include the plural and vice versa. This Lease shall not be construed as if prepared by one of the Parties, but rather according to its fair meaning as a whole, as if both Parties had prepared it.

29. Binding Effect; Choice of Law. This Lease shall be binding upon the Parties, their personal representatives, successors and assigns and be governed by the laws of the State in which the Premises are located. Any litigation between the Parties hereto concerning this Lease shall be initiated in the county in which the Premises are located. Signatures to this Lease accomplished by means of electronic signature or similar technology shall be legal and binding.

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30. Subordination; Adornment; Non-Disturbance.

30.1 Subordination. This Lease and any Option granted hereby shall be subject and subordinate to any ground lease, mortgage, deed of trust, or other hypothecation or security device (collectively, “**Security Device**”), now or hereafter placed upon the Premises, to any and all advances made on the security thereof, and to all renewals, modifications, and extensions thereof. Lessee agrees that the holders of any such Security Devices (in this Lease together referred to as “**Lender**”) shall have no liability or obligation to perform any of the obligations of Lessor under this Lease. Any Lender may elect to have this Lease and/or any Option granted hereby superior to the lien of its Security Device by giving written notice thereof to Lessee, whereupon this Lease and such Options shall be deemed prior to such Security Device, notwithstanding the relative dates of the documentation or recordation thereof.

30.2 Attornment. In the event that Lessor transfers title to the Premises, or the Premises are acquired by another upon the foreclosure or termination of a Security Device to which this Lease is subordinated (i) Lessee shall, subject to the non-disturbance provisions of Paragraph 30.3, attorn to such new owner, and upon request, enter into a new lease, containing all of the terms and provisions of this Lease, with such new owner for the remainder of the term hereof, or, at the election of the new owner, this Lease will automatically become a new lease between Lessee and such new owner, and (ii) Lessor shall thereafter be relieved of any further obligations hereunder and such new owner shall assume all of Lessor’s obligations, except that such new owner shall not: (a) be liable for any act or omission of any prior lessor or with respect to events occurring prior to acquisition of ownership; (b) be subject to any offsets or defenses which Lessee might have against any prior lessor, (c) be bound by prepayment of more than one month’s rent, or (d) be liable for the return of any security deposit paid to any prior lessor which was not paid or credited to such new owner.

30.3 Non-Disturbance. With respect to Security Devices entered into by Lessor after the execution of this Lease, Lessee’s subordination of this Lease shall be subject to receiving a commercially reasonable non-disturbance agreement (a “**Non-Disturbance Agreement**”) from the Lender which Non-Disturbance Agreement provides that Lessee’s possession of the Premises, and this Lease, including any options to extend the term hereof, will not be disturbed so long as Lessee is not in Breach hereof and attorns to the record owner of the Premises. Further, within 60 days after the execution of this Lease, Lessor shall, if requested by Lessee, use its commercially reasonable efforts to obtain a Non-Disturbance Agreement from the holder of any pre-existing Security Device which is secured by the Premises. In the event that Lessor is unable to provide the Non-Disturbance Agreement within said 60 days, then Lessee may, at Lessee’s option, directly contact Lender and attempt to negotiate for the execution and delivery of a Non-Disturbance Agreement.

30.4 Self-Executing. The agreements contained in this Paragraph 30 shall be effective without the execution of any further documents; provided, however, that, upon written request from Lessor or a Lender in connection with a sale, financing or refinancing of the Premises, Lessee and Lessor shall execute such further writings as may be reasonably required to separately document any subordination, attornment and/or Non-Disturbance Agreement provided for herein.

31. Attorneys’ Fees. If any Party or Broker brings an action or proceeding involving the Premises whether founded in tort, contract or equity, or to declare rights hereunder, the Prevailing Party (as hereafter defined) in any such proceeding, action, or appeal thereon, shall be entitled to reasonable attorneys’ fees. Such fees may be awarded in the same suit or recovered in a separate suit, whether or not such action or proceeding is pursued to decision or judgment. The term, “**Prevailing Party**” shall include, without limitation, a Party or Broker who substantially obtains or defeats the relief sought, as the case may be, whether by compromise, settlement, judgment, or the abandonment by the other Party or Broker of its claim or defense. The attorneys’ fees award shall not be computed in accordance with any court fee schedule, but shall be such as to fully reimburse all attorneys’ fees reasonably incurred. In addition, Lessor shall be entitled to attorneys’ fees, costs and expenses incurred in the preparation and service of notices of Default and consultations in connection therewith, whether or not a legal action is subsequently commenced in connection with such Default or resulting Breach (\$200 is a reasonable minimum per occurrence for such services and consultation).

32. Lessor’s Access; Showing Premises; Repairs. Lessor and Lessor’s agents shall have the right to enter the Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable prior notice for the purpose of showing the same to prospective purchasers, lenders, or tenants, and making such alterations, repairs, improvements or additions to the Premises as Lessor may deem necessary or desirable and the erecting, using and maintaining of utilities, services, pipes and conduits through the Premises and/or other premises as long as there is no material adverse effect on Lessee’s use of the Premises. All such activities shall be without abatement of rent or liability to Lessee.

33. Auctions. Lessee shall not conduct, nor permit to be conducted, any auction upon the Premises without Lessor’s prior written consent. Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to permit an auction.

34. Signs. Lessor may place on the Premises ordinary “**For Sale**” signs at any time and ordinary “**For Lease**” signs during the last 6 months of the term hereof. Except for ordinary “**for sublease**” signs, Lessee shall not place any sign upon the Premises without Lessor’s prior written consent. All signs must comply with all Applicable Requirements. **See Addendum Paragraph #56**

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35. Termination; Merger. Unless specifically stated otherwise in writing by Lessor, the voluntary or other surrender of this Lease by Lessee, the mutual termination or cancellation hereof, or a termination hereof by Lessor for Breach by Lessee, shall automatically terminate any sublease or lesser estate in the Premises; provided, however, that Lessor may elect to continue any one or all existing subtenancies. Lessor's failure within 10 days following any such event to elect to the contrary by written notice to the holder of any such lesser interest, shall constitute Lessor's election to have such event constitute the termination of such interest.

36. Consents. All requests for consent shall be in writing. Except as otherwise provided herein, wherever in this Lease the consent of a Party is required to an act by or for the other Party, such consent shall not be unreasonably withheld or delayed. Lessor's actual reasonable costs and expenses (including but not limited to architects', attorneys', engineers' and other consultants' fees) incurred in the consideration of, or response to, a request by Lessee for any Lessor consent, including but not limited to consents to an assignment, a subletting or the presence or use of a Hazardous Substance, shall be paid by Lessee upon receipt of an invoice and supporting documentation therefor. Lessor's consent to any act, assignment or subletting shall not constitute an acknowledgment that no Default or Breach by Lessee of this Lease exists, nor shall such consent be deemed a waiver of any then existing Default or Breach, except as may be otherwise specifically stated in writing by Lessor at the time of such consent. The failure to specify herein any particular condition to Lessor's consent shall not preclude the imposition by Lessor at the time of consent of such further or other conditions as are then reasonable with reference to the particular matter for which consent is being given. In the event that either Party disagrees with any determination made by the other hereunder and reasonably requests the reasons for such determination, the determining party shall furnish its reasons in writing and in reasonable detail within 10 business days following such request.

38. Quiet Possession. Subject to payment by Lessee of the Rent and performance of all of the covenants, conditions and provisions on Lessee's part to be observed and performed under this Lease, Lessee shall have quiet possession and quiet enjoyment of the Premises during the term hereof.

39. Options. If Lessee Is granted any Option, as defined below, then the following provisions shall apply. See Addendum Paragraph #51

39.1 Definition. "Option" shall mean: (a) the right to extend or reduce the term of or renew this Lease or to extend or reduce the term of or renew any lease that Lessee has on other property of Lessor; (b) the right of first refusal or first offer to lease either the Premises or other property of Lessor; (c) the right to purchase, the right of first offer to purchase or the right of first refusal to purchase the Premises or other property of Lessor.

39.2 Options Personal To Original Lessee. Any Option granted to Lessee in this Lease is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and, if requested by Lessor, with Lessee certifying that Lessee has no intention of thereafter assigning or subletting.

39.3 Multiple Options. In the event that Lessee has any multiple Options to extend or renew this Lease, a later Option cannot be exercised unless the prior Options have been validly exercised.

39.4 Effect of Default on Options.

(a) Lessee shall have no right to exercise an Option: (i) during the period commencing with the giving of any notice of Default and continuing until said Default is cured, (ii) during the period of time any Rent is unpaid (without regard to whether notice thereof is given Lessee), (iii) during the time Lessee is in Breach of this Lease, or (iv) in the event that Lessee has been given 3 or more notices of separate Default, whether or not the Defaults are cured, during the 12 month period Immediately preceding the exercise of the Option.

(b) The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of Paragraph 39.4(a).

(c) An Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and prior to the commencement of the extended term or completion of the purchase, (i) Lessee fails to pay Rent for a period of 30 days after such Rent becomes due (without any necessity of Lessor to give notice thereof), or (ii) if Lessee commits a Breach of this Lease.

40. Multiple Buildings.

41. Security Measures. Lessee hereby acknowledges that the Rent payable to Lessor hereunder does not include the cost of guard service or other security measures, and that Lessor shall have no obligation whatsoever to provide same. Lessee assumes all responsibility for the protection of the Premises, Lessee, its agents and invitees and their property from the acts of third parties.

/s/ RN

/s/ AM

INITIALS

/s/ERD

INITIALS

42. Reservations. Lessor reserves to itself the right, from time to time, to grant, without the consent or joinder of Lessee, such easements, rights and dedications that Lessor deems necessary, and to cause the recordation of parcel maps and restrictions, so long as such easements, rights, dedications, maps and restrictions do not unreasonably interfere with the use of the Premises by Lessee. Lessee agrees to sign any documents reasonably requested by Lessor to effectuate any such easement rights, dedication, map or restrictions.

43. Performance Under Protest. If at any time a dispute shall arise as to any amount or sum of money to be paid by one Party to the other under the provisions hereof, the Party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment and there shall survive the right on the part of said Party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said Party to pay such sum or any part thereof, said Party shall be entitled to recover such sum or so much thereof as it was not legally required to pay. A Party who does not initiate suit for the recovery of sums paid "under protest" within 6 months shall be deemed to have waived its right to protest such payment.

44. Authority; Multiple Parties; Execution.

(a) if either Party hereto is a corporation, trust, limited liability company, partnership, or similar entity, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on its behalf. Each Party shall, within 30 days after request, deliver to the other Party satisfactory evidence of such authority.

(b) If this Lease is executed by more than one person or entity as "Lessee", each such person or entity shall be jointly and severally liable hereunder. It is agreed that any one of the named Lessees shall be empowered to execute any amendment to this Lease, or other document ancillary thereto and bind all of the named Lessees, and Lessor may rely on the same as if all of the named Lessees had executed such document.

(c) This Lease may be executed by the Parties in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

45. Conflict. Any conflict between the printed provisions of this Lease and the typewritten or handwritten provisions shall be controlled by the typewritten or handwritten provisions.

46. Offer. Preparation of this Lease by either Party or their agent and submission of same to the other Party shall not be deemed an offer to lease to the other Party. This Lease is not intended to be binding until executed and delivered by all Parties hereto.

47. Amendments. This Lease may be modified only in writing, signed by the Parties in interest at the time of the modification. As long as they do not materially change Lessee's obligations hereunder, Lessee agrees to make such reasonable non-monetary modifications to this Lease as may be reasonably required by a Lender in connection with the obtaining of normal financing or refinancing of the Premises.

48. Waiver of Jury Trial. THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING INVOLVING THE PROPERTY OR ARISING OUT OF THIS AGREEMENT.

49. Arbitration of Disputes. An Addendum requiring the Arbitration of all disputes between the Parties and/or Brokers arising out of this Lease ☐ is ☒ is not attached to this Lease.

50. Accessibility; Americans with Disabilities Act.

(a) The Premises:

☒ have not undergone an inspection by a Certified Access Specialist (CASp). Note: A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises.

In the event that the Premises have been issued an inspection report by a CASp the Lessor shall provide a copy of the disability access inspection certificate to Lessee within 7 days of the execution of this Lease.

(b) Since compliance with the Americans with Disabilities Act (ADA) and other state and local accessibility statutes are dependent upon Lessee's specific use of the Premises, Lessor makes no warranty or representation as to whether or not the Premises comply with ADA or any similar legislation. In the event that Lessee's use of the Premises requires modifications or additions to the Premises in order to be in compliance with ADA or other accessibility statutes, Lessee agrees to make any such necessary modifications and/or additions at Lessee's expense.

/s/ RN

/s/ AM

INITIALS

/s/ERD

INITIALS

LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN, AND BY THE EXECUTION OF THIS LEASE SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

ATTENTION: NO REPRESENTATION OR RECOMMENDATION IS MADE BY AIR CRE OR BY ANY BROKER AS TO THE LEGAL SUFFICIENCY, LEGAL EFFECT, OR TAX CONSEQUENCES OF THIS LEASE OR THE TRANSACTION TO WHICH IT RELATES. THE PARTIES ARE URGED TO:

1. SEEK ADVICE OF COUNSEL AS TO THE LEGAL AND TAX CONSEQUENCES OF THIS LEASE.
2. RETAIN APPROPRIATE CONSULTANTS TO REVIEW AND INVESTIGATE THE CONDITION OF THE PREMISES. SAID INVESTIGATION SHOULD INCLUDE BUT NOT BE LIMITED TO: THE POSSIBLE PRESENCE OF HAZARDOUS SUBSTANCES, THE ZONING OF THE PREMISES, THE STRUCTURAL INTEGRITY, THE CONDITION OF THE ROOF AND OPERATING SYSTEMS, AND THE SUITABILITY OF THE PREMISES FOR LESSEE’S INTENDED USE.

WARNING: IF THE PREMISES ARE LOCATED IN A STATE OTHER THAN CALIFORNIA, CERTAIN PROVISIONS OF THE LEASE MAY NEED TO BE REVISED TO COMPLY WITH THE LAWS OF THE STATE IN WHICH THE PREMISES ARE LOCATED.

The parties hereto have executed this Lease at the place and on the dates specified above their respective signatures.

Signatures on following page

 /s/ RN
 /s/ AM
INITIALS

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STN-27.22, Revised 06-10-2019

 /s/ERD
INITIALS

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Executed at: ENCINO, CA
On: _____
By LESSOR:
Pacific Industrial Partners, LLC

By: /s/ Adam Milstern
Name Printed: Adam Milstern
Title: Manager

Phone: _____
Fax: _____
Email: _____

By: /s/Robert Neal
Name Printed: Robert Neal
Title: Manager
Phone: _____
Fax: _____
Email: _____

Address: _____
Federal ID No.: _____

BROKER

Attn: _____
Title: _____
Address: _____
Phone: _____
Fax: _____
Email: _____
Federal ID No.: _____
Broker DRE License #: _____
Agent DRE License #: _____

Executed at: _____
On: _____
By LESSOR:
Beta Bionics, Inc.

By: /s/ Edward R. Damiano
Name Printed: Edward R. Damiano
Title: President, CEO and Chairman of
the Board
Phone: [***]
Fax: _____
Email: [***]

By: _____
Name Printed: _____
Title: _____
Phone: _____
Fax: _____
Email: _____

Address: _____
Federal ID No.: _____

BROKER

Attn: _____
Title: _____
Address: _____
Phone: _____
Fax: _____
Email: _____
Federal ID No.: _____
Broker DRE License #: _____
Agent DRE License #: _____

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/s/ RN

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/s/ERD

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**OPTION(S) TO EXTEND
STANDARD LEASE ADDENDUM**

Dated: February 3, 2020

By and Between

Lessor: Pacific Industrial Partners, LLC

Lessee: Beta Bionics, Inc.

Property Address: 11 Hughes, Irvine, CA 92618
(street address, city, state, zip)

Paragraph: 51

A. OPTION(S) TO EXTEND:

Lessor hereby grants to Lessee the option to extend the term of this Lease for 1 additional 60 month period(s) commencing when the prior term expires upon each and all of the following terms and conditions:

(i) In order to exercise an option to extend, Lessee must give written notice of such election to Lessor and Lessor must receive the same at least 9 but not more than 12 months prior to the date that the option period would commence, time being of the essence. If proper notification of the exercise of an option is not given and/or received, such option shall automatically expire. Options (if there are more than one) may only be exercised consecutively.

(ii) The provisions of paragraph 39, including those relating to Lessee's Default set forth in paragraph 39.4 of this Lease, are conditions of this Option.

(iii) Except for the provisions of this Lease granting an option or options to extend the term, all of the terms and conditions of this Lease except where specifically modified by this option shall apply.

(iv) This Option is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and without the intention of thereafter assigning or subletting.

(v) The monthly rent for each month of the option period shall be calculated as follows, using the method(s) indicated below:
(Check Method(s) to be Used and Fill in Appropriately)

☒ **II Market Rental Value Adjustment(s) (MRV)**

a. On (Fill in MRV Adjustment Date(s)) **the first day of the month following the expiration of the lease** the Base Rent shall be adjusted to the "Market Rental Value" of the property as follows:

(1) Four months prior to each Market Rental Value Adjustment Date described above, the Parties shall attempt to agree upon what the new MRV will be on the adjustment date. If agreement cannot be reached, within thirty days, then:

(a) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new MRV within the next 30 days. Any associated costs will be split equally between the Parties, or

(b) Both Lessor and Lessee shall each immediately make a reasonable determination of the MRV and submit such determination, in writing, to arbitration in accordance with the following provisions:

(i) Within 15 days thereafter, Lessor and Lessee shall each select an independent third party ☐ appraiser or ☒ broker ("Consultant" -check one) of their choice to act as an arbitrator (Note: the parties may not select either of the Brokers that was involved in negotiating the Lease). The two arbitrators so appointed shall immediately select a third mutually acceptable Consultant to act as a third arbitrator.

(ii) The 3 arbitrators shall within 30 days of the appointment of the third arbitrator reach a decision as to what the actual MRV for the Premises is, and whether Lessor's or Lessee's submitted MRV is the closest thereto. The decision of a majority of the arbitrators shall be binding on the Parties. The submitted MRV which is determined to be the closest to the actual MRV shall thereafter be used by the Parties.

/s/ RN

/s/ AM

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(iii) If either of the Parties fails to appoint an arbitrator within the specified 15 days, the arbitrator timely appointed by one of them shall reach a decision on his or her own, and said decision shall be binding on the Parties.

(iv) The entire cost of such arbitration shall be paid by the party whose submitted MRV is not selected, ie. the one that is NOT the closest to the actual MRV.

(2) When determining MRV, the Lessor, Lessee and Consultants shall consider the terms of comparable market transactions which shall include, but not limited to, rent, rental adjustments, abated rent, lease term and financial condition of tenants.

(3) Notwithstanding the foregoing, the new Base Rent shall not be less than the rent payable for the month immediately preceding the rent adjustment **increased by 3%**.

b. Upon the establishment of each New Market Rental Value:

(1) the new MRV will become the new "Base Rent" for the purpose of calculating any further Adjustments, and

(2) the first month of each Market Rental Value term shall become the new "Base Month" for the purpose of calculating any further Adjustments.

(3) **the new Base Rent identified above, in II. Market Value Adjustment(s), shall be increased by 3% on June 1 of each year of the option period.**

☐ **IV. Term Adjustments**

B. NOTICE:

Unless specified otherwise herein, notice of any rental adjustments, other than Fixed Rental Adjustments, shall be made as specified in paragraph 23 of the Lease.

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 /s/ RN

 /s/ AM

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 /s/ ERD

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STN-27.22, Revised 06-10-2019

ADDENDUM TO STANDARD INDUSTRIAL/COMMERCIAL SINGLE-TENANT LEASE -NET, DATED FEBRUARY 3, 2020 ("LEASE")
BETWEEN PACIFIC INDUSTRIAL PARTNERS, LLC, A CALIFORNIA LIMITED LIABILITY COMPANY, AND BETA BIONICS, INC., A
MASSACHUSETTS PUBLIC BENEFIT CORPORATION ("LESSEE")

In the event of any inconsistency or contradiction between the terms and conditions of this Addendum and the terms and conditions of the Lease, the terms and conditions of this Addendum shall prevail. Unless otherwise defined in this Addendum, all capitalized terms herein shall have the same meaning and effect as set forth in the Lease.

51. Option

See AIR Addendum Form Paragraph #51.

52. Rent Adjustment

<u>From</u>	<u>To</u>	<u>Monthly Base Rent</u>
6/1/2020	5/31/2021	\$ 37,515
6/1/2021	5/31/2022	\$ 42,517
6/1/2022	5/31/2023	\$ 53,521
6/1/2023	5/31/2024	\$ 56,022
6/1/2024	5/31/2025	\$ 58,523
6/1/2025	5/31/2026	\$ 61,024
6/1/2026	5/31/2027	\$ 63,525

53. Security Deposit

In the event that Lessee exercises its option to extend the term of this lease, the security deposit shall increase to be equivalent to the final month's rent for the option term.

54. Operating Expenses

Lessee shall be responsible for the payment of the property taxes, property insurance, exterior common area maintenance, utilities and a management fee (equal to 3% of the base rent). These charges will be estimated by Lessor annually and billed to Lessee on a monthly basis. The monthly charges for operating expenses (1/12th of the annual estimate) will be due and payable each month at the time that the base rent is due. All operating expenses will be reconciled annually by Lessor.

Notwithstanding the foregoing, Lessee shall not be responsible for the replacement of the roof structure, foundations, and exterior walls. Lessee shall not be responsible for the replacement of below grade plumbing due to any latent defects in the property and not arising from the actions of Lessor or any of its agents.

/s/ RN

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/s/ AM

/s/ ERD

55. Assignment and Subletting

Lessor's Consent to Assignment, Subletting or Other Transfer. Notwithstanding anything to the contrary in the Lease and in particular, in Par. 36 thereof, Lessee shall have the right to sublease a portion of the premises for the first 24 months of the Lease, subject to the approval of Lessor. Such approval shall not be unreasonably withheld or delayed. Beginning in month 25, Lessor's consent to any request to assign, hypothecate or transfer Lessee's interest in the Lease, or to allow Lessee to sublet or license the Premises, may be withheld by Lessor for any reason, or no reason at all, and Lessor shall be under no obligation to consider any such request from Lessee. Tenant shall have the right to assign or sublease all or any portion of the Premises during the initial term and any renewal term without the consent of the Lessor, to (i) any entity resulting from a merger or consolidation, (ii) any entity succeeding in the business and assets of Lessee, (iii) any entity arising from the transaction pursuant to which Lessee becomes a publicly traded company; or (iv) any subsidiary or affiliate of Tenant or Parent companies.

Lessor's Recapture Right. Notwithstanding anything to the contrary in the Lease, whenever Lessee has obtained an offer or entered into an agreement to assign this Lease or to sublease all or part of the Premises, Lessee shall provide to Lessor the name and address of the proposed assignee or sublessee and the rent offered, the proposed use by the proposed assignee or sublessee, the proposed effective date of the assignment or subletting, and any other business terms which are material to the offer or agreement and which differ from the provisions of this Lease ("Notice of Offer"). Lessee shall also provide to Lessor information concerning the nature of the business to be conducted at the Premises, and financial statements and a business experience resume for the immediately preceding five (5) years for the proposed assignee or sublessee, and such other information concerning such proposed assignee or sublessee as Lessor may require, including a copy of the proposed assignment or sublease. The foregoing information shall be in writing and shall be provided to Lessor not less than forty-five (45) days prior to the effective date of the proposed assignment or sublease.

Excess Profits Payable to Lessor-Subletting. Should Lessee sublet or license all or any portion of the Premises, Lessee shall pay to Lessor on a monthly basis, as additional Rent, within ten (10) days after receipt by Lessee, fifty percent (50%) of the "Subletting Transfer Consideration", which term shall mean: (i) the excess of the Rent payable by the sublessee or licensee over the amount of Base Rent and additional Rent payable by Lessee under this Lease for the subleased or licensed space, less any brokerage commission fees and costs paid by Lessee to procure the sublease or license, as the case may be; and (ii) any non-rent consideration paid or payable by the sublessee in connection with the sublease, including any "key money", other sums paid by or on behalf of the sublessee or licensee for the use or occupancy of the Premises, and any non-monetary consideration received by Lessee. Any such brokerage commissions shall be amortized on a straight-line basis over the initial term of the sublease and credited (on a monthly basis) against the amount of the Subletting Transfer Consideration payable to Lessor until such credit is extinguished. In the event that the subleased space is less than the total square footage of the Premises, the amount of the excess Rent shall be calculated on a pro rata basis taking into consideration the Rent per square foot charged to sublessee, as compared to the Rent payable by Lessee to Lessor calculated on a per square foot basis. The provisions of this Paragraph shall apply regardless of whether or not such subleasing or licensing is made in compliance with the terms of this Lease. Any payments made to Lessor pursuant to this Paragraph shall not cure or waive any default under this Lease arising from such subletting or licensing arrangement.

/s/ RN

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/s/ AM

/s/ ERD

56. Signage Criteria

Prior to April 1, 2020, Lessor shall remove any existing signage on or at the Premises at Lessor's sole expense.

Lessee shall not make any changes to the exterior of the Premises, install any exterior lights, decorations, balloons, flags, pennants, banners, or painting, or erect or install any signs, windows or door lettering, placards, decorations, or advertising media of any type which can be viewed from the exterior of the Premises, without **Lessor's prior written consent**, which consent may be withheld in Lessor's sole discretion.

Lessee shall obtain all applicable governmental permits and approvals for sign and exterior treatments. All signs, decorations, advertising media, blinds, draperies and other window treatment or bars or other security installations visible from outside the Premises shall be subject to Lessor's approval and conform in all respects to Lessor's Signage Criteria as depicted on the attached "Exhibit B". Lessor reserves the right to revise, update, or otherwise amend the approved installation requirements upon written notice to Lessee.

Upon surrender or vacation of the Premises, Lessee, at Lessee's sole cost, shall have removed all signs and repair, paint, and/or replace the building facia surface to which its signs are attached. Lessee's repair work shall be completed in accordance with Lessor's Signage Criteria as depicted on the attached "Exhibit B".

57. Tenant Improvements

Lessor, at Lessor's sole cost and expense, shall complete the following upon delivery of the premises:

- Lessor shall paint the interior office area; paint color to be mutually determined by Lessor and Lessee
- Lessor shall install new carpet tiles in all office areas; carpet color and style to be mutually determined by Lessor and Lessee;
- Lessor shall demolish two (2) existing rooms in warehouse; or Lessee may elect to apply the equivalent cost of such demolition (\$15,000) towards interior tenant improvements
- Lessor shall install one (1) loading door with ramp access;
- Lessor shall slurry and stripe the parking lot;

/s/ RN

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/s/ AM

/s/ ERD

- Lessor shall install two (2) dual electric vehicle charging stations at a location to be mutually determined by Lessor and Lessee.
- Lessor shall provide ADA compliant access to the parking lot and front entrance of the premises
- Lessor shall provide roof maintenance/repair services

The following process shall apply to any Tenant Improvements that fall outside of the scope delineated above:

- Lessee shall have the right to use its own interior designer or architect and project management firm(s) for the design and construction of the Tenant Improvements, subject to Lessor’s reasonable approval;
- During normal business hours, Lessor shall provide all utilities for the construction of the Tenant Improvements at no cost to Lessee.

58. Other Terms and Conditions

All other terms and conditions of the Lease shall remain unchanged and in full force and effect.

59. Counterparts

The Lease may be executed by facsimile and in counterparts, and a fully executed facsimile copy of the Lease shall be deemed to be an original for all purposes.

60. Qualified Exchange Accommodation Agreement

Lessor, Pacific Industrial Partners, LLC, is currently the property manager and tenant for Smart 1031, LLC (Property Owner) under the rules and provisions of a Qualified Exchange Accommodation Agreement (“QEAA”). During the term of the QEAA, Pacific Industrial Partners, LLC retains the right to execute any lease or sublease of the Premises on any terms, in its sole discretion and for its sole benefit. Upon the successful completion of the QEAA, Pacific Industrial Partners, LLC will become the Property Owner of the Premises and Smart 1031, LLC shall be dissolved.

Signature page to follow

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/s/ RN

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/s/ AM

/s/ ERD

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/s/ RN
/s/ AM

LESSOR:

By: Pacific Industrial Partners, LLC a California limited liability company

By: /s/ Adam Milstein
Adam Milstein
Manager

Dated: 2/4/2020

By: /s/ Robert Neal
Robert Neal
Manager

Dated: 2/4/2020

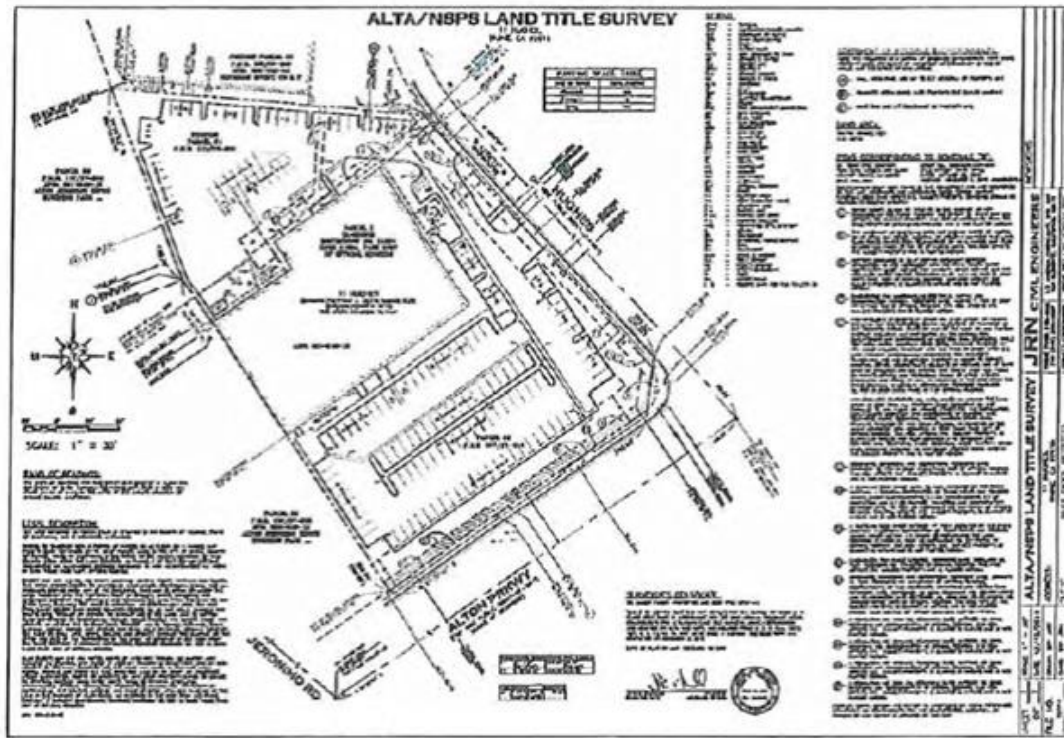
LESSEE:

By: Beta Bionics, Inc.
a Massachusetts public benefit corporation

By: /s/ Edward Damiano
Name: Edward Damiano
Title: President & CEO

Dated: Feb 3, 2020

Exhibit A
Premises



/s/ RN
/s/ AM
INITIALS

/s/ ERD
INITIALS

Exhibit B
SIGNAGE CRITERIA

A. LESSEE SIGN CRITERIA:

The following sign criteria has been established for the purpose of maintaining the overall appearance of 11 Hughes, Irvine, for the benefit of Lessee. No deviation from these criteria will be permitted without Lessor's prior approval in writing. The criteria has also been established to provide maximum continuity with the environment and an architectural Integration with the project.

B. ADMINISTRATION:

- 1) Lessee is responsible for the installation, maintenance, and removal of its Primary Identification sign in a manner acceptable to and consistent with the high standards of Lessor. All costs incurred to provide sign maintenance will be at Lessee's expense. Lessee is responsible for obtaining approval of exterior signage from the Lessor and the City of Irvine prior to installation. All costs associated with sign permit approval are the responsibility of the Lessee. Inside signs that will be visible from outside the building must be approved by Lessor.
- 2) Upon termination of Lessee's Lease, the sign will be removed at the Lessee's expense and any damage to the building shall be repaired at the Lessee's expense.
- 3) No additional exterior signage will be allowed on the face of the structure.
- 4) Signs installed without approval or contrary to the criteria, will be removed by Lessor at Lessee's expense. A scale drawing showing proposed signage and the building elevation must be submitted to Lessor for approval.
- 5) In the event of any conflict between Lessee and Lessor in regard to the application of these criteria, the Lessor's decision shall be final and binding upon the Lessee.

C. SIGN SPECIFICATIONS:

1) Lessee Signage

- a) Lessees' names will be limited to the upper concrete wall facade of the individual lessee space. Lessees shall locate signage over main entry doors or as close thereto as practical.
- b) **The letters for lessee signs shall be 18" minimum height, 2" minimum thickness (unless a variation is approved by Lessor), HDU #10 signfoam mounted to the building with VHB tape and silicone adhesive.** All signs should be non-illuminated and painted of a color approved by the Lessor. Maximum sign coverage will not exceed 36 square feet and must be placed on the concrete panel to the right of Lessee's main entry door(s). Lessee signage may contain logos or more than one row of information provided that the total sign area does not exceed 24" in height and 18 feet in width and presents a professional appearance.

/s/ RN

/s/ AM

INITIALS

/s/ERD

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2) Store Front/Window Signs

- a) Each lessee is allowed to display their company name and logo and business hours on the glass panel to the left or right of their entrance door.
- b) All window signs will be pressure-sensitive vinyl in a color to be mutually determined by Lessor and Lessee.

3) Monument Signage

- a) Lessee shall be allowed to install monument signage in conformance with the City requirements and the CC&R's of the surrounding area. Lessor shall reserve the right to approve such signage.

(4) Banners, Posters and Sandwich Boards

- a) Banners, posters, sandwich boards, etc. will only be allowed to be hung in the windows or placed in other locations of the Lessee space on a temporary basis and only with prior written lessor approval.

/s/ RN

/s/ AM

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Exhibit C
Move Out Conditions

- All lighting is to be placed into good working order. This includes replacement of bulbs, ballasts, and lenses as needed.
- All truck doors and dock levels should be serviced and placed in good operating order (including, but not limited to, overhead door springs, rollers, tracks and motorized door operator). This would include the necessary (a) replacement of any dented truck door panels, broken panels and cracked lumber, and (b) adjustment of door tension to insure proper operation. All door panels that are replaced shall be painted to match the building standard.
- All structural steel columns in the warehouse and office should be inspected for damage and must be repaired. Repairs of this nature shall be pre-approved by the Landlord prior to implementation.
- HVAC system shall be in good working order, including the necessary replacement of any part to return the unit to a well-maintained condition. This includes, but is not limited to, filters, thermostats, and exhaust fans. Upon move out, Landlord will have an exit inspection performed by a certified mechanical contractor to determine the condition of the HVAC system.
- All holes in the sheet rock wall shall be repaired prior to move-out. All walls shall be clean.
- The carpets and vinyl tiles shall be in a clean condition and shall not have any holes or chips in them. Lessor shall accept normal wear on the carpet, tiles, and flooring, provided they appear to be in a maintained condition. Flooring shall be free of excessive dust, dirt, grease, oil and stains. Cracks in concrete and asphalt shall be acceptable as long as they are ordinary wear and tear and are not the result of misuse.
- Facilities shall be returned in a clean condition, including, but not limited to, the cleaning of the coffee bar, restroom areas, windows, and other portions of the Premises.
- There shall be no protrusion of anchors from the warehouse floor and all holes shall be patched. If machinery/equipment is removed, the electrical lines shall be properly terminated at the nearest junction box.

/s/ RN

/s/ AM

INITIALS

/s/ERD

INITIALS

- All mechanical and electrical systems shall be left in a condition that conforms to the code that was applicable at the time of installation of such system. Bare wires and dangerous installations shall be corrected to Landlord's reasonable satisfaction.
- All plumbing fixtures shall be in good working order, including, but not limited to, the water heater. Faucets and toilets shall not leak.
- All dock bumpers shall be left in place and well-secured.
- Drop grid ceiling shall be free of excessive dust from lack of changing filters.
- No ceiling tiles may be missing, stained or damaged.
- All trash shall be removed from both inside and outside of the building.
- All signage including but not limited to building surface mounted, monuments and on glass shall be removed.

/s/ RN

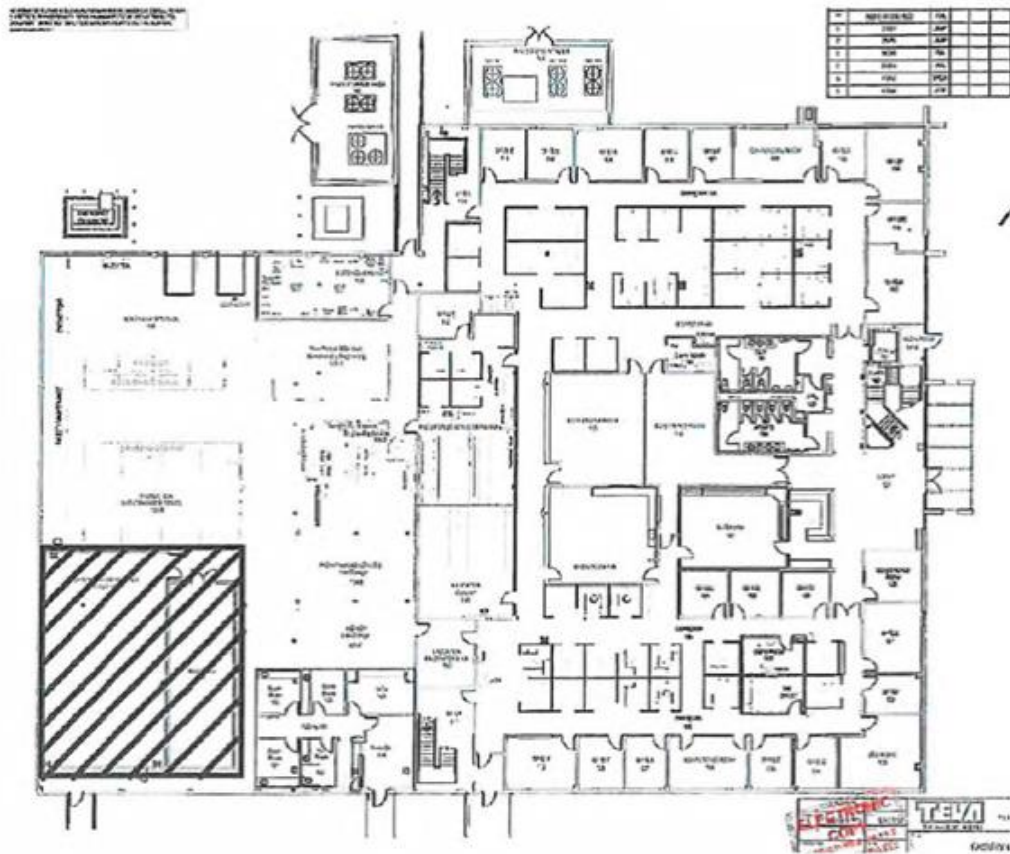
/s/ AM

INITIALS

/s/ERD

INITIALS

Exhibit D Demolition Plan

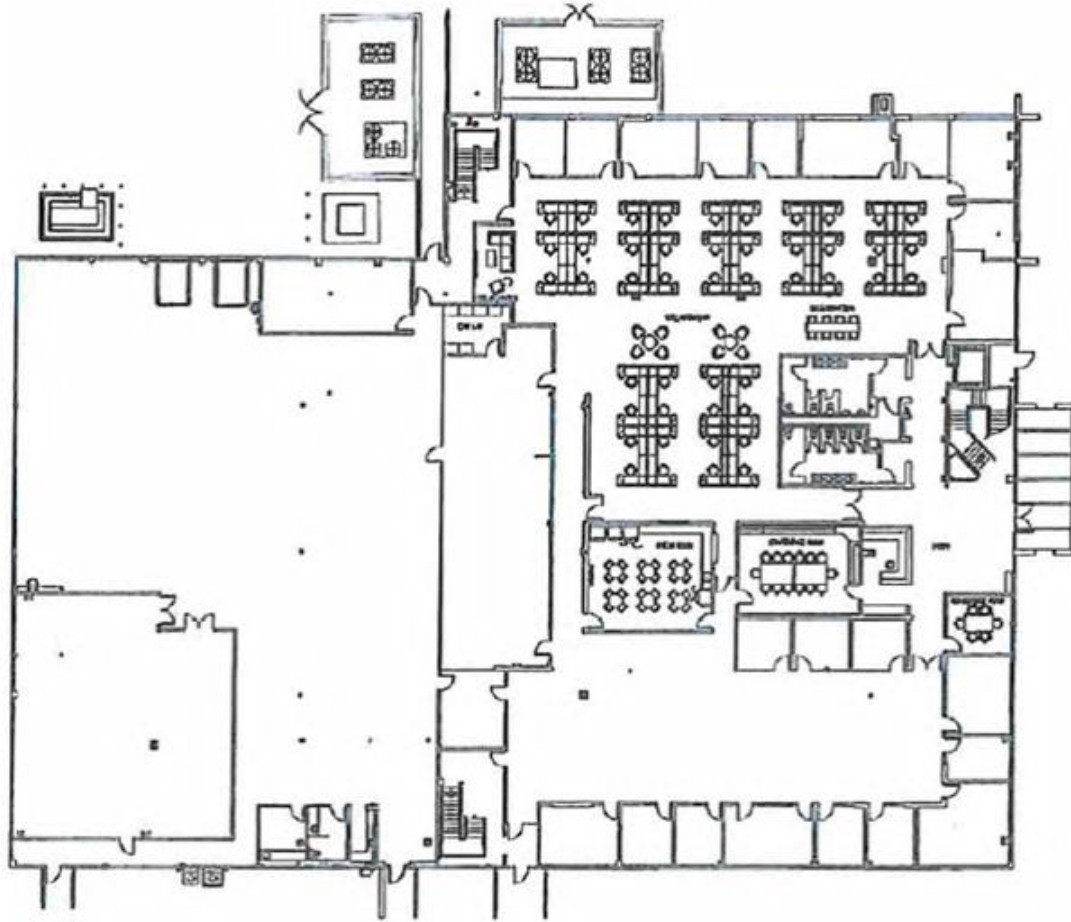


Cross hatched portions indicate the proposed demolition area

/s/ RN
 /s/ AM
 INITIALS

/s/ERD
 INITIALS

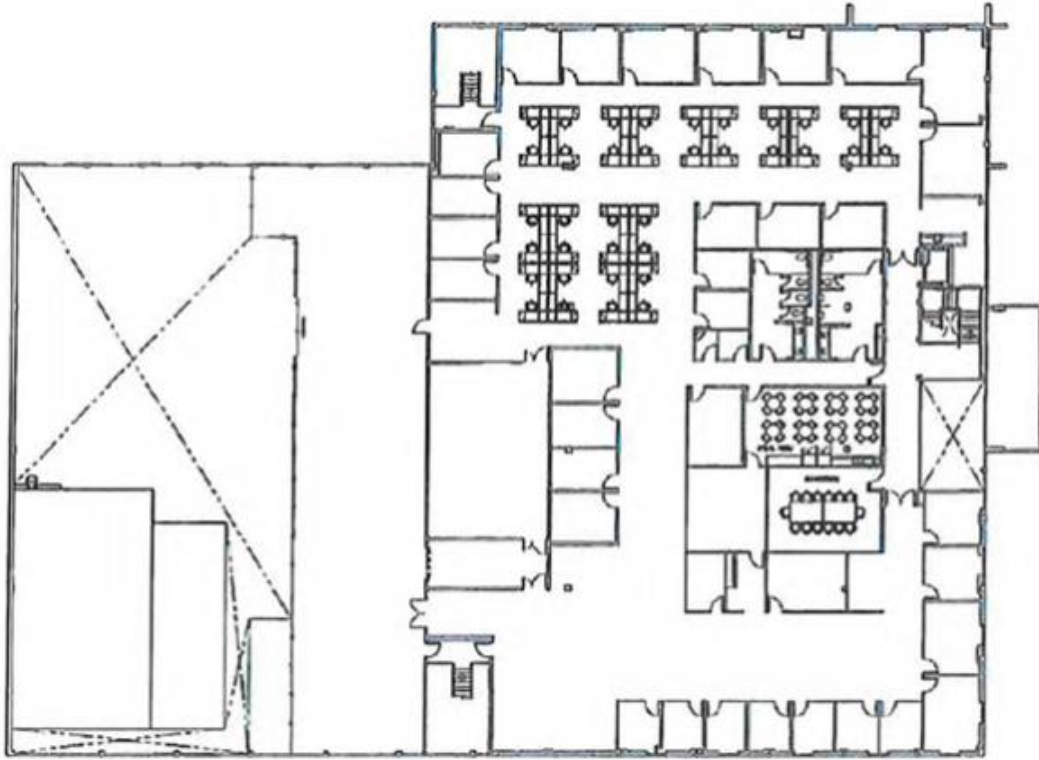
Exhibit D
Proposed Space Plan
First Floor



/s/ RN
/s/ AM
INITIALS

/s/ERD
INITIALS

Exhibit D
Proposed Space Plan
Second Floor



/s/ RN
/s/ AM
INITIALS

/s/ERD
INITIALS

11 Hughes, Irvine—2020 Estimated Expense

Estimated Expenses 2020

	PROPERTY TOTAL Annualized	Monthly Estimates
<u>Utilities</u>	<u>Annual Estimates</u>	
Trash Services*	\$ —	\$ —
Electric Service*	\$ —	\$ —
Solar Energy**	\$ —	\$ —
Water & Sewer Service*	\$ —	\$ —
Gas*	\$ —	\$ —
Waste Management*	\$ —	\$ —
Utility Subtotal	\$ —	\$ —
 <u>Alarm System</u>		
Monitoring/Maintenance***	\$ 2,400.00	\$ 200.00
Telephone***	\$ 900.00	\$ 75.00
Alarm Subtotal	\$ 3,300.00	\$ 275.00
 <u>Fire System</u>		
Monitoring/Maintenance***	\$ 900.00	\$ 75.00
Telephone***	\$ 500.00	\$ 41.67
Fire System Subtotal	\$ 1,400.00	\$ 116.67
 <u>Exterior R&M</u>		
Landscaping***	\$ 18,600.00	\$ 1,550.00
Parking Lot Sweeping***	\$ 3,540.00	\$ 295.00
Window Washing***	\$ 2,560.00	\$ 213.33
HVAC R&M Subtotal	\$ 24,700.00	\$ 2,058.33
 <u>HVAC R&M</u>		
Maintenance*	\$ —	\$ —
Misc	\$ —	\$ —
HVAC R&M Subtotal	\$ —	\$ —
 <u>Insurance</u>		
General Liability/Property	\$ 5,726.00	\$ 477.17
DIC Coverage	\$ 3,444.00	\$ 287.00
Insurance Subtotal	\$ 9,170.00	\$ 764.17
Management Fee (3% of Base Rent)	\$ 13,505.40	\$ 1,125.45
 <u>Property Tax</u>		
OC County Property Tax	\$ 79,992.00	\$ 6,666.00
	\$	
TOTAL ESTIMATED EXPENSES FOR 2020	132,067.40	\$ 11,005.62
Less Reimbursements Paid for 2020		
Estimated Expenses for Balance of 2020	\$ 66,033.70	
Payments Left in 2020	6	
PER MONTH OPERATING EXPENSE PAYMENT FOR 2020		\$ 11,005.62
BASE RENT (6/1/2020-12/31/2020)		\$ 37,515.00
TOTAL DUE MONTHLY BEGINNING June 1, 2020		\$ 48,520.62

* Expense directly payable by Lessee

** Solar energy is directly payable by Lessee on a quarterly basis (kWh Rate for February 3, 2020 - February 2, 2021 Is \$0.183 per kWh)

*** Expense for estimate purposes, expense is directly payable by tenant

/s/ RN

/s/ AM
INITIALS

/s/ERD

INITIALS

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [*], HAS BEEN EXCLUDED FROM THIS EXHIBIT
BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL
AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

Boston University

Beta Bionics, Inc.

Device License Agreement

Effective as of December 16, 2015

[***]

Principal Terms & Milestones List

University Case Numbers:	See Exhibits A & B
University Case Titles:	See Exhibits A & B
Licensee Name:	BetaBionics, Inc.
Business Organization Type:	Benefit Corporation
Patent Filing Entity Type (Small or Large: see 37 C.F.R. § 1.27)	Small Entity
State or Country of Organization:	Massachusetts
Licensee Fiscal Year:	December 31 close
Licensee Lead Contact:	Edward Damiano
Licensee Notice Address:	***
Licensee Notice E-mail:	***
Prior Patent Costs incurred as of	***
License Issue Fee as equity under the Equity Agreement:	***
Threshold (Anti-Dilution Protection) Minimum Royalty Amount, from the Effective Date:	***
***	***
***	***
***	***
Royalty Percentage	***
Sublicensee Consumable Running Royalty Percentage	***
Sublicensee Running Royalty Percentage	***
Sublicense Lump Sum Percentage	***
Commercial Activity Reference Date (§ 3.06):	***
Territory:	***
Field of Use:	***

Milestones		Due Date
***		***
***		***
***		***
***		***
***		***
***		***
***		***
***		***

General Terms & Conditions

LICENSE AGREEMENT effective as of December 16, 2015 (the “**Effective Date**”), is by and between Trustees of Boston University, a Massachusetts non-profit corporation with a principal address at One Silber Way, Boston, MA 02215 (the “**University**”) and Beta Bionics, Inc., a corporation existing under the laws of the Commonwealth of Massachusetts, having a place of business at 22 Putnam Rd., Acton, MA 01720 (as further defined herein, **Licensee**).

WHEREAS, the University is an owner of certain rights by assignment from Rajendranath Selagamsetty (solely with respect to University Case Number [***]), Edward R. Damiano, Firas El-Khatib and Kirk Ramey of their individual right, title and interest in the Patent Rights (as each is defined herein) in the University Cases Numbers [***] as further set forth on Exhibits A and B; and

WHEREAS, Licensee is a Massachusetts Benefit Corporation established under Mass. Gen. L. Ch. 156E and which allows the directors and officers of the corporation to consider and prioritize the social impacts of their corporate decision making in addition to their fiduciary duties to investors; and

WHEREAS, Licensee has conducted its own diligence review of the Patent Rights, understands and acknowledges that certain of the Patent Rights are subject to the Government Rights, Reserved Rights and Other Rights (as defined below); and

WHEREAS, Licensee desires to obtain a license to use and practice the Patent Rights to develop, produce, market and sell products; and

WHEREAS, University and Licensee understand and accept that it may serve the public good for there to be competitive sources of Licensed Products and/or Licensed Processes in certain markets, with appropriate safeguards to Licensee’s economic interests in other markets, as more fully specified herein and that the result of this will be the availability of drugs and/or medical devices at affordable prices to poor segments of the world’s populations;

NOW, THEREFORE, in consideration of the mutual promises and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the University and Licensee hereby agree as follows:

ARTICLE I. DEFINITIONS.

1.01 Capitalized terms used in this Agreement will have the meanings set forth in Schedule 1 annexed hereto.

ARTICLE II. LICENSE.

2.01 Grant. Subject to all of the terms, conditions, reservations and exclusions expressly set forth in this Agreement, the University hereby grants to Licensee, and Licensee hereby accepts, a right and license under the Patent Rights, to make, have made, use, lease, offer to sell, sell and import Licensed Products; and/or to practice Licensed Processes (i) directly or by Sublicense (subject to Section 2.03 hereof); and (ii) only in the Field of Use within the Territory during the Term.

2.02 Exclusivity. Subject to the Reserved Rights, Government Rights (if any), and Other Rights, which are expressly reserved in this Agreement, the license granted under Section 2.01 hereof is exclusive during the Exclusive Period, and thereafter is non-exclusive. All other aspects of the license granted in Section 2.01 are non-exclusive to Licensee.

2.03 Sublicenses. Subject to Sections 2.03(A)-(K), below, the grant under Section 2.01, above, includes a right for Licensee to enter into Sublicenses provided that Licensee shall not grant any Sublicense (other than a Label License) after the expiration or termination of the Exclusive Period.

- (A) **Obligations To University.** Any Sublicense other than a Label License will specify that it is subject to this Agreement and that the Sublicensee agrees to be bound directly to the University in respect of all obligations of Licensee to the University including but not limited to those set forth in ARTICLE II, Sections 2.03, 2.04, 2.05, 2.06 and 2.07, ARTICLE III, Sections 3.02(C) and 3.02(F), ARTICLE IV, Sections 4.01(D) and (E) as applicable, ARTICLE V (all), ARTICLE VI, Sections 6.01, 6.03, 6.03 and 6.04, ARTICLE VII (all), ARTICLE IX (all), ARTICLE X (all) and ARTICLE XI, Section 11.01, 11.06 and 11.07.
- (B) **Copy To University.** A copy of each Sublicense and each amendment thereto or waiver issued in connection therewith will be sent by Licensee to the University within [***] of execution by the parties thereto and Licensee will send a contemporaneous copy to University of any termination notice sent to a Sublicensee.
- (C) **Consideration.** Subject to Section 2.03(K), Licensee is not permitted to grant sublicenses to the Patent Rights for no consideration without prior written consent of University. Moreover, without the prior written consent of the University, consideration for any Sublicense will not include anything of value in lieu of cash payments. For the avoidance of any doubt, the requirements of this Section 2.03(C) forbid Licensee from sublicensing the Patent Rights as part of a cross-license agreement or as part of a settlement agreement without the University's prior written consent after full disclosure of the entire transaction contemplated by Licensee that in any way involves the Patent Rights.
- (D) **No Waivers.** Without the prior written consent of the University, Licensee will not waive any material default or breach under any Sublicense and will not waive any breach or default of any of the requirements of Section 2.03(A).
- (E) **Termination.** Any Sublicense may specify that in the event of termination of this Agreement, so long as the Sublicense complies with this Agreement said Sublicense will continue in full force and effect and all rights and obligations of the Sublicensee, including without limitation the payment of royalties specified in said Sublicense, will inure to the benefit of the University or its designee. Notwithstanding any other provision of this Agreement, the University shall not assume any obligation under any Sublicense without its prior written consent.

- (F) **Further Sublicensing.** Without the prior written consent of University, a Sublicensee shall not grant any sublicense except that a Sublicensee may: 1) grant a Label License so that any product it sells to an End-User may be used for its intended purpose only with respect to amounts of product purchased; and/or 2) grant a royalty-free Sublicense solely to conduct Clinical Trials as specified in Section 2.03(K). Any purported sublicense granted by a Sublicensee (other than as expressly permitted herein) that has not been authorized by written consent of the University will be null and void and a Sublicensee's effort to grant such a sublicense will constitute a material breach of this Agreement.
- (G) **No Enforcement of Patents.** Without prior written consent of University, no Sublicense granted by Licensee may grant any Sublicensee a right to enforce the Patent Rights.
- (H) **Compulsory Licensing.** Licensee or its Sublicensee(s) (as applicable) will promptly notify University should a compulsory license be granted, or be the subject of a possible grant, by Licensee or a Sublicensee to a third party under the applicable laws, rules, regulations, guidelines, or other directives of any governmental or supranational agency in the Territory under the Patent Rights. Said notice will include any material information concerning such compulsory license, and the running royalty rates payable. To the extent that any terms and/or conditions of said compulsory license are: 1) inconsistent with Licensee's obligations under this Agreement; and 2) dictated by said applicable laws, rules, regulations, guidelines, or other directives of any governmental or supranational agency, there is no breach of this Agreement. Notwithstanding the foregoing, to the extent permitted by law Licensee must still pay to University all applicable royalties and fees due under Section 4.01 on amounts actually collected under said compulsory license(s).

- (I) **Sublicensing To A Large Entity.** For so long as Licensee remains a ‘small entity’, Licensee will notify University within [***] after granting a Sublicense to any entity that is not a ‘small entity’ within the meaning set forth in 37 C.F.R. § 1.27. For so long as Licensee and its Sublicensees all remain a ‘small entity’, Licensee will likewise require its Sublicensees to notify University within [***] in the event that any Sublicensee grants a sublicense to any entity that is not a ‘small entity’ within the meaning set forth in 37 C.F.R. § 1.27. For the avoidance of any doubt, a Label License is not a Sublicense for purposes of this Section 2.03(I).
- (J) **Label Licenses.** Any Label License (or the product associated therewith) is subject to this Agreement and, in particular, must comply, or be consistent, with Sections 2.03(G), 6.01, 6.02, 6.03 and 6.04. All Licensed Product sold under a Label License will be subject to all of ARTICLE VII provided that the Licensee or its Sublicensee, rather than the End User, will be the responsible/liable party. Any right or license under a Label License applies only to the amount of Licensed Product contained in the container or packaging bearing the Label License. Any dispute with University associated with any Label License or product under a Label License will be resolved in accordance with ARTICLE X.
- (K) **Clinical Trials.** Licensee and its Sublicensees may grant to a third party a royalty- free Sublicense solely for the purpose of conducting a clinical trial or other research and/or development activity associated with the use of Licensed Products and/or Licensed Processes as may be required by the Food and Drug Administration (FDA) or other governmental regulatory agency from time to time (collectively “*Clinical Trials*”). This grant is limited to the duration of and activities directly associated with any Clinical Trials. Licensee agrees to provide written notice to (i) University per the notice provision in Section 11.07 of this Agreement and (ii) University’s Office of Research Compliance: Conflicts of Interest, Boston University, [***], at least [***] prior to commencing any Clinical Trial at Boston Medical Center.

2.04 Reserved Rights. University reserves the right to itself, Boston Medical Center Corporation (“BMCC”) and other non-profit institutions (individually and collectively the “***Institutions***”) to practice and/or use the Patent Rights for any non-profit purpose, including sponsored research and/or collaborations (collectively, the “***Reserved Rights***”). Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce any of the Patent Rights against the Institutions when used by them for a non-profit purpose. Licensee also agrees that the Institutions have the right to publish any information included in the Patent Rights.

2.05 Government Rights. This Agreement is subject to, and University hereby reserves, any applicable Government Rights including, but not limited to the rights, conditions and limitations imposed by U.S. law (see 35 U.S.C. § 202 et seq. and regulations pertaining thereto) including, without limitation, a royalty-free non-exclusive license granted to the U.S. government.

2.06 Other Rights. The license granted in this Agreement shall not be construed to confer any rights upon Licensee by implication, estoppel or otherwise: (a) to any technology or other intellectual property right of University or BMCC not specifically set forth in the Patent Rights regardless of whether such technology or patent rights shall be dominate or subordinate to any Patent Rights; or (b) beyond such rights as are expressly set forth herein. Without limitation, the University and BMCC further reserve all right to practice, license or otherwise commercialize or use (A) all intellectual property rights that are not Patent Rights and/or (B) any of the Patent Rights outside the Field of Use and/or outside of the Territory.

2.07 Non-suit. University and Licensee on behalf of themselves and any successors-in-interest to the Licensed Products and Licensed Processes covenant that they will not, before or after the Effective Date, assert any claim of patent infringement (including direct infringement, contributory infringement, and induced infringement) under any of the patents in the Patent List, any Licensed Processes or any Orange Book Patent Right for manufacture, use, sale, offer for sale or importation of Licensed Products against any third party engaged in the manufacture, use, sale offer for sale, or importation of Licensed Products in or for Non-Suit Countries for sale to Public Sector entities. The above notwithstanding, this non-suit provision will only apply to products which when offered for sale to End Users are in a Trade Dress that is different from Licensee’s Trade Dress in every respect.

ARTICLE III. REPRESENTATIONS & DUE DILIGENCE

3.01 Due Diligence. Prior to the Effective Date, Licensee acknowledges that it has conducted a due diligence review to its satisfaction of any records concerning the Patent Rights, including but not limited to the various assignments, the funding and sponsor agreements, and research consulting agreements. The University is in the process of assessing inventorship with respect to the Patent Rights to address issues that arose regarding inventorship. Licensee has not relied on any representation, written or oral, formal or informal, by or from the University concerning the Patent Rights or any other aspect of this Agreement.

3.02 Licensee Representations. Licensee represents and warrants to University at all times that:

- (A) **Commercialization Plan.** Licensee is a start-up venture having the strategic commitment to commercialize the Licensed Products and/or Licensed Processes in the Field of Use in the Territory, as appropriate, and Licensee has provided to the University a copy of its most recent Commercialization Plan;
- (B) **Organization & Power.** Licensee is a corporation duly organized, validly existing, and in good standing under the laws of its state of incorporation and has all requisite corporate power and authority to enter into this Agreement;
- (C) **Due Care.** Licensee will exercise due care in its manufacturing and other regulated activities pertaining to Licensed Products;
- (D) **Authorization.** The execution, delivery and performance by Licensee of this Agreement and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite action on the part of the Licensee and do not conflict with or cause a default with respect to Licensee's obligations under any other agreement;

- (E) **Execution & Delivery.** This Agreement has been duly executed and delivered by the Licensee;
- (F) **Insurance.** The insurance coverage required pursuant to Section 7.03 will be obtained, and will be maintained in accordance with Section 7.03, and Licensee will present proof of coverage in a form satisfactory to the University;
- (G) **Progress Reports.** Licensee will submit a Progress Report to University on or before each [***] during the Term of this Agreement provided however that if the Effective Date of this Agreement occurs during the period from [***] to [***], inclusive, Licensee's first Progress Report will not be due until the next [***] following said period; and
- (H) **Small Entity/Large Entity.** Licensee is a 'small entity' within the meaning set forth in 37 C.F.R. § 1.27. Licensee agrees to give University prompt notice if, and when, Licensee no longer qualifies as a 'small entity' within the meaning set forth in 37 C.F.R. § 1.27 or Licensee grants a Sublicense to any entity that is not a 'small entity'.

3.03 Commercially Reasonable Efforts. Licensee will use commercially reasonable efforts to bring the Licensed Products to market in the United States and throughout the remainder of the Territory through a diligent program for exploiting the Patent Rights in the Field of Use and will, throughout the Term, use commercially reasonable efforts to continue development and marketing efforts with respect to the Licensed Products and/or Licensed Processes, in each case consistent with reasonable business practices and judgments.

3.04 Milestones.

- (A) Licensee will meet or accomplish each of the Milestones by its Milestone Date and will notify the University in writing when each Milestone is met.

- (B) Notwithstanding Section 3.04(A), if Licensee learns that it will not meet a Milestone by its Milestone Date because of delay caused by the FDA or another relevant regulatory authority, Licensee shall notify the University and describe the nature of the delay and the expected time to meet the Milestone. If the University takes no action under Sections 3.05 and 9.02(A) before the Milestone that is the subject of Licensee's notice provided in accordance with this Section 3.04(B) is achieved (the "***Delayed Milestone***"), then the Milestone Date for each subsequent Milestone will be extended by the same amount of time between Delayed Milestone's original Milestone Date and the date the Delayed Milestone was actually achieved.

3.05 Material Breach. Breach of any provision of Sections [***] is a material breach of this Agreement thereby permitting University to terminate the Agreement in whole, or in part, in accordance with Section 9.02(A).

3.06 Continuing Commercial Activity. Provided that this Agreement has not previously been terminated for a material breach under Section 3.05, if in any applicable period after the Commercial Activity Reference Date, Licensee fails to achieve Running Royalties during any applicable Calendar Year in an amount that represents at least [***] of the applicable [***], then University may, at its option, [***] terminate the Exclusive Period by written notice delivered to Licensee within [***] after the end of the applicable Calendar Year. If University does not deliver such notice of termination of the Exclusive Period to Licensee within such period, University shall be deemed to have waived its rights under this Section 3.06 with respect to that Calendar Year (but not with respect to any subsequent Calendar Year). University may, at its option, elect not to terminate the Exclusive Period as a result of Licensee's failure to achieve Running Royalties as specified herein for [***] without being deemed to have forgone its right to enforce this Section 3.06 with respect to any subsequent Calendar Year.

3.07 Required Sublicensing. University would like its intellectual property to address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies in the developing world. If Licensee is unable or unwilling to serve or develop a potential market or market territory for which there is a company willing to address therapeutics, diagnostics and/or agricultural technologies in the developing world by utilization of the Patent Rights, Licensee will, at University's request, negotiate in good faith a Sublicense with any such company to enable such company to address said neglected patient populations or geographic areas.

ARTICLE IV. ROYALTIES & PAYMENTS

4.01 Royalties. In consideration for the license and rights granted under this Agreement, Licensee will: 1) execute and deliver to University all documents (as appropriate); and 2) promptly pay all of the following royalties (collectively, the "***Royalties***") and/or fees to the University:

- (A) Equity as an Issue Fee.** In consideration of the license granted to Licensee, Licensee will: (i) issue equity shares of Licensee to the University in the amounts and upon the terms set forth in the Principal Terms & Milestones List; and (ii) execute and deliver an Equity Agreement in a form acceptable to University. Additionally, Licensee will, concurrent with its execution and delivery of this Agreement to University, deliver to University a complete and accurate copy of Licensee's capitalization table, reflecting the above referenced issuance of shares to University. Execution of the Equity Agreement and delivery of the shares required to be delivered to University in accordance therewith is a condition precedent to the validity and enforceability of the license granted pursuant to ARTICLE II of this Agreement and Licensee's failure to both issue the equity shares and to execute and deliver to University an Equity Agreement will render this Agreement null and void *ab initio*.
- (B) Milestone Payments.** Within [***] after the occurrence of each Milestone, Licensee will pay to the University an amount equal to the Milestone Payment for each respective Milestone event.

- (C) **Minimum Royalty Amounts.** During the Exclusive Period, on or before each [***] following the Effective Date, Licensee will pay to the University the Minimum Royalty Amount (“**MRA**”) as specified in the Principal Terms & Milestones List for the indicated MRA Year, wherein MRA Year 0 begins on the [***] following the Effective Date, MRA Year 1 begins on the second [***] following the Effective Date, etc.
- (D) **Running Royalties.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to:
- (i) **Net Sales by Licensee.** The Running Royalty Amount for such Calendar Quarter (if any); plus
 - (ii) **Net Sales by Sublicensee.** The Sublicensee Running Royalty Amount for such Calendar Quarter (if any) (collectively, 4.01(D)(i) and (ii) refer to the “**Running Royalties**”);
- provided that amounts payable under 4.01(D)(i-ii) with respect to any Calendar Year are fully creditable against the Minimum Royalty Amount paid by Licensee to University in said Calendar Year such that Licensee need only make payments to University when the cumulative amount payable under this Section 4.01(D)(i-ii) exceeds the Minimum Royalty Amount and further provided that any available credit not taken against the Minimum Royalty Amount in any Calendar Year will be forfeited and thus not available as an offset in any subsequent Calendar Year.
- (E) **Sublicense Lump Sum.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to the Sublicense Lump Sum for such Calendar Quarter.
- (F) **Combination Product.** If a Licensed Product is sold as part of a Combination Product, Net Sales will be calculated by multiplying Net Sales for such Combination Product [***].

- (G) **Third-Party Royalty Deduction.** Except as set forth in Schedule 2, Licensee knows of no third party intellectual property rights for which license fees must be paid to produce any Licensed Product or to practice any Licensed Process. In the event that Licensee is required to pay Third Party Royalties, then Licensee may deduct an amount equal to [***] of any Third Party Royalties actually paid by Licensee from any Running Royalty Amount due University hereunder, [***] of the Running Royalty Amount otherwise owing under Section 4.01(D)(i) if and only if: [***]. Notwithstanding the foregoing, the Running Royalty Amount otherwise due University may never be less than [***]. In the event that it is determined after the Effective Date that University does not own all right, title, and interest in the Patent Rights, and Licensee obtains, by license(s), assignment(s), or otherwise, rights to any third party(ies') interest(s) in the Patent Rights, any amounts paid by Licensee to such third party(ies) to obtain any rights in any third party interest(s) in such Patent Rights will be treated as Third Party Royalties.
- (H) **Board Observer Rights.** Licensee will, concurrent with its execution and delivery of this Agreement to University, execute and deliver to University a Board Observer Rights Letter Agreement pertaining to board observer rights for the University.

4.02 Payments. All payments due under this Agreement will be paid: (a) in full without deduction of exchange, collection, taxes or other fees that may be imposed by any government; and (b) in United States dollars in Boston, Massachusetts or at such other place as the University may designate consistent with applicable law. All amounts paid to University shall be non-refundable. Currency conversions will be made by reference to the prevailing exchange rate for bank transfers from the foreign currency to U.S. Dollars, as quoted at the Bank of America or its successor on the last business day of the Calendar Quarter immediately preceding the payment due date. In the event that the Bank of America (or its successor) ceases to publish currency quotes, Licensee will use currency quotes from another US headquartered multinational bank. Specifically, Licensee will use J.P. Morgan Chase, Citicorp, Wells Fargo or US Bank (using this order to determine which bank's currency conversion to use taking into account any mergers, acquisitions or renaming that may occur from time to time and using the first in this list until it ceases to exist then moving to the next and so on) to calculate royalty payments due. If by law, regulation or fiscal policy of any country, conversion from that country's currency into U.S. dollars is restricted or forbidden, written notice thereof will be given to the University and payment of amounts from that country shall be made through such lawful means as the University will designate, including, without limitation, deposit of local currency in such recognized banking institution and/or accounts as the University will designate. When in any country the law or regulation prohibits both the transmittal and the deposit of royalties on sales in that country, royalty payments from that country will be suspended for as long as the prohibition is in effect and, as soon as the prohibition ceases, all Royalties that Licensee or its Sublicensees would have been obligated to pay, but for the prohibition, will promptly be deposited or transmitted, as the case may be, to the extent then allowed. If payments are made by check, said check will be made payable to "Trustees of Boston University" and will be sent to University mailing address pursuant to Section 11.07. If Licensee elects to make payments by wire, Licensee will pay all fees associated with processing the wired payment and will follow the wire instructions below:

[***]

Licensee agrees that University may provide alternative wire instructions to Licensee at any time, which instructions will supersede and replace the wire instructions provided in this Section 4.02 for all further wire transfers. Said new wire instructions may be sent to the Licensee pursuant to the notice provisions of Section 11.07 (below), in which case they will be deemed received in accordance with Section 11.07.

4.03 Interest. Any payments by Licensee that are not paid on or before the date such payments are due under this Agreement will bear interest at [***]. Interest will accrue beginning on the first date following the due date for payment and will be compounded quarterly. Payment of interest will not foreclose any other right that the University may have as a consequence of late payment. In the event of default in payment of any payment owing to University under the terms of this Agreement, and if it becomes necessary for University to undertake legal action to collect said payment, Licensee agrees to, and will, pay reasonable, documented legal fees and costs incurred by University in connection therewith.

ARTICLE V. REPORTS, RECORDS & AUDIT

5.01 Books & Records. Licensee will keep, in accordance with generally accepted accounting principles, up-to-date, complete, true and accurate books of account in sufficient detail to permit calculation of all amounts due hereunder, including without limitation, copies of all invoices, which will be properly itemized. Such books of account will be maintained at Licensee's principal place of business (or at its election, the principal place of business of the division of Licensee to which this Agreement relates). The books of account and supporting records shall be retained by Licensee and, as applicable, each Sublicensee, for at least as long as required to comply with the audit requirements in Section 5.05. Licensee will inform the University in writing of the location of such books and records within [***] of a request for such location.

5.02 Quarterly Reports.

- (A) Within [***] after the end of each Calendar Quarter during the Term (without regard to whether any payments are due to the University in respect of such quarter), Licensee will deliver to the University, a complete and accurate report which will contain the following:
- (i) identification of all Sublicenses related to the Patent Rights entered into during such quarter, together with a summary of the principal economic terms of each;
 - (ii) a summary of those activities of Licensee and its Sublicensees directed toward promoting the sale and use of the Licensed Products and/or Licensed Processes; and
 - (iii) identification of all Milestone Dates occurring during such quarter and an indication of whether the corresponding Milestone was met (and if not, a summary of the progress as of the end of such quarter and projected completion dates).
- (B) After the First Commercial Sale by Licensee and/or its Sublicensee(s) that gives rise to Running Royalties or fees under Section 4.01(D) or Section 4.01(E), within [***] after the end of each Calendar Quarter during the Term, Licensee will deliver to the University, a complete and accurate report which will contain the following:
- (i) the number of each type of: 1) Licensed Product made, used, leased, sold, offered for sale or imported; and/or 2) Licensed Process (as appropriate) practiced by Licensee and/or a Sublicensee during such quarter;
 - (ii) the total amount of Net Sales (with itemized total by Licensee and each Sublicensee, if applicable) during such quarter;
 - (iii) the Running Royalty Amount for such quarter;

- (iv) the total Sublicensee Running Royalty Amount for such quarter;
- (v) the Sublicense Lump Sum for such quarter (with itemized total for each Sublicense);
- (vi) calculations of exchange rates, when applicable; and
- (vii) calculations of each amount due under this Agreement in respect of such quarter, including without limitation, deductions applicable to Net Sales.

The reports described in this Section 5.02 are each referred to herein as a “**Quarterly Report**.” Each Quarterly Report will [***], or be sent to University [***], the payment under Sections 4.01(D) and 4.01(E). If Licensee elects to wire transfer payments to University, the Quarterly Report will be transmitted to University in accordance with Section 11.07 [***] that the wire transfer is made.

5.03 Annual Reports. Within [***] after the end of Licensee’s Fiscal Year during which Licensee is not listed on a public exchange that requires filing of publicly available financial statements, Licensee will provide to the University a copy of its financial statements for such year, certified as to their completeness and accuracy by Licensee’s chief financial officer. Licensee will also provide to the University written evidence of the annual renewal of insurance within [***] of such renewal. Notwithstanding the foregoing, the obligations contained in this Section 5.03 which pertain to financial statements will terminate upon the consummation of the Licensee’s Initial Public Offering.

5.04 Other Reports. Promptly upon written request of the University or as otherwise required by the terms of this Agreement, Licensee will provide to the University any annual report to stockholders of Licensee or, if there is no annual report to stockholders, annual updates to the Business Plan and Commercialization Plan, including any changes to the management team. Licensee will also promptly provide to University all relevant notices consistent with the Board Observer Rights Letter Agreement.

5.05 Audit. The University may, itself or using a third party agent, audit the books and records of Licensee upon [***] advance written notice specifying any time of day during Licensee's business hours (or if Licensee has no set business hours then during the hours of 8AM to 4PM) at Licensee's place of business for the purpose of verifying Licensee's reports and compliance by Licensee in all other respects with this Agreement. No such audits shall be conducted hereunder more frequently than once every [***] nor shall University be permitted to repeat an audit of books for a period previously audited unless: (i) there is reason to believe that any of the circumstances described in Section 9.02 has occurred; or (ii) with respect to a repeat audit, Licensee has undergone a restatement of its records for that period. Notwithstanding the foregoing, Licensee will grant University, or its auditor, access to all of Licensee's records for all prior periods to the extent necessary to perform a proper audit. If any audit identifies an underpayment by Licensee, Licensee will promptly pay the underpayment to University including interest as provided for in Section 4.03. If any audit identifies an overpayment by Licensee, Licensee may deduct such overpayment from the next scheduled payments due University until such overpayment has been recovered by Licensee. If any audit leads to the discovery of an underpayment by Licensee in respect of any Calendar Quarter of [***] between amounts due in respect of such quarter and amounts reported to be due by Licensee in its quarterly report for such quarter or otherwise reveals a previously undisclosed material breach of this Agreement, Licensee will, within [***] after written notice from the University, reimburse the University for all of its costs related to the audit. Otherwise, any audit will be at the University's expense. Licensee will, in any event and without regard to the size of the discrepancy, [***] pay to the University the amount of any previous underpayment, including interest from the time such amount was due until paid in full in accordance with Section 4.03. Any audit conducted pursuant to this Section 5.05 will be conducted, at University's option, by the University itself or by an auditor selected by University and reasonably acceptable to the Licensee. For the avoidance of any doubt, University's right to audit books under this Section 5.05 applies to all Affiliates that sell Licensed Products or practice Licensed Processes and to all Sublicensees to the same extent that it applies to Licensee. Failure by Licensee, an

Affiliate or a Sublicensee to permit University to conduct an audit as set forth in this Section 5.05 will [***] give University the right to suspend the non-compliant party's rights under the Patent Rights until such time as said party becomes compliant with this Section 5.05. University's right to audit Licensee's books in accordance with this Section 5.05 will extend for [***] after the expiration or termination of this Agreement for any reason. With respect to any University's rights under a continuing Sublicense under Sections 2.03(A) and 2.03(E), University's right to audit the Sublicensee's books will extend for [***] after the expiration or termination of said Sublicense for any reason.

ARTICLE VI. REGULATORY MATTERS & PATENT COSTS

6.01 United States Manufacture. Licensee agrees to comply with any obligations imposed on University and/or Licensee by 35 U.S.C. § 204 and/or other provisions of the Bayh-Dole Act as codified in 35 U.S.C. § 200-212, and implemented by 37 C.F.R. 401 in connection with any Licensed Products used or sold in the United States. In the event that the Licensee or Sublicensee seeks a waiver of such requirement, the University agrees, if requested by Licensee, to take reasonable steps to assist the Licensee or Sublicensee to obtain such waiver to the extent permissible under current law.

6.02 Compliance with Laws. Licensee and its Sublicensee(s) shall comply with all applicable local, state, federal and foreign laws and regulations.

6.03 Export Control. It is understood that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling both actual and deemed exports, including the Export Administration Regulations of the United States Department of Commerce, the International Traffic in Arms Regulations of the Department of State, and the Office of Foreign Assets Control of the Department of Treasury. Licensee hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and/or technical data, that it will be solely responsible for any violation of such by Licensee, its Affiliate(s) and/or its Sublicensee(s), and that it will defend, indemnify and hold University harmless in the event of any legal action of any nature occasioned by such violation.

6.04 Compliance & Marking. Licensee will comply with, and will require its Affiliates and Sublicensees to comply with, all applicable laws and regulations concerning the manufacture (including without limitation, if applicable, Good Manufacturing Practices set forth by the United States Food and Drug Administration), marking, marketing and safety of all Licensed Products. Without limiting the foregoing, all Licensed Products sold, leased or shipped in, through or to: (a) the United States will be marked with all applicable U.S. patent numbers; and (b) any other country will be marked in conformity with all of the laws and regulations of such country. Licensee further agrees to promptly remove the relevant patent markings from Licensed Products upon expiration or invalidation of a Licensed Patent. Licensee still further agrees to remove patent markings from Licensed Products as may be reasonably requested by University from time to time.

6.05 Patent Filings. The University will, using patent attorneys selected by it, use commercially reasonable efforts to apply for, seek issuance of and maintain the Patent Rights during the Term in the United States and such other countries as are agreed to by the Parties in writing or as Licensee may request in writing; provided that: (a) Licensee will cooperate with the University in such filing, prosecution and maintenance; and (b) Licensee will be given at least [***] to advise and comment upon such filings and actions as are undertaken by the University and further provided that in all cases University retains the absolute right to make all decisions with respect to preparation, filing, prosecution and maintenance. The University shall direct its patent counsel to: a) provide Licensee with a copy of the application or other filing as filed, together with notice of its filing date and serial number when available; and b) provide to Licensee copies of all communications between patent counsel and any foreign associates responsible for the filing, prosecution and/or maintenance of any foreign Patent Rights. The University may, in its discretion, decline to apply for, prosecute or maintain any

Patent Rights in any country, but will give timely notice to Licensee of any such determination, whereupon Licensee may undertake such action, in the name and on behalf of the University, at Licensee's own expense. The University agrees to cooperate with Licensee as reasonably necessary to permit Licensee to be able to file, prosecute or maintain any Patent Rights in those countries that the University declines to undertake action. Licensee further acknowledges and agrees that University may file for and obtain patent protection in countries that are not of interest to Licensee (the "**Unfunded Countries**") but which are of interest to either the University or other licensee(s) of University whose license(s) is/are in a field of use that differs from the Field of Use. In such case, if Licensee has elected to not reimburse University for Patent Costs associated with the Unfunded Countries as set forth in Section 6.06, below, said Unfunded Countries are [***] removed from the Territory under this Agreement for the remainder of the Term.

6.06 Patent Costs.

- (A) Licensee will bear the cost of all reasonable, documented Patent Costs incurred by University in connection with the Patent Rights as of the Effective Date and continuing for the Term of this Agreement. Within [***] of the Effective Date, Licensee shall make a non-creditable, nonrefundable payment to the University to reimburse the University for its prior Patent Costs in the amount set forth on Principal Terms & Milestones List (the "**Prior Patent Costs**"). For all other Patent Costs, Licensee will pay to University within [***] of the University's transmittal to Licensee of an invoice of all Patent Costs (a "**Patent Cost Invoice**") so transmitted.
- (B) Overdue amounts will accrue interest pursuant to Section 4.03. Licensee may decline payment of ongoing Patent Costs by giving [***] written notice in advance of the University incurring such costs, whereupon Licensee's license to the Patent Rights affected by such Patent Costs will terminate, including but not limited to, the deletion of such patent from the Patent List and the termination of the license granted with respect to such patent or patent application. If Licensee's decision to decline payment of Patent Costs would result in the abandonment of

all of patent(s) and/or patent application(s) (of the Patent Rights) in any one or more country(ies) and/or region(s) (regardless of whether or not University actually abandons said patent(s) and/or patent application(s)), then the grant under Section 2.01 with respect to said country(ies) and/or region(s) of the Territory will also terminate.

- (C) Notwithstanding the foregoing, if the due date for National Phase Entry of one or more of the patent applications of the Patent Rights is scheduled to occur or if any other Substantial Patent Prosecution Event occurs, University will take the following actions:
- (i) With Respect to a National Phase Entry, University will ask Licensee into which countries Licensee wishes the patent application to be nationalized and obtain estimates for entry into the national phase in those countries. Upon receipt of instructions from Licensee, University will (to the extent there is, in University's opinion or in University counsel's opinion, sufficient time to take such action and further provided that University is in receipt of the *Estimated National Phase Entry Payment* (as defined below)), with respect to said patent application, instruct its counsel to enter the national phase in those countries (other than the United States) so designated by Licensee provided that Licensee pays to University [***] of the estimated costs of said national phase filings (the "***Estimated National Phase Entry Payment***") at the time of such instructions from the Licensee.
 - (ii) With respect to a Substantial Patent Prosecution Event, University will obtain an estimate from counsel for services associated with said Substantial Patent Prosecution Event and then confer with Licensee to determine whether or not Licensee will support the action by paying [***] of the estimated costs to University. If Licensee pays University said [***] of the estimated costs, University will proceed to address the Substantial Patent Prosecution Event. If Licensee elects to not pay University said [***] of the estimated costs when due, University may, at its option, elect to proceed to address the Substantial Patent Prosecution Event or may decline to take any other action it deems proper.

For the avoidance of doubt, any payments made under this Section 6.05(C) are fully creditable against the fulfillment of Licensee's obligations under 6.05(A) as they come due but are not intended to release Licensee of any of its payment obligations under 6.05(A).

ARTICLE VII. WARRANTIES, LIMITATIONS & INDEMNIFICATION

7.01 University Limitation. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE UNIVERSITY MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR WITH RESPECT TO: (1) THE SCOPE OR VALIDITY OF ANY OF THE PATENT RIGHTS; (2) WHETHER THE PATENT RIGHTS MAY BE EXPLOITED BY LICENSEE OR ANY SUBLICENSEE WITHOUT INFRINGING THE RIGHTS (INCLUDING PATENT RIGHTS) OF OTHERS; OR (3) THE RESULTS TO BE OBTAINED BY USE OF THE PATENT RIGHTS, THE LICENSED PRODUCTS AND/OR THE LICENSED PROCESSES. THE PATENT RIGHTS ARE DELIVERED "AS IS" IN EVERY RESPECT. IF BIOLOGICAL MATERIALS ARE TRANSFERRED (BY WAY OF LICENSE, BAILMENT OR OTHERWISE) HEREUNDER, UNIVERSITY MAKES NO REPRESENTATIONS OR WARRANTIES THAT SUCH BIOLOGICAL MATERIALS AND/OR THE METHODS USED TO MAKE OR USE SUCH BIOLOGICAL MATERIALS ARE FREE FROM LIABILITY FOR PATENT INFRINGEMENT.

7.02 Indemnification. Licensee will at all times during the Term and thereafter, defend, indemnify and hold the University and its affiliated hospital, BMCC, their current and former trustees, officers, employees, students, agents and affiliates (together, "**Indemnitees**") harmless from and against all claims, suits, demands, liability and expenses, including legal expenses and reasonable attorneys' fees, arising out of: [***].

7.03 Insurance.

- (A) **Scope & Expense.** (a) Licensee shall procure and maintain in full force and effect commercial general liability insurance policies that protect and name the Indemnitees, including Trustees of Boston University, as additional insureds as their interests appear as provided for in ISO form CG 20 26 04 13 with coverage amounts of [***]. Licensee shall procure and provide to University proof of such coverage within [***] of the Effective Date, in a form satisfactory to University. Delivery of proof of coverage to University within such time is a condition precedent to the validity and enforceability of the grant in Section 2.01 of this Agreement. University may in its reasonable discretion, by [***] written notice to Licensee, require greater liability coverage. (b) Notwithstanding section 7.03(A)(a) above, prior to the earlier of: (i) the first use of a Licensed Process or Licensed Product by or on humans (including human testing) or (ii) the First Commercial Sale of any Licensed Process or Licensed Product, Licensee will, at its own expense, procure and maintain in full force and effect commercial general liability insurance policies that protect and name the Indemnitees as additional insureds with coverage amounts of [***].

but the University may in its reasonable discretion, by [***] written notice to Licensee, require greater liability coverage. Coverage under the commercial general liability insurance will include product liability and coverage for Licensee's indemnification obligations under Section 7.02. If the product liability insurance is not for occurrence liability coverage, Licensee will maintain commercial general liability insurance for not less than [***] after it has ceased commercial distribution or use of any Licensed Product or Licensed Processes, or in the alternative, procure an extended tail reporting period for not less than [***]. University may in its reasonable discretion, by [***] written notice to Licensee, require greater liability coverage. The minimum amounts of insurance coverage required under this Section 7.03(A) shall not be construed to create a limit on Licensee's liability with respect to its indemnification under Section 7.02 of this Agreement.

- (B) **Notice, Renewal & Cancellation.** Licensee will provide the University with written evidence of such insurance upon issuance and within [***] of each renewal. Licensee will give the University at least [***] written notice prior to any cancellation, non-renewal or material change in such insurance. Notwithstanding anything to the contrary in Section 9.02(A), failure to maintain insurance as required by this Section 7.03 shall constitute a material breach of the Agreement and, in the event of such breach, the University may terminate this Agreement [***].

7.04 University Liability.

- (A) THE UNIVERSITY'S TOTAL LIABILITY FOR ANY AND ALL CAUSES OF ACTION ARISING IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, IN AGGREGATE, AND REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT OR IN TORT, INCLUDING NEGLIGENCE, OR OTHERWISE WILL BE LIMITED TO DIRECT DAMAGES NOT EXCEEDING IN THE AGGREGATE [***]. LICENSEE WAIVES AND DISCLAIMS (AND WILL CAUSE ALL ITS SUBLICENSEES TO WAIVE AND DISCLAIM) ANY RIGHT TO RECOVER ANY DAMAGES IN THE AGGREGATE IN EXCESS OF SUCH AMOUNT FROM THE UNIVERSITY.

- (B) UNIVERSITY SHALL NOT BE LIABLE TO LICENSEE AND/OR SUBLICENSEES FOR, INCLUDING BUT NOT LIMITED TO, ANY LOST OR ANTICIPATED REVENUES, PROFITS OR SAVINGS, OR ANY INCIDENTAL, INTANGIBLE, EXEMPLARY, PUNITIVE, SPECIAL INDIRECT OR CONSEQUENTIAL DAMAGES, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT OR IN TORT, INCLUDING NEGLIGENCE, OR OTHERWISE AND WHETHER OR NOT THE UNIVERSITY WAS ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES.

ARTICLE VIII. INFRINGEMENT

8.01 Notice. Each party will notify the other party promptly in writing of any alleged infringement of the Patent Rights by a third party of which it becomes aware and will provide any available evidence thereof.

8.02 Prosecution by Licensee.

- (A) **Procedure.** For so long as the grant in ARTICLE II of this Agreement remains exclusive to Licensee and Licensee is not in breach of this Agreement, Licensee will have the first right, at its sole discretion, to prosecute, at its own expense, any alleged infringement of the Patent Rights within the Territory and Field of Use. The University agrees to allow the Licensee to include the University, at the Licensee's expense, as a party plaintiff in any suit brought with respect to any such infringement. The University will have the right to participate in any action, at Licensee's expense. Prior to commencing any such action, Licensee shall

consult with University and shall consider the views of University regarding the advisability of the proposed action. In addition, Licensee agrees to consult with counsel for the University on any significant matters related to the litigation. Notwithstanding anything in the foregoing to the contrary, no settlement, consent judgment or other voluntarily final disposition of any such suit may be entered into without the prior written consent of the University, which consent will not be unreasonably withheld. Licensee will indemnify, defend and hold harmless the University against any order for any costs that may be made against the University in such proceedings brought by Licensee in accordance with this Section 8.02(A). For the avoidance of any doubt, if the grant under ARTICLE II of this Agreement becomes non-exclusive for any reason, Licensee will not have any right to prosecute infringers under this Section 8.02(A).

- (B) **Damages.** In the event that Licensee undertakes litigation pursuant to Section 8.02(A) for the enforcement of Patent Rights, any recovery of monetary damages by Licensee for each suit will be applied as follows: [***].

8.03 Prosecution By University.

- (A) **Procedure.** If the Licensee; (i) within [***] after having been notified of any alleged infringement, has been unsuccessful in negotiating with the alleged infringer to cease and desist such infringement and has not brought an infringement action (or has not defended against any material counterclaim), and/or Licensee continues to be unsuccessful in persuading the alleged infringer to desist and continues not to initiate an infringement action within [***] after written notice from University that University intends to exercise its rights under this paragraph, or (ii) if the Licensee notifies the University at any time prior to the end of such [***] period of its intention not to bring suit

against any alleged infringer in the Territory for the Field of Use, then, and in those events only, the University will have the right, but not be obligated, to prosecute at its own expense any such infringement of the Patent Rights in the Territory for the Field of Use. In such circumstances, and provided that the license granted pursuant to ARTICLE II remains in force, the University will have the right to name the Licensee as a party plaintiff if necessary for the prosecution of the infringement suit. Notwithstanding anything in the foregoing to the contrary and further provided that the Exclusive Period of the license granted pursuant to ARTICLE II remains in force, no settlement, consent judgment or other voluntarily final disposition of any such suit may be entered into without the consent of the Licensee, which consent will not be unreasonably withheld.

(B) **Damages.** In the event that University undertakes litigation pursuant to Section 8.03(A) for the enforcement of Patent Rights, any recovery of monetary damages by University for each suit will be applied as follows: [***]

(C) [***].

8.04 Actions Against Licensee or University. In the event that an action alleging invalidity or noninfringement of any of the Patent Rights is brought against the University or against Licensee (whether as an independent action or as a counterclaim of a suit filed by Licensee), relating to the Field of Use, the University, at its sole option, will have the right, within [***] after the commencement of such action, to take or regain control of the action at its own expense. If the University determines not to exercise this right and the grant under ARTICLE II remains exclusive to Licensee, Licensee may take over or remain as lead counsel for the action at Licensee's sole expense, with any settlement or recovery subject to the approval provisions of Section 8.02(A) and allocation provisions of Section 8.02(B); *provided* that the University will have the right to refuse, in its sole discretion, to accept any settlement offer that would, in its sole judgment, result in the lessening or weakening of any Patent Rights.

8.05 Cooperation. In any infringement suit, either party shall provide cooperation and assistance to the other party, at the requesting party's expense, as may be reasonably necessary for the suit. Each party agrees to make available relevant records, papers, information, samples and specimens, as well as to have its employees testify upon request, except as restricted by law.

8.06 Sublicense Settlements. In the event that Licensee elects to grant a Sublicense to any alleged infringer in the Territory for the Field of Use for future use of the Patent Rights (e.g., as permitted by Section 2.03(C)), any amounts paid by the alleged infringer as a part of the Sublicense or settlement of allegations regarding infringement of the Patent Rights will be shared by Licensee and the University in the same ratio as amounts received as Sublicense Lump Sum payments under Section 4.01(E). Sublicensing Revenues and/or Net Sales received from any such Sublicensee will otherwise be shared by Licensee and University in accordance with Section 4.01(D) or 4.01(E), as applicable.

ARTICLE IX. TERMINATION

9.01 License. Unless earlier terminated as provided for in this Agreement, the license granted pursuant to Section 2.01 for Licensed Products and Licensed Processes will continue in each country (on a country by country basis) until the occurrence in the applicable country of the following: the expiration, invalidation (where invalidation requires the final decision rendered by a court of competent jurisdiction from which no further appeal has or may be taken) or termination of the last to expire, invalidate or terminate of the Patent Rights upon which the Licensed Products and/or Licensed Processes are based (if any). Nothing herein shall limit Licensee's obligation to pay the Minimum Royalty Amounts set forth in Section 4.01(C).

9.02 Early Termination. Notwithstanding the foregoing, all licenses granted pursuant to ARTICLE II and this Agreement will terminate as follows:

- (A) **Material Breach.** If Licensee materially breaches this Agreement, fails to account for or make any payment to University that is required by this Agreement, fails to make any payment referred to in the Principal Terms & Milestones List, fails to meet any Milestone as set forth in the Principal Terms & Milestones List, fails to maintain insurance as required in Section 7.03 or if a Sublicensee materially breaches any of the provisions to which it is required to be bound directly to the University as set forth in Section 2.03 (a “**Breaching Sublicensee**”), the University will have the right, at its election, to terminate: (i) the Exclusive Period; (ii) any or all licenses granted by the University under this Agreement (including the right to sublicense); (iii) a Breaching Sublicensee’s sublicense; or (iv) this Agreement in its entirety upon [***] prior written notice, subject to the survival of the obligations set forth in Section 9.05. Termination will take effect [***] after written notice unless Licensee cures the breach within said [***] period. For the avoidance of doubt, if the Exclusive Period terminates but this Agreement does not terminate, University may (subject to the continuation of Licensee’s and/or any valid Sublicensee’s rights, as expressly provided for in this Agreement) [***] engage in marketing and/or licensing of any of the Patent Rights. University’s right to terminate in accordance with this Section 9.02(A) is in addition to, and not in lieu of, the exercise of any other right University may have for breach of this Agreement by Licensee.
- (B) **Insolvency, Etc.** If Licensee files a petition in bankruptcy or if an involuntary petition is filed against Licensee and such petition is not dismissed within [***], or if the Licensee will cease or suspend the conduct of its usual business or if the Licensee will become, or in light of its usual business is likely to become, insolvent and is unable to pay its debts when due, this Agreement will terminate [***].

- (C) **Challenge to Validity of Patent Rights.** To the maximum extent permitted by law, if Licensee, or any of its Affiliates, files a lawsuit or otherwise challenges the validity, scope or enforceability of any of the Patent Rights, University shall have the right, at its election, [***] after the filing of said lawsuit or notice of any other challenge to terminate this Agreement [***]. If any Sublicensee (or an Affiliate thereof) files a lawsuit or otherwise challenges the validity, scope or enforceability of any of the Patent Rights, University shall have the right, at its election, [***] after the filing of said lawsuit or notice of any other challenge to demand that Licensee terminate said agreement under which said Sublicensee takes license/rights in the Patent Rights, which termination must occur and be effective within the cure provided in Section 9.02(A). In the event that, and for any period during which University does not choose to exercise its rights to terminate this Agreement or a Sublicense pursuant to this Section 9.02(C), Licensee will pay to University [***]. In the event that such a patent challenge is successful, Licensee will have no right to recoup any royalties or other payments due and payable to University during the period of challenge. In the event that such a patent challenge by Licensee or any Sublicensee is unsuccessful, Licensee shall also reimburse University for all University's reasonable legal fees and expenses incurred in its defense of said challenge to the Patent Rights. This obligation to reimburse University for defense of Licensee's unsuccessful challenge to the validity, scope or enforceability of any of the Patent Rights shall survive any expiration or termination of this Agreement. A lawsuit shall be deemed 'unsuccessful' for purposes of this Section 9.02(C) if: (i) the lawsuit is terminated for any reason prior to a settlement or judgment from which no appeal can be or is taken; (ii) any of the Patent Rights challenged by said lawsuit remain enforceable after any such settlement or judgment is in effect; or (iii) if Licensee or such Sublicensee would still require a license to any of the Patent Rights to sell any of its products after any such settlement or judgment is in effect.
- (D) **Claim of Implied License.** If Licensee, or any of its Affiliates, files a lawsuit claiming, or otherwise claims or argues in writing, that Licensee is granted an implied license to any invention or patent right (other than the expressly defined Patent Rights), the University shall have the option to terminate this Agreement [***] (or at any time thereafter) [***].

9.03 Licensee's Right To Terminate. After the [***] of the Effective Date, upon [***] advanced notice, Licensee may terminate this Agreement by giving written notice to University as provided for in Section 11.07.

9.04 Accrued Obligations.

- (A) Upon expiration or termination of this Agreement for any reason, each party will remain liable for those obligations which came into existence prior to the effective date of the expiration or termination including, without limitation, payment of accrued Running Royalties, Minimum Royalty Amount(s), Sublicense Lump Sums, Patent Costs and the recovery from actions pursuant to Section 8.02(B) and Section 8.04, as well as legal fees and expenses as set forth in Section 9.02(C). For the avoidance of doubt, upon termination of this Agreement, Licensee will remain liable to University for payment to University of University's portion of any royalties and/or fees collected by Licensee for Sublicenses. However, Licensee will no longer be a party to any Sublicense which is continued after the termination of this Agreement as permitted under Section 2.03(E).
- (B) Provided Licensee has not materially breached this Agreement, Licensee may, for a period of no longer than [***] after the effective date of the termination of this Agreement, complete any or all Licensed Products that it can demonstrate were in the process of manufacture on the effective date of the termination and sell any and all Licensed Products that it can demonstrate were in the process of manufacture or in inventory on the date of termination; *provided* that Licensee will remain obligated to pay any applicable Running Royalties and fees thereon and prepare and send appropriate reports to University with respect to said Running Royalties as provided in this Agreement. Within [***] after a written request by the University, Licensee will provide the University with an accounting of Licensed Products then on hand and in process and its best estimate of when within the [***] period such sales of Licensed Products will conclude.

9.05 Survival. ARTICLE I (all - including Schedule 1); ARTICLE II, Sections 2.03(E), 2.03(F), 2.04, 2.05, and 2.06; ARTICLE IV (all — to the extent applicable to obligations to pay Milestone Payments, Minimum Royalty Amounts, Running Royalties, Sublicense Lump Sums, interest and all other amounts accrued as of the date of expiration or termination); ARTICLE V (Sections 5.01, 5.02 and 5.05, each for [***] from the date of expiration or termination); ARTICLE VI, Sections 6.01, 6.02, 6.03, and 6.06 (with respect to accrued costs as of the date of expiration or termination); ARTICLE VII (all); ARTICLE VIII for actions filed by Licensee prior to expiration or termination; ARTICLE IX, Sections 9.02(C), 9.04, 9.05 and 9.06; ARTICLE X (all); ARTICLE XI, Sections 11.01, 11.02, 11.03, 11.05, 11.06, 11.07, 11.08, 11.09, 11.10, 11.11, 11.12 and 11.13 and all other sections which by their nature should survive, will survive the expiration or termination of this Agreement. Exhibit C (Equity Agreement) as executed by the parties shall also survive the expiration or any termination of this Agreement as an independent agreement in accordance with its respective terms.

9.06 Information. Upon termination of this Agreement for any reason, Licensee shall, promptly upon written request by the University, make available to the University, at the University's sole option, the rights to use, license or own all Information then in Licensee's possession that is relevant to the commercialization of Licensed Products or Licensed Processes. Any Information returned to University under this Section 9.06 shall not be considered Licensee's Confidential Information.

ARTICLE X. DISPUTE RESOLUTION

10.01 Mediation. In the event of any dispute arising between the parties in connection with this Agreement, the construction thereof, or the rights, duties or liabilities of either party, representatives designated by each party will meet at the University or confer by conference call within [***] of a written request by either party, and attempt to amicably resolve the dispute. If the dispute is not resolved by such efforts within [***] after such written request for a meeting or conference call, the parties will refer the matter to non-binding mediation in Boston, the costs of which will be shared equally. In the event that such dispute is not amicably resolved by such non-binding mediation, then the parties may, at their option, agree to arbitrate or unilaterally employ civil litigation or any other dispute resolution mechanism available to them.

10.02 Injunctive Remedies. Notwithstanding Section 10.01 above, the parties acknowledge and agree that, in the event of a breach or a threatened breach by either party of Sections 11.01 or 11.06 hereof, the other party may suffer irreparable damage for which it will have no adequate remedy at law and, accordingly, will be entitled [***] to seek injunctive and other equitable remedies to prevent or restrain such breach or threatened breach, without having first complied with the provisions of Section 10.01, and without the necessity of posting any bond or surety, in addition to any other remedy it might have at law or at equity.

10.03 Governing Law. The validity, interpretation, performance and enforcement of this Agreement, and all rights and obligations of the parties will be governed and construed in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to its rules concerning conflicts of laws.

10.04 Exclusive Venue; Consent to Jurisdiction. Except for mediation as stipulated in Section 10.01, any action, suit or other proceeding pursuant to, arising under, or touching or concerning this Agreement or the transactions contemplated hereby, including any challenge to the validity or enforceability of the Patent Rights, will be brought exclusively in any court of competent jurisdiction in Suffolk County, Commonwealth of Massachusetts. The parties agree to take any and all necessary or appropriate action to submit to the exclusive jurisdiction of any such court.

ARTICLE XI. GENERAL PROVISIONS

11.01 Confidentiality. It is contemplated that in the course of the performance of this Agreement each party may, from time to time, disclose Confidential Information to the other. Each party agrees to use reasonable efforts: i) to not use the other party's Confidential Information except in the course of the performance of this Agreement or as required to comply with laws or with legal process; and ii) to take all reasonable steps, but no less than the steps it takes to keep its own Confidential Information confidential, to prevent disclosure to a third party; *provided* that no provision of this Agreement will be construed to preclude such disclosure of Confidential Information as may be necessary or appropriate to: (A) obtain from any governmental agency any necessary approval or license or to obtain patents that are to be included in Patent Rights; or (B) where University is the receiving party, for University to provide Licensee's Confidential Information when required for the performance of University's obligations under any third party agreement pertaining to the Patent Rights. The obligations of confidentiality set forth in this Section 11.01 shall survive termination of this Agreement for a period of [***]. Notwithstanding the forgoing, if the University terminates this Agreement in accordance with Section 9.02, the University may use and/or provide any of Licensee's information to a third party for purposes of attempting to relicense any of the Patent Rights. Notwithstanding any other provision of this Agreement, Licensee agrees not to disclose to University any information that may be subject to export controls under any applicable laws or regulations, including but not limited to the Export Administration Regulations of the United States Department of Commerce, the International Traffic in Arms Regulations of the Department of State, and the Office of Foreign Assets Control of the Department of Treasury.

11.02 Amendment and Waiver. This Agreement may be amended only by an instrument in writing signed by an authorized officer of each party. No provision of or right under this Agreement will be deemed to have been amended or waived by any act or acquiescence on the part of either party, its agents or employees, but only by an instrument in writing signed by an authorized officer of each party. No waiver by either party of any breach of this Agreement by the other party will be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver.

11.03 Independent Contractors. Each party represents that it is acting on its own behalf as an independent contractor and is not acting as an agent for or on behalf of any third party. This Agreement and the relations hereby established by and between the University and Licensee do not constitute a partnership, joint venture, agency or contract of employment between them.

11.04 Assignment.

- (A) This license is personal to the Licensee. Without prior written consent of University, this Agreement may be assigned or transferred by Licensee: (i) to an Affiliate (and only for so long as said Affiliate remains an Affiliate); or (ii) in connection with any merger, consolidation or reorganization of Licensee; provided, that (a) Licensee shall deliver written notice to University at least [***] prior to any such proposed assignment, such notice to include the assignee's contact information as well as a description of all of the material terms and conditions of the agreement (as well as any changes thereto, as applicable, within the [***] notice period) between Licensee and the proposed assignee, (b) the proposed assignee agrees in writing to assume all obligations and liabilities of Licensee hereunder, and (c) Licensee is not in default of any of its obligations under this Agreement (including without limitation payment of any amounts due under this Agreement and/or diligence obligations) at the time of such proposed assignment. Any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will be null and void. Moreover, any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will [***] terminate this Agreement.

- (B) Without prior written consent of University, this Agreement may be assigned or transferred by Licensee in connection with any sale of all, or substantially all, of a Licensee's assets related to the Patent Rights provided that (a) Licensee shall deliver written notice to University at least [***] prior to any such proposed assignment, such notice to include the assignee's contact information as well as a description of all of the material terms and conditions of the agreement (as well as any changes thereto, as applicable, within the [***] notice period) between Licensee and the proposed assignee, (b) the proposed assignee agrees in writing to assume all obligations and liabilities of Licensee hereunder, and (c) Licensee is not in default of any of its obligations under this Agreement (including without limitation payment of any amounts due under this Agreement and/or diligence obligations) at the time of such proposed assignment. Any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will be null and void. Moreover, any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will [***] terminate this Agreement. Any such assignment requires payment to University of an amount to be agreed upon by Licensee and University at the time of said proposed assignment (the "**Assignment Fee**"). No attempt to assign this Agreement will be valid and enforceable in the absence of the payment of said Assignment Fee to University.
- (C) Licensee, or its permitted assignee, will within [***] of the effective date of any assignment permitted under Sections 11.04(A) or 11.04(B), notify University of the assignment and advise if the assignee does not qualify for 'small entity' status in accordance with 37 C.F.R. § 1.27.

11.05 Successors and Assigns. This Agreement will bind and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

11.06 Use of Names. Neither party will use the name of the other party or any staff member, officer, employee or student of the other party or any adaptation thereof in any advertising, promotional or sales literature, publicity or in any document employed to obtain funds or financing without the prior written approval of the party or individual whose name is to be used; *provided* that Licensee may state that Licensed Products are based on research originally carried out at Boston University and that it is licensed by the

University under the Patent Rights so long as such statement(s) do not suggest University's endorsement of the Licensed Products, Licensed Processes or the Licensee. Licensee may, without seeking permission of University, make reference to publications authored or co-authored by the inventor(s). Licensee will submit to the University for review and written approval, which approval will not be unreasonably withheld or delayed, any references to Licensed Products, this Agreement, the University or the inventors in submissions required by the Securities and Exchange Commission or any stock exchange or market system on which its shares are listed or being considered for listing. For the University and its officers, employees and students, such approval will be obtained from the Managing Director of the University's Office of Technology Development or its successor. In addition, the University may disclose the name of Licensee in publications by the University. Licensee and University agree that if any public announcement is made about this Agreement, they will jointly make said announcement about the existence of this Agreement.

11.07 Notices. All communications hereunder must be in writing and must be sent to the addresses set forth below, or such other address as either party may specify by notice sent in accordance with this Section:

If to the University:

Boston University

[***]

Attention: [***]

Facsimile: [***]

Email: [***]

with a copy to:

Boston University

[***]

Attention: [***]

Facsimile: [***]

If to Licensee, to the Licensee Notice Address set forth in the Principal Terms & Milestones List. Notices, statements, reports or requests required or permitted hereunder will be in writing and will be deemed effective and properly given [***] by any courier (e.g. FedEx) that provides evidence of delivery, registered or certified mail, Express Mail, or e-mail (provided that delivery to the recipient is confirmed) to the recipient as indicated above or such other recipient as may, in the future, be designated by University or Licensee by such communication.

11.08 Severability. In the event any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other term or provision hereof. The parties agree that they will negotiate in good faith or will permit a court to replace any provision hereof so held invalid, illegal or unenforceable with a valid provision that is as similar as possible in substance to the invalid, illegal or unenforceable provision.

11.09 Conflict or Inconsistency. In the event of any conflict or inconsistency between the terms and conditions hereof and any terms or conditions set forth in any purchase order, sponsored research agreement, confidentiality agreement, material transfer agreement, terms sheet or other document relating to, or affecting, the transactions contemplated by this Agreement, the terms and conditions set forth in this Agreement will prevail.

11.10 Captions/Headings. Captions and Headings of the sections and subsections of this Agreement are for reference purposes only and do not constitute terms or conditions of this Agreement and will not limit or affect the terms and conditions hereof.

11.11 Word Meanings. Words such as *herein*, *hereinafter*, *hereof* and *hereunder* refer to this Agreement as a whole and not merely to a section or paragraph in which such words appear, unless the context otherwise requires. The singular will include the plural, and each masculine, feminine and neuter reference will include and refer also to the others, unless the context otherwise requires.

11.12 Entire Agreement. This Agreement contains the entire understanding of the parties hereto with respect to the transactions and matters contemplated hereby, supersedes all prior agreements and understandings relating to the subject matter hereof, and no representations, inducements, promises or agreements, whether oral or otherwise, between such parties not contained herein or incorporated herein by reference will be of any force or effect. No provision of this Agreement will be interpreted in favor of, or against, either of the parties by reason of the extent to which any such party or its counsel participated in the drafting thereof or by reason of the extent to which any such provision is inconsistent with any prior draft of this Agreement or such provision.

11.13 Counterparts. This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Facsimile or PDF copies of this Agreement will be enforceable as originals. In making proof of this Agreement, it will not be necessary to produce or account for more than one such counterpart.

[Remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized officers, and have duly delivered and executed this Agreement under seal as of the date first set forth above.

BETA BIONICS, INC.

TRUSTEES OF
BOSTON UNIVERSITY

/s/ Ed Damiano

Name: Ed Damiano
Title: President
Date: Dec 16, 2015

/s/ Martin J. Howard

Martin J. Howard
Treasurer
Dec 17, 2015

Schedule 1

Definitions

When used as capitalized terms in the Device License Agreement to which this Schedule 1 is attached, the following terms will have the respective meanings set forth below. The definition of terms defined in the singular tense will include the plural tense and *vice versa*.

Affiliate means with respect to any person or Entity, any other person or Entity that controls, is controlled by or is under common control with the specified person or Entity. As used in this definition, the term ‘**control**’ means: (a) direct or indirect control of at least fifty percent (50%) of the voting stock of an Entity; or (b) in the absence of ownership of at least fifty percent (50%) of the voting stock of the Entity, or in the case of a non-corporate Entity or person, possession of, directly or indirectly, the power to direct or cause the direction of the management and policies of such person or Entity.

Agreement means the Device License Agreement to which this Schedule 1 is attached, together with all Schedules and Exhibits annexed thereto, as the same shall be modified and in effect from time to time.

Assignment Fee has the meaning set forth in Section 11.04(B).

BMCC has the meaning set forth in Section 2.04.

Board Observer Rights Letter Agreement means the letter agreement between the Licensee and the University pursuant to which the University receives board observer rights in the Licensee, and which letter agreement shall be in, or substantially in, the form attached hereto as Exhibit D.

Breaching Sublicensee has the meaning set forth in Section 9.02(A).

Business Plan means a detailed document covering Licensee’s plans as to projected product development, markets and sales forecasts, manufacturing and operations, and financial forecasts.

Calendar Quarter means each three-month period of the Calendar Year beginning on January 1, April 1, July 1 and October 1.

Calendar Year means the period of January 1 through December 31.

Claim means any issued, unexpired, valid claim or pending claim contained in the Patent Rights. For purposes of this definition, **valid claim** means any claim that has not been: i) formally disclaimed by University; ii) dedicated to the public by University; or iii) held to be invalid or unenforceable by a final judgment of a court or administrative agency of competent jurisdiction from which no appeal can be, or is, taken.

Clinical Trial has the meaning set forth in Section 2.03(K).

Combination Product means any product comprised of a combination of: (i) a Licensed Product; and (ii) any active ingredient(s), device(s), delivery system(s) or other technology(ies) for which rights are not included in the license granted under this Agreement but, with respect to said item(s) in (ii), which may each or collectively form the basis for a separately saleable product (an “**Independent Subproduct**”).

Commercial Activity Reference Date has the meaning set forth in the Principal Terms & Milestones List.

Commercialization Plan means a detailed report describing Licensee's progress toward and plans for commercialization of the Licensed Products, including work completed, key scientific discoveries, summary of work-in-progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Product, Licensed Process and significant corporate transactions involving Licensed Product.

Confidential Information means all confidential and proprietary information and data of one party that is provided by that party (the "**disclosing party**") to the other party (the "**receiving party**") hereunder in written or other tangible medium and marked as confidential at the time of disclosure, except any portion thereof which:

- (a) was known to the receiving party, before receipt thereof under this Agreement, as evidenced by the receiving party's written record;
- (b) is or becomes generally known through no fault of the receiving party;
- (c) was provided to the receiving party by a third party, provided that such information was lawfully disclosed by such third party free of restrictions upon disclosure and, to the receiving party's knowledge, without breach of any obligation to the disclosing party;
- (d) is independently developed by persons at the receiving party not having knowledge of, or access to, the Confidential Information; or
- (e) is disclosed pursuant to valid court order or other governmental directive, so long as receiving party has provided to the disclosing party [***] notice of such order or directive so as to enable the disclosing party to interpose appropriate objections thereto.

Consumables means pharmaceutical agents sold in packaging that is comprised of Licensed Products or made with Licensed Processes.

Covered In Whole Or In Part By A Claim means, but for the license rights granted under this Agreement, the Licensee's or Sublicensee's activity (alone or in combination with other persons or Entity(ies) acting under instructions from, or on behalf of, a Licensee and/or Sublicensee) would in some way constitute direct or indirect infringement of a Claim even if not all elements of the Claim are carried out by the same Entity or practiced in the same geographic location.

Current Market Value means, as to any issuance of equity by Licensee in connection with a Sublicense: [***]

[***].

Delayed Milestone has the meaning set forth in Section 3.04(B).

Effective Date has the meaning set forth in the preamble to this Agreement.

End-User means any person or Entity whose use of a product or Licensed Product results in utilization, consumption, destruction, loss of activity or loss of value of said product or Licensed Product.

Entity means any corporation, association, partnership (general or limited), joint venture, trust, estate, limited liability company, limited liability partnership or other legal entity or organization.

Equity Agreement means the agreement between the Licensee and the University pursuant to which the University receives an equity interest in the Licensee, and which agreement shall be in, or substantially in, the form attached hereto as Exhibit C.

Estimated National Phase Entry Payment has the meaning set forth in Section 6.06(C)(i).

Exclusive Period means the Term of the licenses granted pursuant to Section 2.01 unless such period of exclusivity is earlier terminated by the University pursuant to Sections 3.06 or 9.02(A).

Field of Use has the meaning specified in the Principal Terms & Milestones List.

First Commercial Sale means the first sale of a Licensed Product by Licensee (or Sublicensee) to any third party in an arm's length transaction anywhere in the world.

Government Rights means the rights of the United States of America or other government entity in subject matter licensed under this Agreement, including without limitation those set forth in 35 U.S.C. § 200 et seq. or any successor thereto, as well as federal regulations promulgated thereunder, all as modified and in effect from time to time.

Indemnitees has the meaning specified in Section 7.02.

Independent Subproduct has the meaning specified in the definition of Combination Product.

Information means research results, toxicology data, assays, preclinical data, prototypes, mask works, manufacturing processes including cell lines and unused, unexpired amounts of Licensed Products, clinical results, regulatory submissions, approvals, customer lists, papers, photographs, computer programs and databases, manuals, prototypes, models, plans, drawings, designs, formulations, specifications, methods, techniques, formulas, supplier lists, engineering information, price lists, costing information, accounting and financial data, profit margin, marketing and sales data, and/or strategic plans related to the Patent Rights.

Initial Public Offering means the first underwritten public offering of Common Stock of the Licensee for the account of the Licensee registered under the Securities Act of 1933, as amended.

Institutions has the meaning specified in Section 2.04.

Label License means a non-exclusive sublicense right to practice a Licensed Process that is granted directly and solely to an End-User by the Licensee or a Sublicensee and which is fully compliant with the terms, conditions and obligations set forth in Section 2.03(J), and wherein said sublicense right is memorialized: i) on a product label; ii) on product packaging; iii) on an insert that accompanies a product sold to the End-User so that said End-User may use said product said End-User purchased (and only in the amounts purchased) for its intended purpose.

Licensed Process means any process that is Covered In Whole Or In Part By A Claim practiced within any country of the Territory.

Licensed Product means any product or product part made, used, sold or imported into, or exported from, any country of the Territory that: (a) is Covered In Whole Or In Part By A Claim; or (b) is manufactured by using a Licensed Process; or (c) is employed to practice a Licensed Process.

Licensee means the person(s), Entity or Entities so identified in the preamble to the Agreement, and its Affiliates.

Licensee Fiscal Year has the meaning set forth in the Principal Terms & Milestones List.

Licensee Notice Address means the address so identified in the Principal Terms & Milestones List.

Licensee Notice E-mail means the e-mail so identified in the Principal Terms & Milestones List.

Market Countries means: [***].

Milestone means each of the events so identified in the Principal Terms & Milestones List.

Milestone Date means for any Milestone, the date appearing opposite such Milestone in the Principal Terms & Milestones List.

Milestone Payment means for any Milestone, the dollar amount (if any) appearing opposite such Milestone in the Principal Terms & Milestones List.

Minimum Royalty Amount (or **MRA**) means for: (a) any year identified in the Principal Terms & Milestones List under the phrase “Minimum Royalty Amount”, the dollar amount appearing opposite the designation of such year; and (b) any year after the termination of the Exclusive Period, zero.

MRA Year means the period identified in the Principal Terms & Milestones List and defined in Section 4.01(C).

National Phase has the meaning given by the World Intellectual Property Organization with respect to patent prosecution activity under the Patent Cooperation Treaty.

National Phase Entry means, entry into the National Phase under the Patent Cooperation Treaty as defined by the World Intellectual Property Organization (WIPO).

Net Sales means [***]

[***].

Non-Suit Countries means all countries other than Market Countries.

Orange Book Patent Rights means any US patent assigned to or co-assigned to Licensee or any Sublicensee that is listed or co-listed with any patent included in Patent Rights in the FDA's listing "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book.

Patent Costs means all costs, fees and/or expenses of any kind incurred in respect of the Patent Rights and paid by University or invoiced to University, including without limitation: [***].

Patent List means Exhibit A and Exhibit B annexed hereto as they may be amended and in effect from time to time.

Patent Rights means all of the following University intellectual property:

(a) the patents and/or patent applications identified in the Patent List (including PCT application(s) and/or the U.S. utility application(s) filed on or before the one-year conversion date of any such provisional applications and related by a priority claim thereto); (b) any patent application(s) that claim(s) priority to and is/are a conversion, continuation, continuations-in-part, divisional, reissue, renewal, reexamination, substitution or extension of any patent application identified in (a); (c) any patents issuing on any of the patent applications identified in (a) or (b), including any reissues, renewals, reexaminations, substitutions or extensions thereof; and (d) if the Territory includes countries other than the United States, any foreign counterpart(s) (including PCTs) of the foregoing and any patents which issue thereon, provided that Claim(s) in any said continuations-in-part not identified in the Patent List as of the Effective Date will only be included in Patent Rights to the extent any said Claim(s) of said continuations-in-part is/are directed to subject matter specifically described in a patent or patent application identified in the original Patent List (i.e. the Patent List as of the Effective Date). For the avoidance of doubt, no other inventions or patent rights are included in the meaning of Patent Rights except as expressly set forth in this definition.

Public Sector will include:

- (a) the sovereign government of a country;
- (b) agencies of the United Nations and the World Health Organization;
- (c) organizations which are members of the International Committee of the Red Cross and Red Crescent;
- (d) international charitable agencies (also known as Non-Governmental Agencies) including but not limited to Oxfam, Medecins Sans Frontieres, and so forth;
- (e) organizations substantially supported by philanthropic organizations including but not limited to the Bill and Melinda Gates Foundation, the Rockefeller Foundation and so forth, specifically including global product development and distribution public-private partnerships.

Progress Report means a written report summarizing Licensee's material technical and other efforts made towards First Commercial Sale for all Licensed Products under development. Such reports will include, without limitation, reasonably detailed summaries of: (i) development and commercialization of Licensed Products; (ii) collaborations with third parties and sublicensing efforts; (iii) progress toward completing milestones described in the Principal Terms & Milestones List; (iv) key management changes and total number of employees; (v) Licensee's finances; (vi) scientific and business goals for the next year; (vii) summary of any payments due under ARTICLE IV; and (viii) any other company information which may materially adversely impact Licensee's ability to develop Licensed Product.

Quarterly Report has the meaning set forth in Section 5.02.

Reserved Rights has the meaning set forth in Section 2.04.

Royalties has the meaning set forth in Section 4.01.

Royalty Percentage has the meaning set forth in the Principal Terms & Milestones List.

Running Royalties has the meaning set forth in Section 4.01(D).

Running Royalty Amount means, in respect of any Calendar Quarter during the Term, [***] Net Sales [***] multiplied by the Royalty Percentage [***].

Sublicense means any agreement between Licensee (or a Sublicensee as permitted by University's written consent given in accordance with Section 2.03(F)) and a third party, as permitted by this Agreement, that contains a grant to rights taken by Licensee under Section 2.01 of this Agreement regardless of the name given to said agreement by the parties.

Sublicense Lump Sum means, in respect of any Calendar Quarter during the Term, the product of the Sublicense Lump Sum Percentage (expressed as a decimal) multiplied by the applicable amount of Sublicensing Revenue.

Sublicense Lump Sum Percentage has the meaning set forth in the Principal Terms & Milestones List.

Sublicensee means any person or Entity to whom a Sublicense is granted as permitted by this Agreement.

Sublicensee Consumable Running Royalty Percentage has the meaning set forth in the Principal Terms & Milestones List

Sublicensee Running Royalty Amount means, in respect of any Calendar Quarter during the Term, [***]

(a) [***] Net Sales [***] multiplied by the Sublicensee Consumable Running Royalty Percentage [***] plus

(b) [***] multiplied by the Sublicensee Running Royalty Percentage [***].

***]

Sublicensee Running Royalty Percentage has the meaning set forth in the Principal Terms & Milestones List.

Sublicensing Revenue means [***].

Substantial Patent Prosecution Event means an opposition, interference, reexamination, reissue or other patent prosecution event where it is anticipated that costs in excess of [***] are likely to be incurred by University.

Term means with respect to any license granted by the University under this Agreement, the period beginning on the Effective Date and terminating in accordance with ARTICLE IX.

Territory has the meaning specified in the Principal Terms & Milestones List.

Third Party Royalties means any royalties Licensee pays to one or more third parties pursuant to one or more licenses to intellectual property rights entered into by Licensee to avoid infringement of such rights by the practice of the Patent Rights in the manufacture, use, or sale of any Licensed Product, or to avoid infringement-related litigation with respect to the practice of the Patent Rights, as determined by Licensee in its reasonable discretion. Third-Party Royalties shall not include: 1) royalties owed to any Affiliate or Sublicensee; or 2) royalties paid under a patent application filed, or having a priority claim, more than [***] prior to the Effective Date.

Trade Dress will mean the physical appearance of Product as sold in any Market Country by Licensee, including but not limited to such characteristics as shape, color, tradename, trademark or service mark.

Unfunded Countries has the meaning set forth in Section 6.05.

World Intellectual Property Organization means the specialized agency of the United Nations charged with developing a balance and accessible international intellectual property system (see: <http://www.wipo.int/portal/index.html.en>).

None

EZ-Start – License Agreement

EXHIBIT A

US PATENT RIGHTS

***]

EXHIBIT B

FOREIGN PATENT RIGHTS

***]

UNIVERSITY - BETA BIONICS
EQUITY AGREEMENT

This Equity Agreement (the “**Agreement**”), effective as of December 16, 2015 (the “**Effective Date**”), is by and between **Beta Bionics, Inc.**, a Massachusetts benefit corporation with a principal address at 22 Putnam Road, Acton, MA 01720 (the “**Company**”), and **Trustees of Boston University**, a Massachusetts non-profit corporation with a principal address at One Silber Way, Boston, MA 02215 (the “**University**”).

WHEREAS, the Company desires and the University has agreed pursuant to the terms of a Device License Agreement dated as of the Effective Date (the “**Device License Agreement**”) to license certain technology for which the University shall be entitled to certain royalty payments as set forth therein and, additionally, shares of the Company’s Capital Stock on the terms set forth herein; and WHEREAS, the parties hereto are willing to execute this Agreement to effect the purchase and sale of such Capital Stock and to be bound by the provisions hereof.

NOW, THEREFORE, in consideration of the mutual covenants herein contained and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the University and the Company hereby agree as follows:

1. **Definitions**

(a) “**Capital Stock**” shall mean, individually, the Common Stock or Preferred Stock, and, collectively, the Common Stock and the Preferred Stock.

(b) “**Common Stock**” shall mean shares of the Company’s common stock, no par value.

(c) “**Eligible Financing**” shall mean the first capital raising transaction closing after the Effective Date after which the Company will have raised aggregate gross proceeds of [***] or more (inclusive of all amounts raised in such transaction including debt obligations that convert into Capital Stock and in any capital raising transaction occurring before such transaction).

(d) “**Fully Diluted Capitalization**” shall mean, at a specified time, without double counting, the sum of (a) the number of shares of Common Stock outstanding at such time, (b) the number of shares of Common Stock issuable upon the conversion, exercise or exchange of all securities or rights, including options and warrants, outstanding at such time, and (c) the number of shares of Common Stock reserved for issuance pursuant to any outstanding options or other securities exercisable for or convertible into Common Stock under the Company’s equity incentive plans.

(e) “**IPO**” shall mean the Company’s first underwritten public offering of its Common Stock under the Securities Act (as defined below).

(f) “**New Securities**” shall mean shares of new securities of the Company constituting, or units of any new securities of the Company including, shares of Capital Stock or any warrants, options or rights to purchase shares of Capital Stock or any securities convertible into or exchangeable for shares of Common Stock (or any warrants, options or rights with respect to such convertible or exchangeable securities), excluding any securities (i) issued or issuable by reason of a dividend, stock split, split-up or other distribution on outstanding shares of Capital Stock, (ii) issued in a public offering, or (iii) issued in connection with an acquisition, joint venture, commercial arrangement, or similar corporate partnering transaction.

(g) “**Preferred Stock**” shall mean shares of the Company’s preferred stock, no par value.

2. Sale and Issuance of Shares.

(a) Subject to the terms and conditions of this Agreement, and in partial consideration of the license granted to the Company pursuant to the Device License Agreement, the Company will hereby issue and deliver to the University at the closing 2,286 shares of Series B Common Stock which shares represent two and one-half percent (2.5%) of the Company’s Fully Diluted Capitalization immediately following such issuance (such shares of Common Stock issued to the University are referred to herein as the “**Shares**”).

(b) The obligations of the Company hereunder are subject to the fulfillment of each of the following conditions:

(i) The University shall have executed and delivered the Device License Agreement; and

(ii) All authorizations, approvals or permits, if any, of any governmental authority or regulatory body of the United States or of any state that may be required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall have been duly obtained and shall be effective at the closing, other than filings which are required to be made after the closing and which will be duly made on a timely basis.

3. Representations.

(i) Representations and Warranties of the University. The University represents, warrants and acknowledges that the University: (a) has had an opportunity to ask questions of and receive answers from a Company representative concerning the terms and conditions of this investment; (b) is acquiring the Shares for the University’s own account for the purpose of investment, and not with a view to any resale or other distribution thereof in violation of the Securities Act of 1933, as amended (the “**Securities Act**”); (c) is a sophisticated investor with such knowledge and experience in financial and business matters as to be able to evaluate the merits and risks of an investment in the Shares; (d) is able to and must bear the economic risk of the investment in the Shares for an indefinite period of time because the Shares have not been registered under the Securities Act, and therefore, cannot be offered or sold unless the Shares are subsequently registered under the Securities Act or an exemption from such registration is available; and (e) that the University is an “accredited investor” as that term is defined in Regulation D under the Securities Act. The University acknowledges and understands that the

Common Stock has not been registered under the Securities Act, nor registered pursuant to the provisions of the securities laws or other laws of any other applicable jurisdictions, in reliance on exemptions for private offerings contained in Section 4(2) of the Securities Act and in the laws of such jurisdictions. The University further understands that the Company has no intention and is under no obligation to register the Shares under the Securities Act or to comply with the requirements for any exemption that might otherwise be available, or to supply the University with any information necessary to enable the University to make routine sales of the Shares under Rule 144 or any other rule of the Securities and Exchange Commission.

(ii) Representations and Warranties of the Company. The Company represents and warrants to the University that:

- a. The Company is a corporation duly organized, validly existing and in good standing under the laws of the Commonwealth of Massachusetts with full corporate power and authority to own or lease its properties and to conduct its business in the manner and in the places where such properties are owned or leased or such business is conducted by it.
- b. Immediately prior to consummating the transactions contemplated by this Agreement, the authorized Capital Stock of the Company consists of [***] shares of Common Stock, of which [***] shares are issued and outstanding and [***] shares are reserved under the Company's equity incentive plans.
- c. All currently issued and outstanding shares of Company Capital Stock are duly authorized, validly issued, fully-paid, non-assessable and free of all preemptive rights. When the Shares are issued to the University pursuant to this Agreement, they will be duly authorized, validly issued, fully-paid, non-assessable and free of all preemptive rights.
- d. The Company has all necessary power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement and the consummation by the Company of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action. This Agreement has been duly and validly executed and delivered by the Company and constitutes a valid and binding obligation of the Company, enforceable against the Company in accordance with its terms.
- e. Neither the execution, delivery or performance of this Agreement nor the performance of the transactions contemplated hereby, will: (i) constitute a breach or violation of the Company's Certificate of Incorporation or Bylaws; (ii) constitute (with or without the passage of time or the giving of notice) a breach of, or default under any material agreement, instrument or obligation to which the Company is a party or by which its assets are bound; or (iii) violate any court order, judgment, administrative order, writ, decree, stipulation, arbitration award or injunction or statute, law, ordinance, rule and regulation applicable to the Company.

4. Dilution Protection. The Company agrees to issue and deliver to the University, for no additional fee or consideration, from time to time, such number of additional shares of Capital Stock so as to cause the University to continue to hold shares of Capital Stock representing two and one-half percent (2.5%) of the Fully Diluted Capitalization until (i) immediately following the consummation of an Eligible Financing, (ii) immediately before the consummation of an IPO, or (iii) immediately prior to any sale of all or substantially all of the Company's assets, merger or other acquisition, whichever event occurs first.

5. Other Investor Rights. The Company shall grant the University no less favorable registration and co-sale rights as and when the Company shall grant any such rights to third party investors before and in connection with the Eligible Financing.

6. Pre-Emptive Rights. If at any time after the issuance and delivery of the Shares to the University pursuant to this Agreement, the Company shall issue or sell any New Securities of the Company (other than shares of Common Stock or options to purchase shares of Common Stock issued or issuable pursuant to any equity incentive plans of the Company), the Company shall offer to sell such additional New Securities to the University at a purchase price equal to and on the same terms the Company offers to other investors in order to maintain the University's proportional ownership of the Fully Diluted Capitalization calculated in accordance with this paragraph. Within [***] following the sale of New Securities by the Company, the Company shall deliver a notice to the University (the "**Offer Notice**") stating the terms of the New Securities and the opportunity for the University to purchase New Securities. By giving written notice within [***] after the date of the Offer Notice, the University may elect to purchase, at the price and on the terms specified in the Offer Notice, such number of shares of New Securities needed to maintain the University's proportional ownership of the Fully-Diluted Capitalization after giving effect to the issuance of (i) all New Securities (including New Securities purchased by the University under this paragraph) and (ii) if applicable, Additional Shares pursuant to paragraph 4 above. The exercise or non-exercise by the University of its rights pursuant to this paragraph shall be without prejudice to its rights under this paragraph with respect to any future sales of New Securities. The covenants set forth in this paragraph shall terminate and be of no further force or effect (i) immediately before the consummation of an IPO, or (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act of 1934, whichever event occurs first.

7. Miscellaneous Provisions.

(a) Legends. The University acknowledges that all certificates evidencing the Shares shall bear a legend in substantially the following form, in addition to all other legends required by law or any other agreements to which the University is a party:

"THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD, PLEDGED, OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT OR AN OPINION OF COUNSEL, SATISFACTORY TO THE COMPANY AND ITS COUNSEL, THAT SUCH REGISTRATION IS NOT REQUIRED."

(b) Adjustment for Stock Splits, Stock Dividends, etc.

(i) If from time to time during the term of this Agreement there is any stock split-up, stock dividend, stock distribution or other reclassification of the Common Stock of the Company, any and all new, substituted or additional securities to which the University is entitled by reason of its ownership of Shares shall be automatically subject to the restrictions on transfer and the other provisions of this Agreement in the same manner and to the same extent as the shares of Shares.

(ii) If the Shares are converted into or exchanged for, or stockholders of the Company receive by reason of any distribution in total or partial liquidation, securities of another corporation or other property (including cash), or pursuant to any merger or consolidation of the Company or acquisition of its assets, then the rights of the Company under this Agreement shall apply to the securities or other property received upon such conversion, exchange, distribution, merger or consolidation in the same manner and to the same extent as the Shares.

(c) Notice. Any notice required by the terms of this Agreement shall be given in writing and shall be deemed effective upon (i) personal delivery; (ii) [***] by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the [***]; (iii) [***] after deposit with a nationally recognized overnight courier, specifying [***] delivery, with written verification of receipt; or (iv) [***] after deposit with the United States Postal Service, by registered or certified mail, return receipt requested, with postage and fees prepaid. Notice shall be addressed to the Company at its principal executive office and to the University at the address that he or she most recently provided to the Company in writing.

(d) Entire Agreement. This Agreement, together with the Device License Agreement, each entered into as of the date hereof (in either case, as the same may be amended or restated from time to time), constitutes the entire understanding between the parties hereto with regard to the subject matter hereof, and supersedes any other agreements, representations or understandings (whether oral or written and whether express or implied) which relate to the subject matter hereof.

(e) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties hereto.

(f) Choice of Law. This Agreement shall be governed by, and construed and enforced in accordance with, the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by, and construed and enforced in accordance with, the internal laws of the Commonwealth of Massachusetts without giving effect to the conflicts of laws principles thereof.

(g) Severability. The parties hereby agree that each provision herein shall be treated as a separate and independent clause, and the unenforceability of any one clause shall in no way impair the enforceability of any of the other clauses herein. In case any provisions (or portions thereof) contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, the parties agree that such invalidity, illegality or unenforceability

shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject so as to be unenforceable at law, University agrees that such provision or provisions shall be construed by the appropriate judicial body by limiting and reducing it or them, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

(h) Amendments; Waivers. This Agreement may only be amended or modified in writing signed by the University and the Company. No party shall be deemed to waive any rights hereunder unless such waiver is in writing and signed by such party. A waiver in writing on or more occasions shall not be deemed to be a waiver for any future occasions.

(i) Counterparts. This Agreement may be executed in counterparts, each of which when executed and delivered shall constitute a duplicate original, but all counterparts together shall constitute one and the same instrument.

(j) Captions. Captions are for convenience only and are not deemed to be part of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the Effective Date.

BETA BIONICS, INC.

TRUSTEES OF
BOSTON UNIVERSITY

/s/ Ed Damiano

/s/ Martin J. Howard

Name: Ed Damiano

Martin J. Howard

Title: President

Treasurer

Date: Dec 16, 2015

Dec 17, 2015

EXHIBIT D

BETA BIONICS, INC.
22 Putnam Road
Acton, MA 01720

December 16, 2015

Re: Board Observer Rights for the Trustees of Boston University

Trustees of Boston University:

This letter will confirm our agreement made in connection with the issuance to Trustees of Boston University (“**BU**”) of shares of Class B common stock, no par value per share (“**Shares**”) of/by Beta Bionics, Inc. (the “**Company**”), pursuant to the terms of the Equity Agreement, effective as of December 16, 2015 (the “**Agreement**”), between BU and the Company. BU shall be entitled to the following board observer rights, in addition to any rights to non-public financial information, inspection rights, and other rights specifically provided to BU herein:

1. The Company shall invite an individual designated by BU and acceptable to the Company (the “**BU Observer**”), to attend all meetings of the Company’s Board of Directors (the “**Board**”) in a nonvoting observer capacity and, in this respect, the Company shall give the BU Observer copies of all notices, minutes, consents, and other materials that it provides to the Company’s directors at the same time and in the same manner as provided to such directors; provided, however, that the BU Observer shall agree to hold in trust and confidence all information so provided; and provided, further, that the Company reserves the right to withhold any information and to exclude the BU Observer from any meeting or portion thereof if access to such information or attendance at such meeting or portion thereof could either (a) adversely affect the attorney-client privilege between the Company and its counsel, or (b) likely result in a conflict of interest between the Company and BU. Upon reasonable notice and at a scheduled meeting of the Board or such other time, if any, as the Board may determine in its sole discretion, the BU Observer may address the Board with respect to BU’s concerns regarding significant business issues facing the Company.
2. BU shall be entitled to discuss with management of the Company significant business issues, including management’s proposed annual operating plans, and management will meet with representatives from BU regularly during each year at the Company’s facilities, outside of the Board meetings, at mutually agreeable times for such discussion and advice and to review progress in achieving said plans.

3. BU may examine the books and records of the Company and inspect its facilities and may request information at reasonable times and intervals concerning the general status of the Company's financial condition and operations, provided that access to highly confidential proprietary information and facilities need not be provided.

The rights granted herein shall terminate and be of no further force or effect upon the earliest of (i) the consummation of the sale of the Company's securities pursuant to a registration statement filed by the Company under the Securities Act of 1933, as amended, in connection with the firm commitment underwritten offering of its securities to the general public, and (ii) the later date of (a) the date any component of the Licensed Product is approved for sale by the FDA or similar regulatory agency outside of the United States or (b) [***] after the effective date of the Agreement. The confidentiality provisions hereof will survive any such termination.

Very truly yours,

BETA BIONICS, INC.

By: /s/ Ed Damiano

Name: Ed Damiano

Title: President

Agreed to and Acknowledged by:

TRUSTEES OF BOSTON UNIVERSITY

By: /s/ Martin J. Howard

Martin J. Howard

Its duly authorized Treasurer

First Amendment to Device License Agreement
between
Trustees of Boston University and Beta Bionics, Inc.

This First Amendment (“**First Amendment**”) effective as of December 11, 2017 (the “**Effective Date**”) amends that certain Device License Agreement (“**Agreement**”) dated as of December 16, 2015 by and between Trustees of Boston University (the “**University**”) and Beta Bionics, Inc. (“**Licensee**”). University and Licensee may hereafter be referred to as the “**Parties**”.

WHEREAS, in support of Licensee seeking a Series B funding round, the Parties wish to amend the Milestones as defined in said Agreement in order to reflect Licensee’s current development plans;

NOW THEREFORE, in accordance with Section 11.02 of the Agreement and for good and valuable consideration, including the mutual obligations undertaken in the Agreement and this First Amendment, the receipt and sufficiency of which are hereby acknowledged, the parties agree to amend the Agreement as of the Effective Date as follows:

1. The list of Milestones set forth in the Principal Terms & Milestones List shall be deleted and the following list of Milestones shall be inserted in its place:

Milestones		Due Date
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]

This First Amendment shall become effective as of the Effective Date upon execution by an authorized officer of each party. Except as expressly amended by this First Amendment, capitalized terms used in this First Amendment which are defined in the Agreement shall have the meanings set forth in the Agreement.

This Agreement may be executed electronically/digitally in compliance with the Massachusetts Uniform Electronic Transactions Act (MUETA) Mass. Gen. Laws ch. 110G and/or The Electronic Signatures In Global And National Commerce Act (ESIGN) 15 USC ch. 96. Persons signing this document agree that, if used, electronic/digital signatures are intended to authenticate this writing and to have the same force and effect as the use of manual signatures.

IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to be executed by their respective duly authorized officers, and have duly delivered and executed this First Amendment under seal as of the date first set forth above.

TRUSTEES OF BOSTON UNIVERSITY

BETA BIONICS, INC.

By: /s/ Martin J. Howard
Name: Martin J. Howard
Title: Senior V.P., Treasurer & CFO
Date: Dec 18, 2017

/s/ Edward R. Damiano
Edward R. Damiano
President and CEO
Dec 18, 2017

**Second Amendment to Device License Agreement
Between
Trustees of Boston University and Beta Bionics, Inc.**

This Second Amendment (“**Second Amendment**”) effective as of September 21, 2020 (the “**Effective Date**”) amends that certain Device License Agreement (“**Agreement**”) dated as of December 16, 2015 as amended by the First Amendment thereto effective as of December 11, 2017 by and between the Trustees of Boston University (the “**University**”) and Beta Bionics, Inc. (“**Licensee**”). University and Licensee may hereafter be referred to as the “**Parties**”.

WHEREAS, the Parties wish to amend certain terms as defined in said Agreement in order to update the Patent List, reflect Licensee’s current development plans, and clarify the agreement between the Parties regarding calculation of Royalties;

NOW THEREFORE, in accordance with Section 11.02 of the Agreement and for good and valuable consideration, including the mutual obligations undertaken in the Agreement and this Second Amendment, the receipt and sufficiency of which are hereby acknowledged, the parties agree to amend the Agreement as of the Effective Date as follows:

1. The Commercial Activity Reference Date set forth in the Principal Terms & Milestones List shall be changed from [***], to [***].
2. The list of Milestones set forth in the Principal Terms & Milestones List shall be deleted, and the following list of Milestones shall be inserted in its place:

Milestone		Due Date
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]

3. EXHIBIT A and EXHIBIT B shall be deleted and replaced with the revised EXHIBIT A and EXHIBIT B that are attached hereto.

4. On Page 4, prior to the last clause beginning with “WHEREAS”, the following paragraph shall be added:

WHEREAS, University and Licensee are also parties to that certain Control Algorithm License Agreement (“Algorithm Agreement”) dated as of December 23, 2015.

5. Section 4.01(D) shall be amended to read as follows:

(D) **Running Royalties.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to:

i. **Net Sales by Licensee.** The Running Royalty Amount for such Calendar Quarter (if any); plus

ii. **Net Sales by Sublicensee.** The Sublicensee Running Royalty Amount for such Calendar Quarter (if any) (collectively, 4.01(D)(i) and (ii) refer to the “**Running Royalties**”);

provided that amounts payable under 4.01(D)(i-ii) with respect to any Calendar Year are fully creditable against the Minimum Royalty Amount paid by Licensee to University in said Calendar Year such that Licensee need only make payments to University when the cumulative amount payable under this Section 4.01(D)(i-ii) exceeds the Minimum Royalty Amount and further provided that any available credit not taken against the Minimum Royalty Amount in any Calendar Year will be forfeited and thus not available as an offset in any subsequent Calendar Year. [***].

6. Section 4.01(E) shall be amended to read as follows:

(E) **Sublicense Lump Sum.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to the Sublicense Lump Sum for such Calendar Quarter. [***].

7. Section 4.01(G) shall be amended to read as follows:

(F) **Combination Product.** If a Licensed Product is sold as part of a Combination Product, Net Sales will be calculated by [***].

8. Section 5.02(B)(i) shall be amended to read as follows:

- (i) the number of each type of: 1) Licensed Product made, used, leased, sold, offered for sale or imported; and/or 2) Licensed Process (as appropriate) practiced by Licensee and/or a Sublicensee during such quarter, including identification of which items reported in 1) and 2) above also qualify as License Products, Licensed Processes, Software-Based Products, and/or Software-Based Processes under the Algorithm Agreement;

9. The final paragraph of Section 5.02(B) shall be amended to read as follows:

All Quarterly Reports shall identify the portion of Net Sales or Running Royalty Amount reported that is due to sales of products and/or processes that also qualify as Licensed Products, Licensed Processes, Software-Based Products, and/or Software-Based Processes under the Algorithm Agreement. The reports described in this Section 5.02 are each referred to herein as a “**Quarterly Report**.” Each Quarterly Report will [***], or be sent to University [***], the payment under Sections 4.01(D) and 4.01(E). If Licensee elects to wire transfer payments to University, the Quarterly Report will be transmitted to University in accordance with Section 11.07 [***] that the wire transfer is made.

This Second Amendment shall become effective as of the Effective Date upon execution by an authorized officer of each party. Except as expressly amended by this Second Amendment, capitalized terms used in this Second Amendment which are defined in the Agreement shall have the meanings set forth in the Agreement.

This Agreement may be executed electronically/digitally in compliance with the Massachusetts Uniform Electronic Transactions Act (MUETA) Mass. Gen. Laws ch. 110G and/or The Electronic Signatures In Global And National Commerce Act (ESIGN) 15 USC ch. 96. Persons signing this document agree that, if used, electronic/digital signatures are intended to authenticate this writing and to have the same force and effect as the use of manual signatures.

IN WITNESS WHEREOF, the parties hereto have caused this Second Amendment to be executed by their respective duly authorized officers, and have duly delivered and executed this Second Amendment under seal as of the date first set forth above.

TRUSTEES OF BOSTON UNIVERSITY

By: /s/ Martin J Howard
Name: Martin J Howard
Title: Treasurer
Date: Dec 10, 2020

BETA BIONICS, INC.

By: /s/ Ed Damiano
Name: Ed Damiano
Title: President & CEO
Date: Dec 11, 2020

EXHIBIT A

US PATENT RIGHTS

	<u>BU Docket No.</u>	<u>Knobbe Docket No.</u>	<u>USSN / PCT / Patent No.</u>	<u>Title</u>	<u>Priority case (line #)</u>	<u>Owner</u>	<u>Filed / Issued</u>
1.	BU-2013-0197-01	BETAB.016PR3	61/895,270	A MANIFOLD FOR THE TRANSFERRAL OF MEDICAMENTS FROM DIFFERENT VIALS WITHOUT MIS-CHANNELING		BU	10/24/2013
2.	BU-2013-0197-02	BETAB.016PR4	61/932,835	A MANIFOLD FOR THE TRANSFERRAL OF MEDICAMENTS FROM DIFFERENT VIALS WITHOUT MIS-CHANNELING		BU	01/29/2014
3.	BU-2013-0197-03	BETAB.016PR5	62/011,306	A MANIFOLD FOR THE TRANSFERRAL OF MEDICAMENTS FROM DIFFERENT VIALS WITHOUT MIS-CHANNELING		BU	06/12/2014
4.	BU-2013-0197-04	BETAB.016WO	PCT/US14/062186	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	1, 2, 3, 5, 7	BU	10/24/2014
5.	BU-2013-0197-03	BETAB.016PR1	61/895,279	DEVICE FOR BRIDGING INFUSION SOURCES WITH SITES OF INFUSION IN A MULTI-CHANNEL INFUSION SYSTEM OF TWO MEDICAMENTS		BU	10/24/2013
6.	BU-2013-0208-02	BETAB.16WO2	PCT/US14/062187	INFUSION SYSTEM EMPLOYING A MULTI-CHANNEL LUMEN ASSEMBLY FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	1, 2, 3, 5, 7	BU	10/24/2014
7.	BU-2013-0234-01	BETAB.016PR1	61/895,288	AN INFUSION SET OR ADMINISTRATION SET FOR INFUSING TWO OR MORE MEDICAMENTS VIA AN ARRAY OF MULTIPLE CATHETERS OR CANULAE		BU	10/24/2013

8.	BU-2013-0234-02	BETAB.016WO3	PCT/US14/062189	INFUSION SYSTEM FOR EMPLOYING AN INFUSION SET FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	1, 2, 3, 5, 7	BU	10/24/2014
9.	BU-2013-0197-07	BETAB.016NP	15/031512	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	1, 2, 3, 4, 5, 7	BU	04/22/2016
10.	BU-2015-0044-01	BETAB.017PR	62/190,212	INFUSION SYSTEM INCLUDING MULTIPLE MEDICAMENT INFUSION PORTS		BU	07/08/2015
11.	2015-062-01	BETAB.017PR2	62/254,950	INFUSION SYSTEM AND COMPONENTS THEREOF		BU	11/13/2015
12.	2015-062-02	BETAB.017PR3	62/353,210	INFUSION SYSTEM AND COMPONENTS THEREOF		BU	06/22/2016
13.	2015-062-03	BETAB.017WO	PCT/US2015/041395	INFUSION SYSTEM AND COMPONENTS THEREOF	10, 11, 12	BU	07/07/2016
14.	2015-062-04	BETAB.017C1	15/848,933	INFUSION SYSTEM AND COMPONENTS THEREOF	10, 11, 12, 13	BU	12/20/2017
15.	2017-002-01	BETAB.018PR	62/443,616	INFUSION SYSTEM AND COMPONENTS THEREOF		BU / Beta	01/06/2017
16.	2017-002-02	BETAB.018PR2	62/444,244	INFUSION SYSTEM AND COMPONENTS THEREOF		BU / Beta	01/09/2017
17.	2017-002-03	BETAB.018WO	PCT/US2018/012636	INFUSION SYSTEM AND COMPONENTS THEREOF	15, 16	BU / Beta	01/05/2018
18.	2017-002-04	BETAB.018C1	16/503,269	INFUSION SYSTEM AND COMPONENTS THEREOF	15, 16, 17	BU / Beta	07/03/2019

EXHIBIT B

FOREIGN PATENT RIGHTS

	<u>BU Docket No.</u>	<u>Knobbe Docket No.</u>	<u>PCT / App / Patent No.</u>	<u>Country</u>	<u>Title</u>	<u>Owner</u>	<u>Filed /Priority / Issued</u>
19.	BU-2013-0197-04	BETAB.016WO	PCT/US14/062186	PCT	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	10/24/2014
20.	BU-2013-0208-02	BETAB.016WO2	PCT/US14/ 062187	PCT	INFUSION SYSTEM EMPLOYING A MULTI-CHANNEL LUMEN ASSEMBLY FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	10/24/2014
21.	BU-2013-0234-02	BETAB.016WO3	PCT/US14/062189	PCT	INFUSION SYSTEM FOR EMPLOYING AN INFUSION SET FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	10/24/2014
22.	BU-2013-0197-08	BETAB.016AU	2014339922	AU	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
23.	BU-2013-0197-19	BETAB.016AUD1	2019216642	AU	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
24.	BU-2013-0197-09	BETAB.016CA	2928557	CA	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
25.	BU-2013-0197-10	BETAB.016CN	201480070961.8	CN	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
26.	BU-2013-0197-11	BETAB.016EP	14799592.2	EP	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1

27.	BU-2013-0197-14	BETAB.016EP1	14799593.0	EP	INFUSION SYSTEM EMPLOYING A MULTI-CHANNEL LUMEN ASSEMBLY FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 2
28.	BU-2013-0197-15	BETAB.016EP2	14799594.8	EP	INFUSION SYSTEM FOR EMPLOYING AN INFUSION SET FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 3
29.	BU-2013-0197-17	BETAB.016HK	17104182.1	HK	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
30.	BU-2013-0197-16	BETAB.016IL	245390	IL	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
31.	BU-2013-0197-12	BETAB.016JP	2016-550675	JP	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
32.	BU-2013-0197-18	BETAB.016JPD1	2019-124894	JP	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
33.	BU-2013-0197-13	BETAB.016MX	MX/a/2016/005252	MX	INFUSION SYSTEM FOR PREVENTING MISCHANNELING OF MULTIPLE MEDICAMENTS	BU	Priority to case in line 1
34.	2015-062-03	BETAB.017WO	PCT/US2015/041395	PCT	INFUSION SYSTEM AND COMPONENTS THEREOF	BU	07/07/2016
35.	2015-062-05	BETAB.017CA	2991058	CA	INFUSION SYSTEM AND COMPONENTS THEREOF	BU	Priority to case in line 16
36.	2015-062-07	BETAB.017EP	16822003.6	EP	INFUSION SYSTEM AND COMPONENTS THEREOF	BU	Priority to case in line 16
37.	2015-062-08	BETAB.017HK	18113567.6	HK	INFUSION SYSTEM AND COMPONENTS THEREOF	BU	Priority to case in line 16
38.	2015-062-06	BETAB.017JP	2017-566331	JP	INFUSION SYSTEM AND COMPONENTS THEREOF	BU	Priority to case in line 16
39.	2017-002-03	BETAB.018WO	PCT/US2018/012636	PCT	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	01/05/2018
40.	2017-002-05	BETAB.018AU	2018206409	AU	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21

41.	2017-002-06	BETAB.018BR	BR 11 2019 013985 0	BR	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
42.	2017-002-07	BETAB.018CA	3049167	CA	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
43.	2017-002-08	BETAB.018CN	201880014499.8	CN	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
44.	2017-002-09	BETAB.018EP	18735988.0	EP	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
45.	2017-002-16	BETAB.018HK	62020007145.9	HK	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
46.	2017-002-15	BETAB.018IL	267822	IL	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
47.	2017-002-10	BETAB.018IN	201917026515	IN	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
48.	2017-002-11	BETAB.018JP	2019-537218	JP	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
49.	2017-002-12	BETAB.018MX	MX/a/2019/008110	MX	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
50.	2017-002-13	BETAB.018RU	2019122012	RU	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21
51.	2017-002-14	BETAB.018SA	519401977	SA	INFUSION SYSTEM AND COMPONENTS THEREOF	BU / Beta	Priority to case in line 21

**Amendment to Device License Agreement
Between
Trustees of Boston University and Beta Bionics, Inc.**

This Amendment (“**Amendment**”) effective as of February 14, 2022 (the “**Effective Date**”) amends that certain Device License Agreement (“**Agreement**”) effective as of December 16, 2015 and last amended as of September 21, 2020 by and between the Trustees of Boston University (the “**University**”) and Beta Bionics, Inc. (“**Licensee**”). University and Licensee may hereafter be referred to as the “**Parties**”.

WHEREAS, the Parties wish to amend certain terms as defined in said Agreement in order to reflect Licensee’s current development plans;

NOW THEREFORE, in accordance with Section 11.02 of the Agreement and for good and valuable consideration, including the mutual obligations undertaken in the Agreement and this Amendment, the receipt and sufficiency of which are hereby acknowledged, the parties agree to amend the Agreement as of the Effective Date as follows:

1. The Commercial Activity Reference Date set forth in the Principal Terms & Milestones List shall be changed from [***], to [***].
2. The list of Milestones set forth in the Principal Terms & Milestones List shall be deleted, and the following list of Milestones shall be inserted in its place:

	Milestone	Due Date
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]
[***]		[***]

This Amendment shall become effective as of the Effective Date upon execution by an authorized officer of each party. Except as expressly amended by this Amendment, capitalized terms used in this Amendment which are defined in the Agreement shall have the meanings set forth in the Agreement.

This Agreement may be executed electronically/digitally in compliance with the Massachusetts Uniform Electronic Transactions Act (MUETA) Mass. Gen. Laws ch. 110G and/or The Electronic Signatures In Global And National Commerce Act (ESIGN) 15 USC ch. 96. Persons signing this document agree that, if used, electronic/digital signatures are intended to authenticate this writing and to have the same force and effect as the use of manual signatures.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective duly authorized officers, and have duly delivered and executed this Amendment under seal as of the date first set forth above.

TRUSTEES OF BOSTON UNIVERSITY

By: /s/ Gary W. Nicksa
Name: Gary W. Nicksa
Title: SVP and Treasurer
Date: Apr-22-2022

BETA BIONICS, INC.

By: /s/ Martha Goldberg Aronson
Name: Martha Goldberg Aronson
Title: Interim Chief Executive Officer
Date: May-11-2022

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [*],
HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED
THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS
AS PRIVATE OR CONFIDENTIAL.**

Boston University

Beta Bionics, Inc.

Control Algorithm License Agreement

Effective as of December 23, 2015

[***]

Principal Terms & Milestones List

University Case Numbers:	See Exhibits A & B
University Case Titles:	See Exhibits A & B
Licensee Name:	Beta Bionics, Inc
Business Organization Type:	Benefit Corporation
Patent Filing Entity Type (Small or Large: see 37 C.F.R. § 1.27) State or Country of Organization:	Small Entity Massachusetts
Licensee Fiscal Year: Licensee Lead Contact:	January 1 - December 31 Edward Damiano
Licensee Notice Address:	[***]
Licensee Notice E-mail:	[***]
Prior Patent Costs incurred as of	[***]
License Issue Fee as equity under the Equity Agreement:	[***]
Threshold (Anti-Dilution Protection)	[***]
Minimum Royalty Amount, from the Effective Date:	
[***]	[***]
[***]	[***]
[***]	[***]
Royalty Percentage	[***]
Software-Based Royalty Percentage	[***]
Sublicensee Running Royalty Percentage	[***]
Sublicense Lump Sum Percentage	[***]
Funding Event Amount	[***]
Commercial Activity Reference Date (§ 3.06(A)):	[***]
Territory:	[***]
Field of Use:	[***]

Milestones

Due Date

General Terms & Conditions

This CONTROL ALGORITHM LICENSE AGREEMENT effective as of December 23, 2015 (the “**Effective Date**”), is by and between TRUSTEES OF BOSTON UNIVERSITY, a Massachusetts non-profit corporation with a principal address at One Silber Way, Boston, MA 02215 (the “**University**”) and BETA BIONICS, INC., a corporation existing under the laws of the Commonwealth of Massachusetts, having a place of business at 22 Putnam Rd., Acton, MA 01720 (as further defined herein, **Licensee**). (University and Licensee may each be referred to individually as a “**Party**” and collectively as the “**Parties**”).

WHEREAS, the University is an owner of certain rights by assignment from Edward R. Damiano and Firas El-Khatib of their individual right, title and interest in the Patent Rights and/or Copyright (as each is defined herein) in the University Case Numbers [***] as further set forth on Exhibits A and B; and

WHEREAS, The General Hospital Corporation, D/B/A Massachusetts General Hospital (“**MGH**”) is an owner of certain rights by assignment from Steven J. Russell of his respective right, title and interest in the Patent Rights in University (MGH) Case Numbers: [***], and has entered into certain MGH JIAAs pursuant to which the University has been granted sole responsibility by MGH to grant options and licenses under MGH’s rights in those jointly owned Patent Rights; and

WHEREAS, The Board Of Trustees Of The University Of Illinois (“**UIUC**”) is an owner of certain rights by assignment from Edward R. Damiano and Firas El-Khatib of their respective right, title and interest in the Patent Rights and/or Copyright in University (UIUC) Case Number: [***], and has entered into a certain UIUC JIAA, as amended, pursuant to which the University has been granted sole responsibility by UIUC to grant options and licenses under UIUC’s rights in those jointly owned Patent Rights and Copyright; and

WHEREAS, Licensee is a Massachusetts Benefit Corporation established under Mass. Gen. L. Ch. 156E and which allows the directors and officers of the corporation to consider and prioritize the social impacts of their corporate decision making in addition to their fiduciary duties to investors; and

WHEREAS, Licensee has conducted its own diligence review of the Patent Rights and/or Copyright, understands and acknowledges that certain of the Patent Rights are subject to the Government Rights (as defined below); and

WHEREAS, Licensee desires to obtain a license to use and practice the Patent Rights and/or Copyright to develop, produce, market and sell products; and

WHEREAS, University and Licensee understand and accept that it may serve the public good for there to be competitive sources of Licensed Products and/or Licensed Processes in certain markets, with appropriate safeguards to Licensee's economic interests in other markets, as more fully specified herein and that the result of this will be the availability of drugs and/or medical devices at affordable prices to poor segments of the world's populations;

NOW, THEREFORE, in consideration of the mutual promises and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the University and Licensee hereby agree as follows:

ARTICLE I DEFINITIONS.

1.01 Capitalized terms used in this Agreement will have the meanings set forth in Schedule 1 annexed hereto.

ARTICLE II LICENSE.

2.01 Grant. Subject to all of the terms, conditions, reservations and exclusions expressly set forth in this Agreement, the University grants to Licensee, and Licensee hereby accepts, a right and license: (a) under the Patent Rights, to make, have made, use, lease, offer to sell, sell and import Licensed Products; and/or to practice Licensed Processes; and/or (b) under the Copyright, to use, reproduce, prepare derivative works, perform, display, and distribute all or any part of the Software, separately or with or as part of any product or service; in each case: (i) directly or by Sublicense (subject to Section 2.03 hereof); and (ii) only in the Field of Use within the Territory during the Term.

2.02 Exclusivity. Subject to the Reserved Rights, Sponsor Rights, Government Rights (if any), and Other Rights, which are expressly reserved in this Agreement, the license granted in Section 2.01 is exclusive during the Exclusive Period, and thereafter is nonexclusive.

2.03 Sublicenses. Subject to Sections 2.03(A)-(K), below, the grant under Section 2.01, above, includes a right for Licensee to enter into Sublicenses provided that Licensee shall not grant any Sublicense (other than a Label License) after the expiration or termination of the Exclusive Period. Licensee shall not grant any exclusive Sublicense (whether for research, development, commercial or other purposes) without prior written consent of the University and JDRF (formerly the Juvenile Diabetes Research Foundation) which consent shall not be unreasonably withheld.

- (A) **Obligations To University.** Any Sublicense other than a Label License will specify that it is subject to this Agreement and that the Sublicensee agrees to be bound directly to the University in respect of all obligations to the University including but not limited to those set forth in ARTICLE II, Sections 2.03, 2.04, 2.05, 2.06, 2.07, 2.08 and 2.09, ARTICLE III, Section 3.02(C) and 3.02(F) ARTICLE IV, Sections 4.01(E) and (F) as applicable, ARTICLE V (all), ARTICLE VI, Sections 6.01, 6.02, 6.03 and 6.04, ARTICLE VII (all), ARTICLE IX (all), ARTICLE X (all) and ARTICLE XI, Section 11.01, 11.06 and 11.07.

- (B) **Copy To University.** A copy of each Sublicense and each amendment thereto or waiver issued in connection therewith will be sent by Licensee to the University within [***] of execution by the parties thereto and Licensee will send a contemporaneous copy to University of any termination notice sent to a Sublicensee.
- (C) **Consideration.** Subject to Section 2.03(K), Licensee is not permitted to grant sublicenses to the Patent Rights and/or Copyright for no consideration without prior written consent of University. Moreover, without the prior written consent of the University, consideration for any Sublicense will not include anything of value in lieu of cash payments. For the avoidance of any doubt, the requirements of this Section 2.03(C) forbid Licensee from sublicensing the Patent Rights and/or Copyright as part of a cross-license agreement or as part of a settlement agreement without the University's prior written consent after full disclosure of the entire transaction contemplated by Licensee that in any way involves the Patent Rights and/or Copyright.
- (D) **No Waivers.** Without the prior written consent of the University, Licensee will not waive any material default or breach under any Sublicense and will not waive any breach or default of any of the requirements of Section 2.03(A).
- (E) **Termination.** Any Sublicense may specify that in the event of termination of this Agreement, so long as the Sublicense complies with this Agreement said Sublicense will continue in full force and effect and all rights and obligations of the Sublicensee, including without limitation the payment of royalties specified in said Sublicense, will inure to the benefit of the University or its designee. Notwithstanding any other provision of this Agreement, the University shall not assume any obligation under any Sublicense without its prior written consent.
- (F) **Further Sublicensing.** Without the prior written consent of University, a Sublicensee shall not grant any sublicense except that a Sublicensee may: 1) grant a Label License so that any product it sells to an End-User may be used for its intended purpose only with respect to amounts of product purchased; and/or 2) grant a royalty-free Sublicense solely to conduct Clinical Trials as specified in Section 2.03(K). Any purported sublicense granted by a Sublicensee (other than as expressly permitted herein) that has not been authorized by written consent of the University will be null and void and a Sublicensee's effort to grant such a sublicense will constitute a material breach of this Agreement.

- (G) **No Enforcement of Patents.** Without prior written consent of University, no Sublicense granted by Licensee may grant any Sublicensee a right to enforce the Patent Rights and/or rights in the Copyright.
- (H) **Compulsory Licensing.** Licensee or its Sublicensee(s) (as applicable) will [***] notify University should a compulsory license be granted, or be the subject of a possible grant, by Licensee or a Sublicensee to a third party under the applicable laws, rules, regulations, guidelines, or other directives of any governmental or supranational agency in the Territory under the Patent Rights and/or Copyright. Said notice will include any material information concerning such compulsory license, and the running royalty rates payable. To the extent that any terms and/or conditions of said compulsory license are: 1) inconsistent with Licensee's obligations under this Agreement; and 2) dictated by said applicable laws, rules, regulations, guidelines, or other directives of any governmental or supranational agency, there is no breach of this Agreement. Notwithstanding the foregoing, to the extent permitted by law Licensee must still pay to University all applicable royalties and fees due under Section 4.01 on amounts actually collected under said compulsory license(s).
- (I) **Sublicensing To A Large Entity.** For so long as Licensee remains a 'small entity', Licensee will notify University within [***] after granting a Sublicense to any entity that is not a 'small entity' within the meaning set forth in 37 C.F.R. § 1.27. For so long as Licensee and its Sublicensees all remain a 'small entity', Licensee will likewise require its Sublicensees to notify University within [***] in the event that any Sublicensee grants a sublicense to any entity that is not a 'small entity' within the meaning set forth in 37 C.F.R. § 1.27. For the avoidance of any doubt, a Label License is not a Sublicense for purposes of this Section 2.03(I).

- (J) **Label Licenses.** Any Label License (or the product associated therewith) is subject to this Agreement and, in particular, must comply, or be consistent, with Sections 2.03(G), 6.01, 6.02, 6.03 and 6.04. All Licensed Product sold under a Label License will be subject to all of ARTICLE VII provided that the Licensee or its Sublicensee, rather than the End User, will be the responsible/liable party. Any right or license under a Label License applies only to the amount of Licensed Product contained in the container or packaging bearing the Label License. Any dispute with University associated with any Label License or product under a Label License will be resolved in accordance with ARTICLE X.
- (K) **Clinical Trials.** Licensee and its Sublicensees may grant to a third party a royalty- free Sublicense solely for the purpose of conducting a clinical trial or other research and/or development activity associated with the use of Licensed Products and/or Licensed Processes as may be required by the Food and Drug Administration (FDA) or other governmental regulatory agency from time to time (collectively “Clinical Trials”). This grant is limited to the duration of and activities directly associated with any Clinical Trials. Licensee agrees to provide written notice to (i) University per the notice provision in Section 11.07 of this Agreement and (ii) University’s Office of Research Compliance: Conflicts of Interest, Boston University, [***], at least [***] prior to commencing any Clinical Trial at Boston Medical Center.

2.04 Reserved Rights. The University reserves the right to University, Boston Medical Center Corporation (“BMCC”), UIUC, MGH, MGH’s affiliates, American Diabetes Association (ADA), JDRF and other non-profit institutions (individually and collectively the “**Institutions**”) to practice and/or use the Patent Rights and/or Copyright for any nonprofit purpose, including sponsored research and/or collaborations (collectively, the “**Reserved Rights**”) and to permit others at academic, government and not-for-profit institutions to make and use the Patent Rights and Copyright for research and educational purposes. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce any of the Patent Rights and/or Copyright against the Institutions when used by them for a non-profit purpose. Licensee also agrees that the Institutions have the right to publish any information included in the Patent Rights and/or Copyright.

2.05 Government Rights. This Agreement is subject to, and University hereby reserves, any applicable Government Rights including, but not limited to the rights, conditions and limitations imposed by U.S. law (see 35 U.S.C. § 202 et seq. and regulations pertaining thereto) including, without limitation, a royalty-free non-exclusive license granted to the U.S. government.

2.06 Sponsor Rights. Licensee acknowledges that it has been informed that certain of the Patent Rights and/or Copyright were developed, at least in part, with funding from JDRF Grants [***] and that University hereby reserves and has granted to JDRF an irrevocable, non-exclusive, worldwide, fully paid-up, royalty-free, perpetual license, with the right to grant sublicenses to others, to use and to practice the JDRF Related Intellectual Property for non-commercial research and development purposes related to the diagnosis, treatment and/or prevention of diabetes and its complications.

2.07 Other Rights. The license granted in this Agreement shall not be construed to confer any rights upon Licensee by implication, estoppel or otherwise: (a) to any technology or other intellectual property right of University or BMCC not specifically set forth in the Patent Rights regardless of whether such technology or patent rights shall be dominate or subordinate to any Patent Rights; or (b) beyond such rights as are expressly set forth herein. Without limitation, the University and BMCC further reserve all right to practice, license or otherwise commercialize or use (A) all intellectual property rights that are not Patent Rights and/or (B) any of the Patent Rights outside the Field of Use and/or outside of the Territory.

2.08 Non-suit. University and Licensee on behalf of themselves and any successors-in- interest to the Licensed Products and Licensed Processes covenant that they will not, before or after the Effective Date, assert any claim of patent infringement (including direct infringement, contributory infringement, and induced infringement) under any of the patents in the Patent List, any Licensed Processes for manufacture, use, sale, offer for sale or importation of Licensed Products against any third party engaged in the manufacture, use, sale offer for sale, or importation of Licensed Products in or for Non-Suit Countries for sale to Public Sector entities. The above notwithstanding, this non-suit provision will only apply to products which when offered for sale to End Users are in a Trade Dress that is different from Licensee's Trade Dress in every respect.

2.09 Licensee Derivative Works.

- (A) Licensee shall be entitled to establish all proprietary rights for itself in the copyright represented by Licensee Derivative Works, provided that all such rights are subject to University's and/or UIUC's Copyright. Any copyright registration by Licensee for Licensee Derivative Works shall give full attribution to University's and/or UIUC's Copyright, as applicable.
- (B) Licensee grants University a perpetual, royalty-free, non-exclusive, worldwide right and license to the copyright in Licensee Derivative Works, to use, reproduce, distribute, publicly display and/or publicly perform, and create derivative works of the Licensee Derivative Works, in print, digital, electronic (including via the internet) or any other medium, whether now known or hereafter existing, for University's educational and academic research purposes and as otherwise necessary or expedient for University to fully practice and comply with the Reserved Rights. In furtherance of the foregoing, Licensee agrees to provide University with copies of object code, executable code, source code, and user and programmer documentation, of each Licensee Derivative Work, and related user and programmer documentation, at the time any of those are made available, directly or indirectly, by Licensee or its Sublicensees.
- (C) In the event Licensee receives a patent on any invention expressed in a Licensee Derivative Work, Licensee hereby grants University a non-exclusive, royalty-free, irrevocable right sufficient for University to fully use and practice the rights granted to University in this Section 2.09, under the Reserved Rights and/or under the Government Right.

2.10 Delivery of Software. Licensee acknowledges that on or before the Effective Date, Licensee has received and accepted from University the Software in its requested format.

ARTICLE III REPRESENTATIONS & DUE DILIGENCE

3.01 Due Diligence. Prior to the Effective Date, Licensee acknowledges that it has conducted a due diligence review to its satisfaction of any records concerning the Patent Rights and Copyright, including but not limited to the MGH JIAAs, UIUC JIAA, as amended, and Government Rights, Reserved Rights, Sponsor Rights as described in the various funding agreements, and Other Rights. Licensee has not relied on any representation, written or oral, formal or informal, by or from the University concerning the Patent Rights and/or the Copyright or any other aspect of this Agreement.

3.02 Licensee Representations. Licensee represents and warrants to University at all times that:

- (A) **Commercialization Plan.** Licensee is a start-up venture having the strategic commitment to commercialize the Licensed Products and/or Licensed Processes in the Field of Use in the Territory, as appropriate, and Licensee has provided to the University a copy of its most recent Commercialization Plan;
- (B) **Organization & Power.** Licensee is a corporation duly organized, validly existing, and in good standing under the laws of its state of incorporation and has all requisite corporate power and authority to enter into this Agreement;
- (C) **Due Care.** Licensee will exercise due care in its manufacturing and other regulated activities pertaining to Licensed Products;
- (D) **Authorization.** The execution, delivery and performance by Licensee of this Agreement and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite action on the part of the Licensee and do not conflict with or cause a default with respect to Licensee's obligations under any other agreement;
- (E) **Execution & Delivery.** This Agreement has been duly executed and delivered by the Licensee;
- (F) **Insurance.** The insurance coverage required pursuant to Section (B) will be obtained, and will be maintained in accordance with Section (B), and Licensee will present proof of coverage in a form satisfactory to the University;

- (G) Progress Reports. Licensee will submit a Progress Report to University on or before each [***] during the Term of this Agreement provided however that if the Effective Date of this Agreement occurs during the period from [***] to [***], inclusive, Licensee's first Progress Report will not be due until the next [***] following said period; and
- (H) Small Entity. Licensee is a 'small entity' within the meaning set forth in 37 C.F.R. § 1.27. Licensee agrees to give University prompt notice if, and when, Licensee no longer qualifies as a 'small entity' within the meaning set forth in 37 C.F.R. § 1.27 or Licensee grants a Sublicense to any entity that is not a 'small entity'.

3.03 Commercially Reasonable Efforts. Licensee will use commercially reasonable efforts to bring the Licensed Products to market in the United States and throughout the remainder of the Territory through a diligent program for exploiting the Patent Rights and/or Copyright in the Field of Use and will, throughout the Term, use commercially reasonable efforts to continue development and marketing efforts with respect to the Licensed Products and/or Licensed Processes, in each case consistent with reasonable business practices and judgments.

3.04 Milestones.

- (A) Licensee will meet or accomplish each of the Milestones by its Milestone Date and will notify the University in writing when each Milestone is met.
- (B) Notwithstanding Section 3.04(A) above, if Licensee learns that it will not meet a Milestone by its Milestone Date because of delay caused by the FDA or another relevant regulatory authority, Licensee shall notify the University and describe the nature of the delay and the expected time to meet the Milestone. If the University takes no action under Sections 3.05 and 9.02(A) before the Milestone that is the subject of Licensee's notice provided in accordance with this Section 3.04(B) is achieved (the "Delayed Milestone"), then the Milestone Date for each subsequent Milestone will be extended by the same amount of time between Delayed Milestone's original Milestone Date and the date the Delayed Milestone was actually achieved.

3.05 Material Breach. Breach of any provision of Sections [***] is a material breach of this Agreement thereby permitting University to terminate the Agreement in whole, or in part, in accordance with Section 9.02(A).

3.06 Continuing Commercial Activity.

- (A) (A) Provided that this Agreement has not previously been terminated for a material breach under Section 3.05, if in any applicable period after the Commercial Activity Reference Date, Licensee fails to achieve Running Royalties during any applicable Calendar Year in an amount that represents at least [***] of the applicable [***], then University may, at its option, [***] terminate the Exclusive Period by written notice delivered to Licensee within [***] after the end of the applicable Calendar Year. If University does not deliver such notice of termination of the Exclusive Period to Licensee within such period, University shall be deemed to have waived its rights under this Section 3.06 with respect to that Calendar Year (but not with respect to any subsequent Calendar Year). University may, at its option, elect not to terminate the Exclusive Period as a result of Licensee's failure to achieve Running Royalties as specified herein for [***] without being deemed to have forgone its right to enforce this Section 3.06 with respect to any subsequent Calendar Year.
- (B) If JDRF determines in good faith that the University, itself or through Licensee, has not diligently pursued commercialization of the JDRF Related Intellectual Property within a commercially reasonable time, then [***] the University shall terminate Licensee's license to the JDRF Related Intellectual Property and assign all rights in such JDRF Related Intellectual Property to JDRF. Notwithstanding the foregoing, in the case of such request from JDRF, University may prevent such termination by providing reasonable cause to JDRF as to why Licensee should retain a license to the JDRF Related Intellectual Property, and University and Licensee agree to cooperate in providing such reasonable cause to JDRF.

3.07 Required Sublicensing. University would like its intellectual property to address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies in the developing world. If Licensee is unable or unwilling to serve or develop a potential market or market territory for which there is a company willing to address therapeutics, diagnostics and/or agricultural technologies in the developing world by utilization of the Patent Rights and/or Copyright, Licensee will, at University's request, negotiate in good faith a Sublicense with any such company to enable such company to address said neglected patient populations or geographic areas.

ARTICLE IV ROYALTIES & PAYMENTS

4.01 Royalties. In consideration for the license and rights granted under this Agreement, Licensee will: 1) execute and deliver to University all documents (as appropriate); and 2) promptly pay all of the following royalties (collectively, the "***Royalties***") and/or fees to the University:

- (A) **Equity as an Issue Fee.** In consideration of the license granted to Licensee, Licensee will: (i) grant shares of common stock of Licensee to the University in the amount and upon the terms set forth in the Equity Agreement; provided that Licensee shall issue UIUC's shares of common stock to and in the name of the University, which shall hold such shares for UIUC's account and as the beneficial owner thereof as agreed by and between University and UIUC. Additionally, Licensee will, [***] its execution and delivery of this Agreement to University, deliver to University a complete and accurate copy of Licensee's capitalization table, reflecting the above referenced issuance of shares to University. Execution of the Equity Agreement and delivery of the shares in accordance therewith is a condition precedent to the validity and enforceability of the license granted pursuant to ARTICLE II of this Agreement and Licensee's failure to both issue the equity shares and to execute and deliver to University the Equity Agreement will render this Agreement null and void *ab initio*.

- (B) **Milestone Payments.** Within [***] after the occurrence of each Milestone, Licensee will pay to the University an amount equal to the Milestone Payment for each respective Milestone event.
- (C) **Change of Control Payment.** Within thirty (30) days of a Change of Control, as defined herein, Licensee shall pay to the University a Change of Control Payment in the amount of sixty-five thousand dollars (\$65,000.00).
- (D) **Minimum Royalty Amounts.** During the Exclusive Period, on or before each [***] following the Effective Date, Licensee will pay to the University the Minimum Royalty Amount (“MRA”) as specified in the Principal Terms & Milestones List for the indicated MRA Year, wherein MRA Year 0 begins on the [***] following the Effective Date, MRA Year 1 begins on the second [***] following the Effective Date, etc.
- (E) **Running Royalties.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to:
- i. **Net Sales by Licensee.** The Running Royalty Amount for such Calendar Quarter (if any); plus
 - ii. **Net Sales by Sublicensee.** The Sublicensee Running Royalty Amount for such Calendar Quarter (if any) (collectively, 4.01(E)(i) and (ii) refer to the “*Running Royalties*”);

provided that amounts payable under 4.01(E)(i-ii) with respect to any Calendar Year are fully creditable against the Minimum Royalty Amount paid by Licensee to University in said Calendar Year such that Licensee need only make payments to University when the cumulative amount payable under this Section 4.01(E)(i-ii) exceeds the Minimum Royalty Amount and further provided that any available credit not taken against the Minimum Royalty Amount in any Calendar Year will be forfeited and thus not available as an offset in any subsequent Calendar Year.

- (F) **Sublicense Lump Sum.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to the Sublicense Lump Sum for such Calendar Quarter.
- (G) **Combination Product.** If a Licensed Product is sold as part of a Combination Product, Net Sales will be calculated by multiplying Net Sales for such Combination Product [***].
- (H) **Third-Party Royalty Deduction.** Except as set forth in Schedule 2, Licensee knows of no third party intellectual property rights for which license fees must be paid to produce any Licensed Product or to practice any Licensed Process. In the event that Licensee is required to pay Third Party Royalties, then Licensee may deduct an amount equal to [***] of any Third Party Royalties actually paid by Licensee from any Running Royalty Amount due University hereunder, [***] of the Running Royalty Amount otherwise owing under Section 4.01(E)(i) if and only if: [***]. Notwithstanding the foregoing, the Running Royalty Amount otherwise due University may never be less than [***]. In the event that it is determined after the Effective Date that University does not own all right, title, and interest in the Patent Rights and/or Copyright, and Licensee obtains, by license(s), assignment(s), or otherwise, rights to any third party(ies') interest(s) in the Patent Rights and/or Copyright, any amounts paid by Licensee to such third party(ies) to obtain any rights in any third party interest(s) in such Patent Rights and/or Copyright will be treated as Third Party Royalties.

(I) **Board Observer Rights.** Licensee will, concurrent with its execution and delivery of this Agreement to University, execute and deliver to University a Board Observer Rights Letter Agreement pertaining to board observer rights for the University.

4.02 Payments. All payments due under this Agreement will be paid: (a) in full without deduction of exchange, collection, taxes or other fees that may be imposed by any government; and (b) in United States dollars in Boston, Massachusetts or at such other place as the University may designate consistent with applicable law. All amounts paid to University shall be non-refundable. Currency conversions will be made by reference to the prevailing exchange rate for bank transfers from the foreign currency to U.S. Dollars, as quoted at the Bank of America or its successor on the last business day of the Calendar Quarter immediately preceding the payment due date. In the event that the Bank of America (or its successor) ceases to publish currency quotes, Licensee will use currency quotes from another US headquartered multinational bank. Specifically, Licensee will use J.P. Morgan Chase, Citicorp, Wells Fargo or US Bank (using this order to determine which bank's currency conversion to use taking into account any mergers, acquisitions or renaming that may occur from time to time and using the first in this list until it ceases to exist then moving to the next and so on) to calculate royalty payments due. If by law, regulation or fiscal policy of any country, conversion from that country's currency into U.S. dollars is restricted or forbidden, written notice thereof will be given to the University and payment of amounts from that country shall be made through such lawful means as the University will designate, including, without limitation, deposit of local currency in such recognized banking institution and/or accounts as the University will designate. When in any country the law or regulation prohibits both the transmittal and the deposit of royalties on sales in that country, royalty payments from that country will be suspended for as long as the prohibition is in effect and, as soon as the prohibition ceases, all Royalties that Licensee or its Sublicensees would have been obligated to pay,

but for the prohibition, will promptly be deposited or transmitted, as the case may be, to the extent then allowed. If payments are made by check, said check will be made payable to “Trustees of Boston University” and will be sent to University mailing address pursuant to Section 11.07. If Licensee elects to make payments by wire, Licensee will pay all fees associated with processing the wired payment and will follow the wire instructions below:

[***]

[***]

Licensee agrees that University may provide alternative wire instructions to Licensee at any time, which instructions will supersede and replace the wire instructions provided in this Section 4.02 for all further wire transfers. Said new wire instructions may be sent to the Licensee pursuant to the notice provisions of Section 11.07 (below), in which case they will be deemed received in accordance with Section 11.07.

4.03 Interest. Any payments due to University by Licensee that are not paid on or before the date such payments are due under this Agreement will bear interest at [***]. Interest will accrue beginning on the first date following the due date for payment and will be compounded quarterly. Payment of interest will not foreclose any other right that the University may have as a consequence of late payment. In the event of default in payment of any payment owing to University under the terms of this Agreement, and if it becomes necessary for University to undertake legal action to collect said payment, Licensee agrees to, and will, pay reasonable, documented legal fees and costs incurred by University in connection therewith.

5.01 Books & Records. Licensee will keep, in accordance with generally accepted accounting principles, up-to-date, complete, true and accurate books of account in sufficient detail to permit calculation of all amounts due hereunder, including without limitation, copies of all invoices, which will be properly itemized. Such books of account will be maintained at Licensee's principal place of business (or at its election, the principal place of business of the division of Licensee to which this Agreement relates). The books of account and supporting records shall be retained by Licensee and, as applicable, each Sublicensee, for at least as long as required to comply with the audit requirements in Section 5.05. Licensee will inform the University in writing of the location of such books and records within [***] of a request for such location.

5.02 Quarterly Reports.

- (A) Within [***] after the end of each Calendar Quarter during the Term (without regard to whether any payments are due to the University in respect of such quarter), Licensee will deliver to the University, a complete and accurate report which will contain the following:
- (i) identification of all Sublicenses related to the Patent Rights and/or Copyright entered into during such quarter, together with a summary of the principal economic terms of each;
 - (ii) a summary of those activities of Licensee and its Sublicensees directed toward promoting the sale and use of the Licensed Products and/or Licensed Processes; and
 - (iii) identification of all Milestone Dates occurring during such quarter and an indication of whether the corresponding Milestone was met (and if not, a summary of the progress as of the end of such quarter and projected completion dates).

(B) After the First Commercial Sale by Licensee and/or its Sublicensee(s) that gives rise to Running Royalties or fees under Section 4.01(E) or Section 4.01(F), within [***] after the end of each Calendar Quarter during the Term, Licensee will deliver to the University, a complete and accurate report which will contain the following:

- (i) the number of each type of: 1) Licensed Product and/or Software-Based Product made, used, leased, sold, offered for sale or imported; and/or 2) Licensed Process and/or Software-Based Process (as appropriate) practiced by Licensee and/or a Sublicensee during such quarter;
- (ii) the total amount of Net Sales (with itemized total by Licensee and each Sublicensee, if applicable) during such quarter;
- (iii) the Running Royalty Amount for such quarter;
- (iv) the total Sublicensee Running Royalty Amount for such quarter;
- (v) the Sublicense Lump Sum for such quarter (with itemized total for each Sublicensee);
- (vi) calculations of exchange rates, when applicable; and
- (vii) calculations of each amount due under this Agreement in respect of such quarter, including without limitation, deductions applicable to Net Sales.

All Quarterly Reports shall provide a breakdown of the data specified in 5.02(B)(ii - iv) above identifying the portion of Net Sales or Running Royalty Amount reported that is due to sales to MGH and/or their Affiliates. The reports described in this Section 5.02 are each referred to herein as a “**Quarterly Report**.” Each Quarterly Report will [***] or be sent to University [***], the payment under Sections 4.01(E) and 4.01(F). If Licensee elects to wire transfer payments to University, the Quarterly Report will be transmitted to University in accordance with Section 11.07 [***] that the wire transfer is made.

5.03 Annual Reports. Within [***] after the end of Licensee's Fiscal Year during which Licensee is not listed on a public exchange that requires filing of publicly available financial statements, Licensee will provide to the University a copy of its financial statements for such year, certified as to their completeness and accuracy by Licensee's chief financial officer. Licensee will also provide to the University written evidence of the annual renewal of insurance within [***] of such renewal. Notwithstanding the foregoing, the obligations contained in this Section 5.03 which pertain to financial statements will terminate upon the consummation of the Licensee's Initial Public Offering.

5.04 Other Reports. Promptly upon written request of the University or as otherwise required by the terms of this Agreement, Licensee will provide to the University any annual report to stockholders of Licensee or, if there is no annual report to stockholders, annual updates to the Business Plan and Commercialization Plan, including any changes to the management team. Licensee will also promptly provide to University all relevant notices consistent with the Board Observer Rights Letter Agreement.

5.05 Audit. The University may, itself or using a third party agent, audit the books and records of Licensee upon [***] advance written notice specifying any time of day during Licensee's business hours (or if Licensee has no set business hours then during the hours of 8AM to 4PM) at Licensee's place of business for the purpose of verifying Licensee's reports and compliance by Licensee in all other respects with this Agreement. No such audits shall be conducted hereunder more frequently than once every [***] nor shall University be permitted to repeat an audit of books for a period previously audited unless: (i) there is reason to believe that any of the circumstances described in Section 9.02 has occurred; or (ii) with respect to a repeat audit, Licensee has undergone a restatement of its records for that period. Notwithstanding the foregoing, Licensee will grant University, or its auditor, access to all of Licensee's records for all prior periods to the extent necessary to perform a proper audit. If any audit identifies an underpayment by Licensee, Licensee will promptly pay the underpayment to University including interest as provided for in Section 4.03. If any

audit identifies an overpayment by Licensee, Licensee may deduct such overpayment from the next scheduled payments due University until such overpayment has been recovered by Licensee. If any audit leads to the discovery of an underpayment by Licensee in respect of any Calendar Quarter of [***] between amounts due in respect of such quarter and amounts reported to be due by Licensee in its quarterly report for such quarter or otherwise reveals a previously undisclosed material breach of this Agreement, Licensee will, within [***] after written notice from the University, reimburse the University for all of its costs related to the audit. Otherwise, any audit will be at the University's expense. Licensee will, in any event and without regard to the size of the discrepancy, [***] pay to the University the amount of any previous underpayment, including interest from the time such amount was due until paid in full in accordance with Section 4.03. Any audit conducted pursuant to this Section 5.05 will be conducted, at University's option, by the University itself or by an auditor selected by University and reasonably acceptable to the Licensee. For the avoidance of any doubt, University's right to audit books under this Section 5.05 applies to all Affiliates that sell Licensed Products or practice Licensed Processes and to all Sublicensees to the same extent that it applies to Licensee. Failure by Licensee, an Affiliate or a Sublicensee to permit University to conduct an audit as set forth in this Section 5.05 will [***] give University the right to suspend the non-compliant party's rights under the Patent Rights and/or Copyright until such time as said party becomes compliant with this Section 5.05. University's right to audit Licensee's books in accordance with this Section 5.05 will extend for [***] after the expiration or termination of this Agreement for any reason. With respect to any University's rights under a continuing Sublicense under Sections 2.03(A) and 2.03(E), University's right to audit the Sublicensee's books will extend for [***] after the expiration or termination of said Sublicense for any reason.

ARTICLE VI REGULATORY MATTERS & PATENT COSTS

6.01 United States Manufacture. Licensee agrees to comply with any obligations imposed on University and/or Licensee by 35 U.S.C. § 204 and/or other provisions of the Bayh-Dole Act as codified in 35 U.S.C. § 200-212, and implemented by 37 C.F.R. 401 in connection with any Licensed Products used or sold in the United States. In the event that the Licensee or Sublicensee seeks a waiver of such requirement, the University agrees, if requested by Licensee, to take reasonable steps to assist the Licensee or Sublicensee to obtain such waiver to the extent permissible under current law.

6.02 Compliance with Laws. Licensee and its Sublicensee(s) shall comply with all applicable local, state, federal and foreign laws and regulations.

6.03 Export Control. It is understood that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling both actual and deemed exports, including the Export Administration Regulations of the United States Department of Commerce, the International Traffic in Arms Regulations of the Department of State, and the Office of Foreign Assets Control of the Department of Treasury. Licensee hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and/or technical data, that it will be solely responsible for any violation of such by Licensee, its Affiliate(s) and/or its Sublicensee(s), and that it will defend, indemnify and hold University harmless in the event of any legal action of any nature occasioned by such violation.

6.04 Compliance & Marking. Licensee will comply with, and will require its Affiliates and Sublicensees to comply with, all applicable laws and regulations concerning the manufacture (including without limitation, if applicable, Good Manufacturing Practices set forth by the United States Food and Drug Administration), marking, marketing and safety of all Licensed Products. Without limiting the foregoing, all Licensed Products sold, leased or shipped in, through or to: (a) the United States will be marked with all

applicable U.S. patent numbers; and (b) any other country will be marked in conformity with all of the laws and regulations of such country. Licensee further agrees to promptly remove the relevant patent markings from Licensed Products upon expiration or invalidation of a Licensed Patent. Licensee still further agrees to remove patent markings from Licensed Products as may be reasonably requested by University from time to time.

6.05 Patent Filings. University will, using patent attorneys selected by it, use commercially reasonable efforts to apply for, seek issuance of and maintain the Patent Rights during the Term in the United States and such other countries as are agreed to by the Parties in writing or as Licensee may request in writing; provided that: (a) Licensee will cooperate with the University in such filing, prosecution and maintenance; and (b) Licensee will be given at least [***] to advise and comment upon such filings and actions as are undertaken by the University and further provided that in all cases University retains the absolute right to make all decisions with respect to preparation, filing, prosecution and maintenance. The University shall direct its patent counsel to: a) provide Licensee with a copy of the application or other filing as filed, together with notice of its filing date and serial number when available; and b) provide to Licensee copies of all communications between patent counsel and any foreign associates responsible for the filing, prosecution and/or maintenance of any foreign Patent Rights. The University may, in its discretion, decline to apply for, prosecute or maintain any Patent Rights in any country, but will give timely notice to Licensee of any such determination, whereupon Licensee may undertake such action, in the name and on behalf of the University, at Licensee's own expense. The University agrees to cooperate with Licensee as reasonably necessary to permit Licensee to be able to file, prosecute or maintain any Patent Rights in those countries that the University declines to undertake action ("**Declined Patent Rights**"). Should Licensee proceed to maintain Declined Patent Rights, Licensee agrees to provide notice to University at least [***] in advance of any subsequent decision to abandon said Declined Patent Rights. Licensee further acknowledges and agrees that University may file for and obtain patent protection in countries that are not of interest to Licensee (the "**Unfunded Countries**") but which are of interest to either the University or other licensee(s) of University whose license(s) is/are in a field of use that differs from the Field of Use. In such case, if Licensee has elected to not reimburse University for Patent Costs associated with the Unfunded Countries as set forth in Section 6.06, below, said Unfunded Countries are [***] removed from the Territory under this Agreement for the remainder of the Term.

6.06 Patent Costs.

- (A) Licensee will bear the cost of all reasonable, documented Patent Costs incurred by University in connection with the Patent Rights accrued prior to the Effective Date and continuing for the Term of this Agreement. For Patent Costs accrued by University for the period [***] (the “**Deferred Patent Costs**”) (the period of time referred to as “**Deferred Patent Costs Period**”), University will send Licensee a single invoice (the “**Deferred Patent Costs Invoice**”) for all such Deferred Patent Costs [***] (as appropriate) and Licensee will pay said Deferred Patent Costs Invoice within [***] of University’s transmittal of such invoice to Licensee in accordance with Section 11.07. For on-going Patent Costs accrued on or after the Deferred Patent Costs Period, Licensee will pay to University within [***] of the University’s transmittal to Licensee of an invoice of all Patent Costs (a “**Patent Cost Invoice**”) so transmitted. Notwithstanding the foregoing, if University grants any third party (other than Government Rights or Reserved Rights) a license to commercially exploit any patent or patent application included within the Patent Rights and said license includes an obligation on said third party to pay patent costs, Licensee’s obligation to bear ongoing patent costs (i.e. Patent Costs accrued by University after the effective date of said third party license) with respect to any said patent or patent application will be reduced by a pro rata amount, based on the number of University licensees having rights with respect to such patent or patent application (e.g. if University has granted rights to two parties (one of which is Licensee) with respect to a particular patent or patent application, then Licensee will thereafter only be obligated to reimburse University with respect to [***] of the relevant patent costs associated with said patent or application) for so long as that/those license(s) to the specific patents and/or patent applications remain in effect.

- (B) Overdue amounts will accrue interest pursuant to Section 4.03. Except in the case of Deferred Patent Costs, Licensee may decline payment of ongoing Patent Costs by giving [***] written notice in advance of the University incurring such costs, whereupon Licensee's license to the Patent Rights affected by such Patent Costs will terminate, including but not limited to, the deletion of such patent from the Patent List and the termination of the license granted with respect to such patent or patent application. If Licensee's decision to decline payment of Patent Costs would result in the abandonment of all of patent(s) and/or patent application(s) (of the Patent Rights) in any one or more country(ies) and/or region(s) (regardless of whether or not University actually abandons said patent(s) and/or patent application(s)), then the grant under Section 2.01 with respect to said country(ies) and/or region(s) of the Territory will also terminate.
- (C) Notwithstanding the foregoing, if during the Deferred Patent Costs Period, the due date for National Phase Entry of one or more of the patent applications of the Patent Rights is scheduled to occur or if any other Substantial Patent Prosecution Event occurs, University will take the following actions:
- (i) With Respect to a National Phase Entry, University will ask Licensee into which countries Licensee wishes the patent application to be nationalized and obtain estimates for entry into the national phase in those countries. Upon receipt of instructions from Licensee, University will (to the extent there is, in University's opinion or in University counsel's opinion, sufficient time to take such action and further provided that University is in receipt of the *Estimated National Phase Entry Payment* (as defined below)), with respect to said patent application, instruct its counsel to enter the national phase in those countries (other than the United States) so designated by Licensee provided that Licensee pays to University [***] of the estimated costs of said national phase filings (the "***Estimated National Phase Entry Payment***") at the time of such instructions from the Licensee.

- (ii) With respect to a Substantial Patent Prosecution Event, University will obtain an estimate from counsel for services associated with said Substantial Patent Prosecution Event and then confer with Licensee to determine whether or not Licensee will support the action by paying [***] of the estimated costs to University. If Licensee pays University said [***] of the estimated costs, University will proceed to address the Substantial Patent Prosecution Event. If Licensee elects to not pay University said [***] of the estimated costs when due, University may, at its option, elect to proceed to address the Substantial Patent Prosecution Event or may decline to take any other action it deems proper.

For the avoidance of doubt, any payments made under this Section 6.05(C) are fully creditable against the fulfillment of Licensee's obligations under 6.05(A) as they come due but are not intended to release Licensee of any of its payment obligations under 6.05(A).

- (D) **Funding Event.** Licensee will provide University with written notice of any Funding Event within [***] of said Funding Event.

6.07 Copyright Notices. All copies of the Software distributed by Licensee as part of Licensed Product shall contain Copyright notices, as applicable, in appropriate locations and forms. Such notices shall be consistent with any instructions which might be provided by University; and shall include all Copyright and other notices in the form supplied by University.

ARTICLE VII WARRANTIES, LIMITATIONS & INDEMNIFICATION

7.01 University Limitation. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE UNIVERSITY MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE, OR WITH RESPECT TO: (1) THE SCOPE OR VALIDITY OF ANY OF THE PATENT RIGHTS, WHETHER ISSUED OR PENDING, AND/OR COPYRIGHT; (2) WHETHER THE PATENT RIGHTS AND/OR COPYRIGHT MAY BE EXPLOITED BY LICENSEE OR ANY SUBLICENSEE WITHOUT INFRINGING THE RIGHTS (INCLUDING PATENT RIGHTS AND/OR COPYRIGHT) OF OTHERS; OR (3) THE RESULTS TO BE OBTAINED BY USE OF THE PATENT RIGHTS, THE SOFTWARE, THE LICENSED PRODUCTS AND/OR THE LICENSED PROCESSES. THE PATENT RIGHTS AND THE SOFTWARE ARE DELIVERED “AS IS” IN EVERY RESPECT. IF BIOLOGICAL MATERIALS ARE TRANSFERRED (BY WAY OF LICENSE, BAILMENT OR OTHERWISE) HEREUNDER, UNIVERSITY MAKES NO REPRESENTATIONS OR WARRANTIES THAT SUCH BIOLOGICAL MATERIALS AND/OR THE METHODS USED TO MAKE OR USE SUCH BIOLOGICAL MATERIALS ARE FREE FROM LIABILITY FOR PATENT INFRINGEMENT.

7.02 Indemnification.

- (A) Licensee will at all times during the Term and thereafter, defend, indemnify and hold UIUC, the University and its affiliated hospital, BMCC, their current and former trustees, officers, employees, students, agents and affiliates (together, “**Indemnitees**”) harmless from and against all claims, suits, demands, liability and expenses, including legal expenses and reasonable attorneys’ fees, arising out of: [***].

(B) MGH.

- (i) Licensee shall indemnify, defend and hold harmless MGH and its affiliates and their respective trustees, directors, officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns (the “MGH Indemnitees”), against any liability, damage, loss or expense (including reasonable attorney’s fees and expenses of litigation) incurred by or imposed upon the MGH Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments arising out of [***].
- (ii) Licensee agrees, at its own expense, to provide attorneys [***] to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought; provided, however, that any MGH Indemnitees shall have the right to retain its own counsel, at the expense of Licensee, if representation of such MGH Indemnitees by counsel retained by Licensee would be inappropriate [***]. Licensee agrees to keep MGH informed of the progress in the defense and disposition of such claim and to consult with MGH prior to any proposed settlement.

7.03 Insurance.

- (A) **Scope & Expense.** (a) Licensee shall procure and maintain in full force and effect commercial general liability insurance policies that protect and name the Indemnitees, including Trustees of Boston University, as additional insureds as their interests appear as provided for in ISO form CG 20 26 04 13 with coverage amounts of [***]. Licensee shall procure and provide to University proof of such coverage on or before January 16, 2016, in a form satisfactory to University. Delivery of proof of coverage to University within such time is a condition precedent to the validity and enforceability of the grant in Section 2.01 of this Agreement. University may in its reasonable discretion, by [***] written notice to Licensee, require greater liability coverage. (b) Notwithstanding section 7.03(A)(a) above, prior to the earlier of: (i) the first use of a Licensed Process or Licensed Product by or on humans (including human testing) or (ii) the First Commercial Sale of any Licensed Process or Licensed Product, Licensee will, at its own expense, procure and maintain in full force and effect commercial general liability insurance policies that protect and name the Indemnitees as additional insureds with coverage amounts of [***], but the University may in its reasonable discretion, by [***] written notice to Licensee, require greater liability coverage. Coverage under the commercial general liability insurance will include product liability and coverage for Licensee's indemnification obligations under Section 7.02. If the product liability insurance is not for occurrence liability coverage, Licensee will maintain commercial general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any such product, process or service is being commercially distributed, sold, leased or otherwise transferred, or performed or used (other than for the purpose of obtaining regulatory approvals) by Licensee, Sublicensee, affiliate or agent of Licensee and a reasonable period after the period referred to in (i) which shall in no event be less than [***] after it has ceased commercial distribution or use of any Licensed Product or Licensed Processes, or in the alternative, procure an extended tail reporting period for not less than [***]. University may in its reasonable discretion, by [***]

written notice to Licensee, require greater liability coverage. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of [***] such self-insurance program must be acceptable to the University, MGH and MGH's Risk Management Foundation. The minimum amounts of insurance coverage required under this Section 7.04(A) shall not be construed to create a limit on Licensee's liability with respect to its indemnification under Section 7.03 of this Agreement.

- (B) **Notice, Renewal & Cancellation.** Licensee will provide the University with written evidence of such insurance upon issuance and within [***] of each renewal. Licensee will give the University at least [***] written notice prior to any cancellation, non-renewal or material change in such insurance. Notwithstanding anything to the contrary in Section 9.02(A), failure to maintain insurance as required by this Section 7.04 shall constitute a material breach of the Agreement and, in the event of such breach, the University may terminate this Agreement [***]. This Section 7.04 shall survive expiration or termination of this Agreement.

7.04 University Liability.

- (A) THE TOTAL LIABILITY OF THE UNIVERSITY, MGH AND UIUC OR ANY OF THEIR AFFILIATES, TRUSTEES, DIRECTORS, OFFICERS, MEDICAL AND PROFESSIONAL STAFF, EMPLOYEES AND AGENTS (JOINTLY AND SEVERALLY) FOR ANY AND ALL CAUSES OF ACTION ARISING IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, IN AGGREGATE, AND REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT OR IN TORT, INCLUDING NEGLIGENCE, OR OTHERWISE WILL BE LIMITED TO DIRECT DAMAGES NOT EXCEEDING IN THE AGGREGATE [***]. LICENSEE WAIVES AND DISCLAIMS (AND WILL CAUSE ALL ITS SUBLICENSEES TO WAIVE AND DISCLAIM) ANY RIGHT TO RECOVER ANY DAMAGES IN THE AGGREGATE IN EXCESS OF SUCH AMOUNT FROM THE UNIVERSITY.

- (B) UNIVERSITY, MGH AND UIUC AND ITS AND/OR THEIR, AFFILIATES, TRUSTEES, DIRECTORS, OFFICERS, MEDICAL AND PROFESSIONAL STAFF, EMPLOYEES AND AGENTS SHALL NOT BE LIABLE TO LICENSEE AND/OR SUBLICENSEES FOR, INCLUDING BUT NOT LIMITED TO, ANY LOST OR ANTICIPATED REVENUES, PROFITS OR SAVINGS, OR ANY INCIDENTAL, INTANGIBLE, EXEMPLARY, PUNITIVE, SPECIAL INDIRECT OR CONSEQUENTIAL DAMAGES, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT OR IN TORT, INCLUDING NEGLIGENCE, OR OTHERWISE AND WHETHER OR NOT THE UNIVERSITY, MGH AND/OR UIUC WERE ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES.

ARTICLE VIII INFRINGEMENT

8.01 Notice. Each party will notify the other party promptly in writing of any alleged infringement of the Patent Rights and/or Copyright in the Software by a third party of which it becomes aware and will provide any available evidence thereof.

8.02 Prosecution by Licensee.

- (A) **Procedure.** For so long as the grant in ARTICLE II of this Agreement remains exclusive to Licensee and Licensee is not in breach of this Agreement, Licensee will have the first right, at its sole discretion, to prosecute, at its own expense, any alleged infringement of the Patent Rights and/or Copyright within the Territory and Field of Use. The University agrees to allow the Licensee to include the University, at the Licensee's expense, as a party plaintiff in any suit brought with respect to any such infringement. Licensee shall not include UIUC as a party plaintiff in any suit brought with respect to any such infringement without prior express written consent of UIUC. The University will have the right to participate

in any action, at Licensee's expense. Prior to commencing any such action, Licensee shall consult with University and shall consider the views of University regarding the advisability of the proposed action. In addition, Licensee agrees to consult with counsel for the University on any significant matters related to the litigation. Notwithstanding anything in the foregoing to the contrary, no settlement, consent judgment or other voluntarily final disposition of any such suit may be entered into without the prior written consent of the University, which consent will not be unreasonably withheld. Licensee will indemnify, defend and hold harmless the University against any order for any costs that may be made against the University in such proceedings brought by Licensee in accordance with this Section 8.02(A). For the avoidance of any doubt, if the grant under ARTICLE II of this Agreement becomes non-exclusive for any reason, Licensee will not have any right to prosecute infringers under this Section 8.02(A).

- (B) **Damages.** In the event that Licensee undertakes litigation pursuant to Section 8.02(A) for the enforcement of Patent Rights and/or Copyright, any recovery of monetary damages by Licensee for each suit will be applied as follows: [***].

8.03 Prosecution By University.

- (A) **Procedure.** If the Licensee; (i) within [***] after having been notified of any alleged infringement, has been unsuccessful in negotiating with the alleged infringer to cease and desist such infringement and has not brought an infringement action (or has not defended against any material counterclaim), and/or Licensee continues to be unsuccessful in persuading the alleged infringer to desist and continues not to initiate an infringement action within [***] after written notice from University that University intends to exercise its rights under this paragraph, or (ii) if the Licensee notifies the University at any time

prior to the end of such [***] period of its intention not to bring suit against any alleged infringer in the Territory for the Field of Use, then, and in those events only, the University will have the right, but not be obligated, to prosecute at its own expense any such infringement of the Patent Rights and/or Copyright in the Territory for the Field of Use. In such circumstances, and provided that the license granted pursuant to ARTICLE II remains in force, the University will have the right to name the Licensee as a party plaintiff if necessary for the prosecution of the infringement suit. Notwithstanding anything in the foregoing to the contrary and further provided that the Exclusive Period of the license granted pursuant to ARTICLE II remains in force, no settlement, consent judgment or other voluntarily final disposition of any such suit may be entered into without the consent of the Licensee, which consent will not be unreasonably withheld.

- (B) **Damages.** In the event that University undertakes litigation pursuant to Section 8.03(A) for the enforcement of Patent Rights and/or Copyright, any recovery of monetary damages by University for each suit will be applied as follows: [***].

8.04 Actions Against Licensee or University. In the event that an action alleging invalidity or noninfringement of any of the Patent Rights and/or Copyright is brought against the University or against Licensee (whether as an independent action or as a counterclaim of a suit filed by Licensee), relating to the Field of Use, the University, at its sole option, will have the right, within [***] after the commencement of such action, to take or regain control of the action at its own expense. If the University determines not to exercise this right and the grant under ARTICLE II remains exclusive to Licensee, Licensee may take over or remain as lead counsel for the action at Licensee's sole expense, with any settlement or recovery subject to the approval provisions of Section 8.02(A) and allocation provisions of Section 8.02(B); *provided* that the University will have the right to refuse, in its sole discretion, to accept any settlement offer that would, in its sole judgment, result in the lessening or weakening of any Patent Rights and/or Copyright.

8.05 Cooperation. In any infringement suit, either party shall provide cooperation and assistance to the other party, at the requesting party's expense, as may be reasonably necessary for the suit. Each party agrees to make available relevant records, papers, information, samples and specimens, as well as to have its employees testify upon request, except as restricted by law.

8.06 Sublicense Settlements. In the event that Licensee elects to grant a Sublicense to any alleged infringer in the Territory for the Field of Use for future use of the Patent Rights and/or Copyright (e.g., as permitted by Section 2.03(C)), any amounts paid by the alleged infringer as a part of the Sublicense or settlement of allegations regarding infringement of the Patent Rights and/or Copyright will be shared by Licensee and the University in the same ratio as amounts received as Sublicense Lump Sum payments under Section 4.01(F). Sublicensing Revenues and/or Net Sales received from any such Sublicensee will otherwise be shared by Licensee and University in accordance with Section 4.01(E) or 4.01(F), as applicable.

ARTICLE IX TERMINATION

9.01 License. Unless earlier terminated as provided for in this Agreement, the license granted pursuant to: i) Section 2.01(a) for Licensed Products and Licensed Processes will continue in each country (on a country by country basis) until the occurrence in the applicable country of the following: the expiration, invalidation (where invalidation requires the final decision rendered by a court of competent jurisdiction from which no further appeal has or may be taken) or termination of the last to expire, invalidate or terminate of the Patent Rights upon which the Licensed Products and/or Licensed Processes are based (if any); and ii) Section 2.01(b) for Software-Based Products and Software-Based Processes will continue for a [***] period from the Effective

Date, or if earlier, in each country (on a country by country basis) until the occurrence in the applicable country of the following: the expiration, invalidation (where invalidation requires the final decision rendered by a court of competent jurisdiction from which no further appeal has or may be taken) or termination of the copyright or other intellectual property based right upon which the Software-Based Products and/or Software-Based Processes (if any) is/are based. Nothing herein shall limit Licensee's obligation to pay the Minimum Royalty Amounts set forth in Section 4.01(C).

9.02 Early Termination. Notwithstanding the foregoing, all licenses granted pursuant to ARTICLE II and this Agreement will terminate as follows:

- (A) **Material Breach.** If Licensee materially breaches this Agreement, fails to account for or make any payment to University that is required by this Agreement, fails to make any payment referred to in the Principal Terms & Milestones List, fails to meet any Milestone as set forth in the Principal Terms & Milestones List, fails to maintain insurance as required in Section 7.04 or if a Sublicensee materially breaches any of the provisions to which it is required to be bound directly to the University as set forth in Section 2.03 (a "***Breaching Sublicensee***"), the University will have the right, at its election, to terminate: (i) the Exclusive Period; (ii) any or all licenses granted by the University under this Agreement (including the right to sublicense); (iii) a Breaching Sublicensee's sublicense; or (iv) this Agreement in its entirety upon [***] prior written notice, subject to the survival of the obligations set forth in Section 9.05. Termination will take effect [***] after written notice unless Licensee cures the breach within said [***] period. For the avoidance of doubt, if the Exclusive Period terminates but this Agreement does not terminate, University may (subject to the continuation of Licensee's and/or any valid Sublicensee's rights, as expressly provided for in this Agreement) [***] engage in marketing and/or licensing of any of the Patent Rights. University's right to terminate in accordance with this Section 9.02(A) is in addition to, and not in lieu of, the exercise of any other right University may have for breach of this Agreement by Licensee.

- (B) **Insolvency, Etc.** If Licensee files a petition in bankruptcy or if an involuntary petition is filed against Licensee and such petition is not dismissed within [***], or if the Licensee will cease or suspend the conduct of its usual business or if the Licensee will become, or in light of its usual business is likely to become, insolvent and is unable to pay its debts when due, this Agreement will terminate [***].
- (C) **Challenge to Validity of Patent Rights or Copyright.** To the maximum extent permitted by law, if Licensee, or any of its Affiliates, files a lawsuit or otherwise challenges the validity, scope or enforceability of any of the Patent Rights and/or Copyright, University shall have the right, at its election, [***] after the filing of said lawsuit or notice of any other challenge to terminate this Agreement [***]. If any Sublicensee (or an Affiliate thereof) files a lawsuit or otherwise challenges the validity, scope or enforceability of any of the Patent Rights and/or Copyright, University shall have the right, at its election, [***] after the filing of said lawsuit or notice of any other challenge to demand that Licensee terminate said agreement under which said Sublicensee takes license/rights in the Patent Rights and/or Copyright, which termination must occur and be effective within the cure provided in Section 9.02(A). In the event that, and for any period during which University does not choose to exercise its rights to terminate this Agreement or a Sublicense pursuant to this Section 9.02(C), Licensee will pay to University [***]. In the event that such a patent challenge is successful, Licensee will have no right to recoup any royalties or other payments due and payable to University during the period of challenge. In the event that such a patent and/or copyright challenge by Licensee or any Sublicensee is unsuccessful, Licensee shall also reimburse University for all University's reasonable legal fees and expenses incurred in its defense of said challenge to the Patent Rights. This obligation to reimburse University for defense of Licensee's unsuccessful challenge to the validity, scope or enforceability of any

of the Patent Rights and/or Copyright shall survive any expiration or termination of this Agreement. A lawsuit shall be deemed 'unsuccessful' for purposes of this Section 9.02(C) if: (i) the lawsuit is terminated for any reason prior to a settlement or judgment from which no appeal can be or is taken; (ii) any of the Patent Rights and/or Copyright challenged by said lawsuit remain enforceable after any such settlement or judgment is in effect; or (iii) if Licensee or such Sublicensee would still require a license to any of the Patent Rights and/or Copyright to sell any of its products after any such settlement or judgment is in effect.

- (D) **Claim of Implied License.** If Licensee, or any of its Affiliates, files a lawsuit claiming, or otherwise claims or argues in writing, that Licensee is granted an implied license to any invention or patent right and/or copyright (other than the expressly defined Patent Rights or Copyright), the University shall have the option to terminate this Agreement [***] (or at any time thereafter) and [***].

9.03 Licensee's Right To Terminate. After the [***] of the Effective Date, upon [***] advanced notice, Licensee may terminate this Agreement by giving written notice to University as provided for in Section 11.07.

9.04 Accrued Obligations.

- (A) Upon expiration or termination of this Agreement for any reason, each party will remain liable for those obligations which came into existence prior to the effective date of the expiration or termination including, without limitation, payment of accrued Running Royalties, Minimum Royalty Amount(s), Sublicense Lump Sums, Patent Costs and the recovery from actions pursuant to Section 8.02(B) and Section 8.04, as well as legal fees and expenses as set forth in Section 9.02(C). For the avoidance of doubt, upon termination of this Agreement, Licensee will remain liable to University for payment to University of University's portion of any royalties and/or fees collected by Licensee for Sublicenses. However, Licensee will no longer be a party to any Sublicense which is continued after the termination of this Agreement as permitted under Section 2.03(E).

- (B) Provided Licensee has not materially breached this Agreement, Licensee may, for a period of no longer than [***] after the effective date of the termination of this Agreement, complete any or all Licensed Products that it can demonstrate were in the process of manufacture on the effective date of the termination and sell any and all Licensed Products that it can demonstrate were in the process of manufacture or in inventory on the date of termination; *provided* that Licensee will remain obligated to pay any applicable Running Royalties and fees thereon and prepare and send appropriate reports to University with respect to said Running Royalties as provided in this Agreement. Within [***] after a written request by the University, Licensee will provide the University with an accounting of Licensed Products then on hand and in process and its best estimate of when within the [***] period such sales of Licensed Products will conclude.

9.05 Survival. ARTICLE I (all - including Schedule 1); ARTICLE II, Sections 2.03(E), 2.03(F), 2.04, 2.05, 2.06 and 2.08; ARTICLE IV (all — to the extent applicable to obligations to pay Milestone Payments, Minimum Royalty Amounts, Running Royalties, Sublicense Lump Sums, interest and all other amounts accrued as of the date of expiration or termination); ARTICLE V (Sections 5.01, 5.02 and 5.05, each for [***] from the date of expiration or termination); ARTICLE VI, Sections 6.01, 6.02, 6.03, 6.06 (with respect to accrued costs as of the date of expiration or termination) and 6.07; ARTICLE VII (all); ARTICLE VIII for actions filed by Licensee prior to expiration or termination; ARTICLE IX, Sections 9.02(C), 9.04, 9.05, 9.06 and 9.07; ARTICLE X (all); ARTICLE XI, Sections 11.01, 11.02, 11.03, 11.05, 11.06, 11.07, 11.08, 11.09, 11.10, 11.11, 11.12 and 11.13 and all other sections which by their nature should survive, will survive the expiration or termination of this Agreement. Exhibit C (Equity Agreement) as executed by the parties shall also survive the expiration or any termination of this Agreement as an independent agreement in accordance with its respective terms.

9.06 Effect of Termination. For the avoidance of doubt, upon termination of this Agreement, Licensee will remain liable to University for payment to University of University's portion of any royalties and/or fees collected by Licensee for Sublicenses. However, Licensee will no longer be a party to any Sublicense which is continued after the termination of this Agreement as permitted under Section 2.03(E).

9.07 Information. Upon termination of this Agreement for any reason, Licensee shall, promptly upon written request by the University, make available to the University, at the University's sole option, the rights to use, license or own all Information then in Licensee's possession that is relevant to the commercialization of Licensed Products or Licensed Processes. Any Information returned to University under this Section 9.06 shall not be considered Licensee's Confidential Information.

ARTICLE X DISPUTE RESOLUTION

10.01 Mediation. In the event of any dispute arising between the parties in connection with this Agreement, the construction thereof, or the rights, duties or liabilities of either party, representatives designated by each party will meet at the University or confer by conference call within [***] of a written request by either party, and attempt to amicably resolve the dispute. If the dispute is not resolved by such efforts within [***] after such written request for a meeting or conference call, the parties will refer the matter to non-binding mediation in Boston, the costs of which will be shared equally. In the event that such dispute is not amicably resolved by such non-binding mediation, then the parties may, at their option, agree to arbitrate or unilaterally employ civil litigation or any other dispute resolution mechanism available to them.

10.02 Injunctive Remedies. Notwithstanding Section 10.01 above, the parties acknowledge and agree that, in the event of a breach or a threatened breach by either party of Sections 11.01 or 11.06 hereof, the other party may suffer irreparable damage for which it will have no adequate remedy at law and, accordingly, will be entitled [***] to seek injunctive and other equitable remedies to prevent or restrain such breach or threatened breach, without having first complied with the provisions of Section 10.01, and without the necessity of posting any bond or surety, in addition to any other remedy it might have at law or at equity.

10.03 Governing Law. The validity, interpretation, performance and enforcement of this Agreement, and all rights and obligations of the parties will be governed and construed in accordance with the internal laws of the Commonwealth of Massachusetts, without regard to its rules concerning conflicts of laws.

10.04 Exclusive Venue; Consent to Jurisdiction. Except for mediation as stipulated in Section 10.01, any action, suit or other proceeding pursuant to, arising under, or touching or concerning this Agreement or the transactions contemplated hereby, including any challenge to the validity or enforceability of the Patent Rights and/or Copyright, will be brought exclusively in any court of competent jurisdiction in Suffolk County, Commonwealth of Massachusetts. The parties agree to take any and all necessary or appropriate action to submit to the exclusive jurisdiction of any such court.

ARTICLE XI GENERAL PROVISIONS

11.01 Confidentiality. It is contemplated that in the course of the performance of this Agreement (the “*Permitted Use*”) each party may, from time to time, disclose Confidential Information to the other. Each party agrees to use reasonable efforts: i) to not use the other party’s Confidential Information except in the course of the performance of this Agreement or as required to comply with laws or with legal process; and ii) to take all reasonable steps, but no less than the steps it takes to keep its own

Confidential Information confidential, to prevent disclosure to a third party; *provided* that no provision of this Agreement will be construed to preclude such disclosure of Confidential Information as may be necessary or appropriate to: (A) obtain from any governmental agency any necessary approval or license or to obtain patents that are to be included in Patent Rights; or (B) where University is the receiving party, for University to provide Licensee's Confidential Information when required for the performance of University's obligations under any third party agreement pertaining to the Patent Rights and/or Copyright . The obligations of confidentiality set forth in this Section 11.01 shall survive termination of this Agreement for a period of [***]. Notwithstanding the forgoing, if the University terminates this Agreement in accordance with Section 9.02, the University may use and/or provide any of Licensee's information to a third party for purposes of attempting to relicense any of the Patent Rights and/or Copyright. Notwithstanding any other provision of this Agreement, Licensee agrees not to disclose to University any information that may be subject to export controls under any applicable laws or regulations, including but not limited to the Export Administration Regulations of the United States Department of Commerce, the International Traffic in Arms Regulations of the Department of State, and the Office of Foreign Assets Control of the Department of Treasury.

11.02 Amendment and Waiver. This Agreement may be amended only by an instrument in writing signed by an authorized officer of each party. No provision of or right under this Agreement will be deemed to have been amended or waived by any act or acquiescence on the part of either party, its agents or employees, but only by an instrument in writing signed by an authorized officer of each party. No waiver by either party of any breach of this Agreement by the other party will be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver.

11.03 Independent Contractors. Each party represents that it is acting on its own behalf as an independent contractor and is not acting as an agent for or on behalf of any third party. This Agreement and the relations hereby established by and between the University and Licensee do not constitute a partnership, joint venture, agency or contract of employment between them.

11.04 Assignment.

- (A) This license is personal to the Licensee. Without prior written consent of University, this Agreement may be assigned or transferred by Licensee: (i) to an Affiliate (and only for so long as said Affiliate remains an Affiliate); or (ii) in connection with any merger, consolidation or reorganization of Licensee; provided, that (a) Licensee shall deliver written notice to University at least [***] prior to any such proposed assignment, such notice to include the assignee's contact information as well as a description of all of the material terms and conditions of the agreement (as well as any changes thereto, as applicable, within the [***] notice period) between Licensee and the proposed assignee, (b) the proposed assignee agrees in writing to assume all obligations and liabilities of Licensee hereunder, and (c) Licensee is not in default of any of its obligations under this Agreement (including without limitation payment of any amounts due under this Agreement and/or diligence obligations) at the time of such proposed assignment. Any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will be null and void. Moreover, any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will [***] terminate this Agreement.
- (B) Without prior written consent of University, this Agreement may be assigned or transferred by Licensee in connection with any sale of all, or substantially all, of a Licensee's assets related to the Patent Rights and/or Copyright provided that (a) Licensee shall deliver written notice to University at least [***] prior to any such proposed assignment, such notice to include the assignee's contact information as well as a description of all of the material terms and conditions of the agreement (as well as any changes thereto, as applicable, within the [***] notice period) between Licensee and the proposed assignee, (b) the proposed assignee agrees in writing to assume all obligations and liabilities of Licensee hereunder, and (c) Licensee is not in default of any of its obligations under this

Agreement (including without limitation payment of any amounts due under this Agreement and/or diligence obligations) at the time of such proposed assignment. Any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will be null and void. Moreover, any attempt by Licensee to transfer/assign this Agreement in violation of these restrictions will [***] terminate this Agreement. Any such assignment requires payment to University of an amount to be agreed upon by Licensee and University at the time of said proposed assignment (the “**Assignment Fee**”). No attempt to assign this Agreement will be valid and enforceable in the absence of the payment of said Assignment Fee to University.

- (C) Licensee, or its permitted assignee, will within [***] of the effective date of any assignment permitted under Sections 11.04(A) or 11.04(B), notify University of the assignment and advise if the assignee does not qualify for ‘small entity’ status in accordance with 37 C.F.R. § 1.27.

11.05 Successors and Assigns. This Agreement will bind and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

11.06 Use of Names. No Party will use the name of the other Party, MGH or UIUC or any trustee, director, staff member, officer, employee, student or agent of any other Party or any adaptation thereof in any advertising, promotional or sales literature, publicity or in any document employed to obtain funds or financing without the prior written approval of the Party or individual whose name is to be used; *provided* that, with respect to the University, Licensee may state that Licensed Products are based on research originally carried out at Boston University and that it is licensed by the University under the Patent Rights and/or Copyright so long as such statement(s) do not suggest University’s endorsement of the Licensed Products, Licensed Processes or the Licensee. Licensee may, without seeking permission of University, make reference to publications authored or co-authored by the inventor(s). Licensee will submit to the University for review and written approval, which approval will not be unreasonably withheld or delayed, any references to Licensed Products, this Agreement, the University or the

inventors in submissions required by the Securities and Exchange Commission or any stock exchange or market system on which its shares are listed or being considered for listing. For the University and its officers, employees and students, such approval will be obtained from the Managing Director of the University's Office of Technology Development or its successor. In addition, the University may disclose the name of Licensee in publications by the University. Licensee and University agree that if any public announcement is made about this Agreement, they will jointly make said announcement about the existence of this Agreement. With respect to obtaining approval for MGH, such approval shall be obtained from MGH's Chief Public Affairs Officer.

11.07 Notices. All communications hereunder must be in writing and must be sent to the addresses set forth below, or such other address as either party may specify by notice sent in accordance with this Section:

If to the University:

Boston University

[***]

Attention: [***]

Facsimile: [***]

Email: [***]

with a copy to:

Boston University

[***]

Attention: [***]

Facsimile: [***]

If to Licensee, to the Licensee Notice Address set forth in the Principal Terms & Milestones List. Notices, statements, reports or requests required or permitted hereunder will be in writing and will be deemed effective and properly given [***] by any courier (e.g. FedEx) that provides evidence of delivery, registered or certified mail, Express Mail, or e-mail (provided that delivery to the recipient is confirmed) to the recipient as indicated above or such other recipient as may, in the future, be designated by University or Licensee by such communication.

11.08 Severability. In the event any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other term or provision hereof. The parties agree that they will negotiate in good faith or will permit a court to replace any provision hereof so held invalid, illegal or unenforceable with a valid provision that is as similar as possible in substance to the invalid, illegal or unenforceable provision.

11.09 Conflict or Inconsistency. In the event of any conflict or inconsistency between the terms and conditions hereof and any terms or conditions set forth in any purchase order, sponsored research agreement, confidentiality agreement, material transfer agreement, terms sheet or other document relating to, or affecting, the transactions contemplated by this Agreement, the terms and conditions set forth in this Agreement will prevail.

11.10 Captions/Headings. Captions and Headings of the sections and subsections of this Agreement are for reference purposes only and do not constitute terms or conditions of this Agreement and will not limit or affect the terms and conditions hereof.

11.11 Word Meanings. Words such as *herein*, *hereinafter*, *hereof* and *hereunder* refer to this Agreement as a whole and not merely to a section or paragraph in which such words appear, unless the context otherwise requires. The singular will include the plural, and each masculine, feminine and neuter reference will include and refer also to the others, unless the context otherwise requires.

11.12 Entire Agreement. This Agreement contains the entire understanding of the parties hereto with respect to the transactions and matters contemplated hereby, supersedes all prior agreements and understandings relating to the subject matter hereof, and no representations, inducements, promises or agreements, whether oral or otherwise, between such parties not contained herein or incorporated herein by reference will be of any force or effect. No provision of this Agreement will be interpreted in favor of, or against, either of the parties by reason of the extent to which any such party or its counsel participated in the drafting thereof or by reason of the extent to which any such provision is inconsistent with any prior draft of this Agreement or such provision.

11.13 Counterparts. This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Facsimile or PDF copies of this Agreement will be enforceable as originals. In making proof of this Agreement, it will not be necessary to produce or account for more than one such counterpart.

[Remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized officers, and have duly delivered and executed this Agreement under seal as of the date first set forth above.

Beta Bionics, Inc.

/s/ Ed Damiano

Name: Ed Damiano
Title: President

Trustees Of Boston University

/s/ Martin J. Howard

Martin J. Howard
Senior VP, CFO & Treasurer

Definitions

When used as capitalized terms in the Control Algorithm License Agreement to which this Schedule 1 is attached, the following terms will have the respective meanings set forth below. The definition of terms defined in the singular tense will include the plural tense and *vice versa*.

Affiliate means with respect to any person or Entity, any other person or Entity that controls, is controlled by or is under common control with the specified person or Entity. As used in this definition, the term ‘**control**’ means: (a) direct or indirect control of at least fifty percent (50%) of the voting stock of an Entity; or (b) in the absence of ownership of at least fifty percent (50%) of the voting stock of the Entity, or in the case of a non-corporate Entity or person, possession of, directly or indirectly, the power to direct or cause the direction of the management and policies of such person or Entity.

Agreement means the Control Algorithm License Agreement to which this Schedule 1 is attached, together with all Schedules and Exhibits annexed thereto, as the same shall be modified and in effect from time to time.

Assignment Fee has the meaning set forth in Section 11.04(B).

BMCC has the meaning set forth in Section 2.04.

Board Observer Rights Letter Agreement means the letter agreement between the Licensee and the University pursuant to which the University receives board observer rights in the Licensee, and which letter agreement shall be in, or substantially in, the form attached hereto as Exhibit D.

Breaching Sublicensee has the meaning set forth in Section 9.02(A).

Business Plan means a detailed document covering Licensee’s plans as to projected product development, markets and sales forecasts, manufacturing and operations, and financial forecasts.

Calendar Quarter means each three-month period of the Calendar Year beginning on January 1, April 1, July 1 and October 1.

Calendar Year means the period of January 1 through December 31.

Change of Control means, with respect to Licensee, (a) a merger or consolidation of Licensee with a third party which results in the voting securities of Licensee outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a third party, together with its Affiliates, becomes the owner of more than fifty percent (50%) of the combined voting power of Licensee’s outstanding securities other than through issuances by Licensee of securities of Licensee in a bona fide financing transaction or series of related bona fide financing transactions, or (c) the sale or other transfer to a third party of all or substantially all of Licensee’s assets or business to which this Agreement relates.

Claim means any issued, unexpired, valid claim or pending claim contained in the Patent Rights. For purposes of this definition, **valid claim** means any claim that has not been: i) formally disclaimed by the University as applicable; ii) dedicated to the public by the University as applicable; or iii) held to be invalid or unenforceable by a final judgment of a court or administrative agency of competent jurisdiction from which no appeal can be, or is, taken.

Clinical Trial has the meaning set forth in Section 2.03(K).

Combination Product means any product comprised of a combination of: (i) a Licensed Product; and (ii) any active ingredient(s), device(s), delivery system(s) or other technology(ies) for which rights are not included in the license granted under this Agreement but, with respect to said item(s) in (ii), which may each or collectively form the basis for a separately saleable product (an **"Independent Subproduct"**).

Commercial Activity Reference Date has the meaning set forth in the Principal Terms & Milestones List.

Commercialization Plan means a detailed report describing Licensee's progress toward and plans for commercialization of the Licensed Products, including work completed, key scientific discoveries, summary of work-in-progress, current schedule of anticipated events or milestones, market plans for introduction of Licensed Product, Licensed Process and/or Software and significant corporate transactions involving Licensed Product.

Confidential Information means all confidential and proprietary information and data of one party that is provided by that party (the **"disclosing party"**) to the other party (the **"receiving party"**) hereunder in written or other tangible medium and marked as confidential at the time of disclosure, except any portion thereof which:

- (a) was known to the receiving party, before receipt thereof under this Agreement, as evidenced by the receiving party's written record;
- (b) is or becomes generally known through no fault of the receiving party;
- (c) was provided to the receiving party by a third party, provided that such information was lawfully disclosed by such third party free of restrictions upon disclosure and, to the receiving party's knowledge, without breach of any obligation to the disclosing party;
- (d) is independently developed by persons at the receiving party not having knowledge of, or access to, the Confidential Information; or
- (e) is disclosed pursuant to valid court order or other governmental directive, so long as receiving party has provided to the disclosing party [***] notice of such order or directive so as to enable the disclosing party to interpose appropriate objections thereto.

Copyright means the University's and/or UIUC's copyrights in the Software as ascribed in Sections 101 et seq. of the Copyright Law of the United States, as amended from time to time, and International Treaty provisions, in effect from time to time, relating to the protection of copyrights worldwide, but excluding any third party rights therein.

Covered In Whole Or In Part By A Claim means but for the license rights granted under this Agreement, the Licensee's or Sublicensee's activity (alone or in combination with other persons or Entity(ies) acting under instructions from, or on behalf of, a Licensee and/or Sublicensee) would in some way constitute direct or indirect infringement of a Claim even if not all elements of the Claim are carried out by the same Entity or practiced in the same geographic location.

Current Market Value means, as to any issuance of equity by Licensee in connection with a Sublicense: [***].

Deferred Patent Costs has the meaning set forth in Section 6.06(A).

Deferred Patent Costs Invoice has the meaning set forth in Section 6.06(A).

Deferred Patent Cost Period has the meaning set forth in Section 6.06(A).

Delayed Milestone has the meaning set forth in Section 3.04(B).

Effective Date has the meaning set forth in the preamble to this Agreement.

End-User means any person or Entity whose use of a product or Licensed Product results in utilization, consumption, destruction, loss of activity or loss of value of said product or Licensed Product.

Entity means any corporation, association, partnership (general or limited), joint venture, trust, estate, limited liability company, limited liability partnership or other legal entity or organization.

Equity Agreement means the agreement between the Licensee and the University pursuant to which the University receives an equity interest in the Licensee, for its account and the account of UIUC, and which agreement shall be in, or substantially in, the form attached hereto as Exhibit C.

Estimated National Phase Entry Payment has the meaning set forth in Section 6.06(C)(i).

Exclusive Period means the Term of the licenses granted pursuant to Section 2.01(a) unless such period of exclusivity is earlier terminated by the University pursuant to Sections 3.06 or 9.02(A).

Field of Use has the meaning specified in the Principal Terms & Milestones List.

First Commercial Sale means the first sale of a Licensed Product by Licensee (or Sublicensee) to any third party in an arm's length transaction anywhere in the world.

Funding Event means receipt of venture capital, angel funding or any other form of funding in exchange for equity in Licensee in a cumulative amount equal to or in excess of the Funding Event Amount as defined in the Principal Terms & Milestones List.

Government Rights means the rights of the United States of America or other government entity in subject matter licensed under this Agreement, including without limitation those set forth in 35 U.S.C. § 200 et seq. or any successor thereto, as well as federal regulations promulgated thereunder, all as modified and in effect from time to time.

Indemnitees has the meaning specified in Section 7.02 and MGH Indemnitees has the meaning specified in Section 7.02(B).

Independent Subproduct has the meaning specified in the definition of Combination Product.

Information means research results, toxicology data, assays, preclinical data, prototypes, mask works, manufacturing processes including cell lines and unused, unexpired amounts of Licensed Products, clinical results, regulatory submissions, approvals, customer lists, papers, photographs, computer programs and databases, manuals, prototypes, models, plans, drawings, designs, formulations, specifications, methods, techniques, formulas, supplier lists, engineering information, price lists, costing information, accounting and financial data, profit margin, marketing and sales data, and/or strategic plans related to the Patent Rights and/or Software.

Initial Public Offering means the first underwritten public offering of Common Stock of the Licensee for the account of the Licensee registered under the Securities Act of 1933, as amended.

Institutions has the meaning specified in Section 2.04.

JDRF means JDRF International, a major charitable 501(c)(3) organization dedicated to funding type 1 diabetes research headquartered at 26 Broadway, 14th floor, New York, NY (formerly known as the Juvenile Diabetes Research Foundation).

JDRF Related Intellectual Property means the intellectual property developed with use of funding from JDRF comprising (i) the subset of Patent Rights disclosed and/or claimed in University Cases [***] and [***]; and (ii) the Copyright in the subset of the Software developed using funding from JDRF.

Label License means a non-exclusive sublicense right to practice a Licensed Process that is granted directly and solely to an End-User by the Licensee or a Sublicensee and which is fully compliant with the terms, conditions and obligations set forth in Section 2.03(J), and wherein said sublicense right is memorialized: i) on a product label; ii) on product packaging; iii) on an insert that accompanies a product sold to the End-User so that said End-User may use said product said End-User purchased (and only in the amounts purchased) for its intended purpose; and/or iv) with respect to Software in either “shrink-wrapped” form or an electronic equivalent that permits the End-User to view and indicate agreement with the license terms.

Licensed Process means any Software-Based Process or any process that is Covered In Whole Or In Part By A Claim practiced within any country of the Territory.

Licensed Product means any Software-Based Product or any product or product part made, used, sold or imported into, or exported from, any country of the Territory that: (a) is Covered In Whole Or In Part By A Claim; or (b) is manufactured by using a Licensed Process; or (c) is employed to practice a Licensed Process.

Licensee means the person(s), Entity or Entities so identified in the preamble to the Agreement, and its Affiliates.

Licensee Derivative Work means any development or modification created by or on behalf of Licensee that includes, or is based in whole or in part, on the Software, including, but not limited to, all works developed by or on behalf of Licensee which would be characterized as derivative works of the Software under the United States Copyright Act of 1976, as amended from time to time, but not limited to, translations, recastings, transformations, or adaptations of the Software to other hardware platforms or computer interfaces, or works consisting of revisions, or other modifications of the Software.

Licensee Fiscal Year has the meaning set forth in the Principal Terms & Milestones List.

Licensee Notice Address means the address so identified in the Principal Terms & Milestones List.

Licensee Notice E-mail means the e-mail so identified in the Principal Terms & Milestones List.

Market Countries means:

[***]

[***].

MGH JIAAs means (a) the Joint Invention Administration Agreement between University and MGH [***], and (b) the Joint Invention Administration Agreement between University and MGH [***].

Milestone means each of the events so identified in the Principal Terms & Milestones List.

Milestone Date means for any Milestone, the date appearing opposite such Milestone in the Principal Terms & Milestones List.

Milestone Payment means for any Milestone, the dollar amount (if any) appearing opposite such Milestone in the Principal Terms & Milestones List.

Minimum Royalty Amount (or **MRA**) means for: (a) any year identified in the Principal Terms & Milestones List under the phrase “Minimum Royalty Amount”, the dollar amount appearing opposite the designation of such year; and (b) any year after the termination of the Exclusive Period, zero.

MRA Year means the period identified in the Principal Terms & Milestones List and defined in Section 4.01(C).

National Phase has the meaning given by the World Intellectual Property Organization with respect to patent prosecution activity under the Patent Cooperation Treaty.

National Phase Entry means, entry into the National Phase under the Patent Cooperation Treaty as defined by the World Intellectual Property Organization (WIPO).

Net Sales means [***]

[***].

Non-Suit Countries means all countries other than Market Countries.

Patent Costs means all costs, fees and/or expenses of any kind incurred in respect of the Patent Rights and paid by University or invoiced to University, including without limitation: [***].

Patent Cost Invoice has the meaning set forth in Section 6.06(A).

Patent List means Exhibit A and Exhibit B annexed hereto as they may be amended and in effect from time to time.

Patent Rights means all of the following University intellectual property:

(a) the patents and/or patent applications identified in the Patent List (including PCT application(s) and/or the U.S. utility application(s) filed on or before the one-year conversion date of any such provisional applications and related by a priority claim thereto); (b) any patent application(s) that claim(s) priority to and is/are a conversion, continuation, continuations-in-part, divisional, reissue, renewal, reexamination, substitution or extension of any patent application identified in (a); (c) any patents issuing on any of the patent applications identified in (a) or (b), including any reissues, renewals, reexaminations, substitutions or extensions thereof; and (d) if the Territory includes countries other than the United States, any foreign counterpart(s) (including PCTs) of the foregoing and any patents which issue thereon, provided that Claim(s) in any said continuations-in-part not identified in the Patent List as of the Effective Date will only be included in Patent Rights to the extent any said Claim(s) of said continuations-in-part is/are directed to subject matter specifically described in a patent or patent application identified in the original Patent List (i.e. the Patent List as of the Effective Date). For the avoidance of doubt, no other inventions or patent rights are included in the meaning of Patent Rights except as expressly set forth in this definition.

Public Sector will include:

- (a) the sovereign government of a country;
- (b) agencies of the United Nations and the World Health Organization;
- (c) organizations which are members of the International Committee of the Red Cross and Red Crescent;
- (d) international charitable agencies (also known as Non-Governmental Agencies) including but not limited to Oxfam, Medecins Sans Frontieres, and so forth;
- (e) organizations substantially supported by philanthropic organizations including but not limited to the Bill and Melinda Gates Foundation, the Rockefeller Foundation and so forth, specifically including global product development and distribution public-private partnerships.

Progress Report means a written report summarizing Licensee's material technical and other efforts made towards First Commercial Sale for all Licensed Products and/or Licensed Processes under development. Such reports will include, without limitation, reasonably detailed summaries of: (i) development and commercialization of Licensed Products and/or Licensed Processes; (ii) collaborations with third parties and sublicensing efforts; (iii) progress toward completing milestones described in the Principal Terms & Milestones List; (iv) key management changes and total number of employees; (v) Licensee's finances; (vi) scientific and business goals for the next year; (vii) summary of any payments due under ARTICLE IV; and (viii) any other company information which may materially adversely impact Licensee's ability to develop Licensed Product and/or Licensed Processes .

Quarterly Report has the meaning set forth in Section 5.02.

Reserved Rights has the meaning set forth in Section 2.04.

Royalties has the meaning set forth in Section 4.01.

Royalty Percentage has the meaning set forth in the Principal Terms & Milestones List.

Running Royalties has the meaning set forth in Section 4.01(E).

Running Royalty Amount means, in respect of any Calendar Quarter during the Term, [***]

- (a) [***] Net Sales [***] multiplied by the Royalty Percentage [***]; plus
- (b) [***] Net Sales [***], multiplied by the Software-Based Royalty Percentage [***].

Software means the computer software, source code, object code, and/or related documentation created by or on behalf of University, related to [***], as it exists on the Effective Date and listed in Schedule 3; but excluding any third party proprietary technology, content, know-how or code.

Software-Based Process means any process covered by, developed using and/or that executes the Software.

Software-Based Product means: 1) any product or product part that includes an executable copy of the Software incorporated therein; and/or 2) fee-based access to a device (e.g. computer or computer network) that executes the Software.

Software-Based Royalty Percentage has the meaning set forth in the Principal Terms & Milestones List. [***]

Sublicense means any agreement between Licensee (or a Sublicensee as permitted by University's written consent given in accordance with Section 2.03(F)) and a third party that contains a grant to rights taken by Licensee under Section 2.01 of this Agreement regardless of the name given to said agreement by the parties.

Sublicense Lump Sum means, in respect of any Calendar Quarter during the Term, the product of the Sublicense Lump Sum Percentage (expressed as a decimal) multiplied by the applicable amount of Sublicensing Revenue.

Sublicense Lump Sum Percentage has the meaning set forth in the Principal Terms & Milestones List.

Sublicensee means any person or Entity to whom a Sublicense is granted as permitted by this Agreement.

Sublicensee Running Royalty Amount means, in respect of any Calendar Quarter during the Term [***]

[***] Net Sales multiplied by the Sublicensee Running Royalty Percentage [***]

[***] Net Sales [***].

Sublicensee Running Royalty Percentage has the meaning set forth in the Principal Terms & Milestones List.

Sublicensing Revenue means [***].

Substantial Patent Prosecution Event means an opposition, interference, reexamination, reissue or other patent prosecution event where it is anticipated that costs in excess of [***] are likely to be incurred by University.

Term means with respect to any license granted by the University under this Agreement, the period beginning on the Effective Date and terminating in accordance with ARTICLE IX.

Territory has the meaning specified in the Principal Terms & Milestones List.

Third Party Royalties means any royalties Licensee pays to one or more third parties pursuant to one or more licenses to intellectual property rights entered into by Licensee to avoid infringement of such rights by the practice of the Patent Rights in the manufacture, use, or sale of any Licensed Product, or to avoid infringement-related litigation with respect to the practice of the Patent Rights, as determined by Licensee in its reasonable discretion. Third-Party Royalties shall not include: [***].

Trade Dress will mean the physical appearance of Product as sold in any Market Country by Licensee, including but not limited to such characteristics as shape, color, tradename, trademark or service mark.

UIUC JIAA means the Joint Invention Administration Agreement between University and UIUC [***].

Unfunded Countries has the meaning set forth in Section 6.05.

World Intellectual Property Organization means the specialized agency of the United Nations charged with developing a balance and accessible international intellectual property system (see: <http://www.wipo.int/portal/index.html.en>).

Schedule 2

None

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Schedule 3

iLet Control Algorithm

US PATENT RIGHTS

***]

FOREIGN PATENT RIGHTS

***]

**UNIVERSITY - BETA BIONICS
EQUITY AGREEMENT**

This Equity Agreement (the “**Agreement**”), effective as of December 23, 2015 (the “**Effective Date**”), is by and between **Beta Bionics, Inc.**, a Massachusetts benefit corporation with a principal address at 22 Putnam Road, Acton, MA 01720 (the “**Company**”), and **Trustees of Boston University**, a Massachusetts non-profit corporation with a principal address at One Silber Way, Boston, MA 02215 (the “**University**”).

WHEREAS, the Company desires and the University has agreed pursuant to the terms of a Control Algorithm License Agreement dated as of the Effective Date (the “**Control Algorithm License Agreement**”) to license certain technology for which the University shall be entitled to certain royalty payments as set forth therein and, additionally, shares of the Company’s Capital Stock on the terms set forth herein; and WHEREAS, the University has agreed with The Board Of Trustees Of The University Of Illinois (“UIUC”) that University will hold the equity in Licensee under the Control Algorithm License Agreement for UIUC’s benefit; and WHEREAS, the parties hereto are willing to execute this Agreement to effect the purchase and sale of such Capital Stock and to be bound by the provisions hereof.

NOW, THEREFORE, in consideration of the mutual covenants herein contained and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the University and the Company hereby agree as follows:

1. Definitions

(a) “**Capital Stock**” shall mean, individually, the Common Stock or Preferred Stock, and, collectively, the Common Stock and the Preferred Stock.

(b) “**Common Stock**” shall mean shares of the Company’s common stock, no par value.

(c) “**Eligible Financing**” shall mean the first capital raising transaction closing after the Effective Date after which the Company will have raised aggregate gross proceeds of [***] or more (inclusive of all amounts raised in such transaction including debt obligations that convert into Capital Stock and in any capital raising transaction occurring before such transaction).

(d) “**Fully Diluted Capitalization**” shall mean, at a specified time, without double counting, the sum of (a) the number of shares of Common Stock outstanding at such time, (b) the number of shares of Common Stock issuable upon the conversion, exercise or exchange of all securities or rights, including options and warrants, outstanding at such time, and (c) the number of shares of Common Stock reserved for issuance pursuant to any outstanding options or other securities exercisable for or convertible into Common Stock under the Company’s equity incentive plans.

(e) “**IPO**” shall mean the Company’s first underwritten public offering of its Common Stock under the Securities Act (as defined below).

(f) “**New Securities**” shall mean shares of new securities of the Company constituting, or units of any new securities of the Company including, shares of Capital Stock or any warrants, options or rights to purchase shares of Capital Stock or any securities convertible into or exchangeable for shares of Common Stock (or any warrants, options or rights with respect to such convertible or exchangeable securities), excluding any securities (i) issued or issuable by reason of a dividend, stock split, split-up or other distribution on outstanding shares of Capital Stock, (ii) issued in a public offering, or (iii) issued in connection with an acquisition, joint venture, commercial arrangement, or similar corporate partnering transaction.

(g) “**Preferred Stock**” shall mean shares of the Company’s preferred stock, no par value.

2. Sale and Issuance of Shares.

(a) Subject to the terms and conditions of this Agreement, and in partial consideration of the license granted to the Company pursuant to the Control Algorithm License Agreement, the Company will hereby issue and deliver to the University at the closing for its own account, 2,247 shares of Series B Common Stock and, for UIUC’s account, 39 shares of Series B Common Stock, which shares together (2,286 total) represent two and one-half percent (2.5%) of the Company’s Fully Diluted Capitalization immediately following such issuance (collectively, such shares of Common Stock issued to the University are referred to herein as the “**Shares**”).

(b) The obligations of the Company hereunder are subject to the fulfillment of each of the following conditions:

(i) The University shall have executed and delivered the Control Algorithm License Agreement; and

(ii) All authorizations, approvals or permits, if any, of any governmental authority or regulatory body of the United States or of any state that may be required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall have been duly obtained and shall be effective at the closing, other than filings which are required to be made after the closing and which will be duly made on a timely basis.

3. Representations.

(i) Representations and Warranties of the University. The University represents, warrants and acknowledges that the University: (a) has had an opportunity to ask questions of and receive answers from a Company representative concerning the terms and conditions of this investment; (b) is acquiring the Shares for the University’s own account for the purpose of investment, and not with a view to any resale or other distribution thereof in violation

of the Securities Act of 1933, as amended (the “**Securities Act**”); (c) is a sophisticated investor with such knowledge and experience in financial and business matters as to be able to evaluate the merits and risks of an investment in the Shares; (d) is able to and must bear the economic risk of the investment in the Shares for an indefinite period of time because the Shares have not been registered under the Securities Act, and therefore, cannot be offered or sold unless the Shares are subsequently registered under the Securities Act or an exemption from such registration is available; and (e) that the University is an “accredited investor” as that term is defined in Regulation D under the Securities Act. The University acknowledges and understands that the Common Stock has not been registered under the Securities Act, nor registered pursuant to the provisions of the securities laws or other laws of any other applicable jurisdictions, in reliance on exemptions for private offerings contained in Section 4(2) of the Securities Act and in the laws of such jurisdictions. The University further understands that the Company has no intention and is under no obligation to register the Shares under the Securities Act or to comply with the requirements for any exemption that might otherwise be available, or to supply the University with any information necessary to enable the University to make routine sales of the Shares under Rule 144 or any other rule of the Securities and Exchange Commission.

(ii) Representations and Warranties of the Company. The Company represents and warrants to the University that:

- a. The Company is a corporation duly organized, validly existing and in good standing under the laws of the Commonwealth of Massachusetts with full corporate power and authority to own or lease its properties and to conduct its business in the manner and in the places where such properties are owned or leased or such business is conducted by it.
- b. Immediately prior to consummating the transactions contemplated by this Agreement, the authorized Capital Stock of the Company consists of [***] shares of Common Stock, of which [***] shares are issued and outstanding and [***] shares are reserved under the Company’s equity incentive plans.
- c. All currently issued and outstanding shares of Company Capital Stock are duly authorized, validly issued, fully-paid, non-assessable and free of all preemptive rights. When the Shares are issued to the University pursuant to this Agreement, they will be duly authorized, validly issued, fully-paid, non-assessable and free of all preemptive rights.
- d. The Company has all necessary power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution, delivery and performance of this Agreement and the consummation by the Company of the transactions contemplated hereby have been duly and validly authorized by all necessary corporate action. This Agreement has been duly and validly executed and delivered by the Company and constitutes a valid and binding obligation of the Company, enforceable against the Company in accordance with its terms.
- e. Neither the execution, delivery or performance of this Agreement nor the performance of the transactions contemplated hereby, will: (i) constitute a breach or violation of the Company’s Certificate of Incorporation or Bylaws; (ii) constitute (with or without the passage of time or the giving of notice) a breach of, or default under any material agreement, instrument or obligation to which the Company is a party or by which its assets are bound; or (iii) violate any court order, judgment, administrative order, writ, decree, stipulation, arbitration award or injunction or statute, law, ordinance, rule and regulation applicable to the Company.

4. Dilution Protection. The Company agrees to issue and deliver to the University, for no additional fee or consideration, from time to time, such number of additional shares of Capital Stock so as to cause the University to continue to hold shares of Capital Stock representing two and one-half percent (2.5%) of the Fully Diluted Capitalization until (i) immediately following the consummation of an Eligible Financing, (ii) immediately before the consummation of an IPO, or (iii) immediately prior to any sale of all or substantially all of the Company's assets, merger or other acquisition, whichever event occurs first.

5. Other Investor Rights. The Company shall grant the University no less favorable registration and co-sale rights as and when the Company shall grant any such rights to third party investors before and in connection with the Eligible Financing.

6. Pre-Emptive Rights. If at any time after the issuance and delivery of the Shares to the University pursuant to this Agreement, the Company shall issue or sell any New Securities of the Company (other than shares of Common Stock or options to purchase shares of Common Stock issued or issuable pursuant to any equity incentive plans of the Company), the Company shall offer to sell such additional New Securities to the University at a purchase price equal to and on the same terms the Company offers to other investors in order to maintain the University's proportional ownership of the Fully Diluted Capitalization calculated in accordance with this paragraph. Within [***] following the sale of New Securities by the Company, the Company shall deliver a notice to the University (the "**Offer Notice**") stating the terms of the New Securities and the opportunity for the University to purchase New Securities. By giving written notice within [***] after the date of the Offer Notice, the University may elect to purchase, at the price and on the terms specified in the Offer Notice, such number of shares of New Securities needed to maintain the University's proportional ownership of the Fully-Diluted Capitalization after giving effect to the issuance of (i) all New Securities (including New Securities purchased by the University under this paragraph) and (ii) if applicable, Additional Shares pursuant to paragraph 4 above. The exercise or non-exercise by the University of its rights pursuant to this paragraph shall be without prejudice to its rights under this paragraph with respect to any future sales of New Securities. The covenants set forth in this paragraph shall terminate and be of no further force or effect (i) immediately before the consummation of an IPO, or (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act of 1934, whichever event occurs first.

7. Miscellaneous Provisions.

(a) Legends. The University acknowledges that all certificates evidencing the Shares shall bear a legend in substantially the following form, in addition to all other legends required by law or any other agreements to which the University is a party:

“THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND MAY NOT BE SOLD, PLEDGED, OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT OR AN OPINION OF COUNSEL, SATISFACTORY TO THE COMPANY AND ITS COUNSEL, THAT SUCH REGISTRATION IS NOT REQUIRED.”

(b) Adjustment for Stock Splits, Stock Dividends, etc.

(i) If from time to time during the term of this Agreement there is any stock split-up, stock dividend, stock distribution or other reclassification of the Common Stock of the Company, any and all new, substituted or additional securities to which the University is entitled by reason of its ownership of Shares shall be automatically subject to the restrictions on transfer and the other provisions of this Agreement in the same manner and to the same extent as the shares of Shares.

(ii) If the Shares are converted into or exchanged for, or stockholders of the Company receive by reason of any distribution in total or partial liquidation, securities of another corporation or other property (including cash), or pursuant to any merger or consolidation of the Company or acquisition of its assets, then the rights of the Company under this Agreement shall apply to the securities or other property received upon such conversion, exchange, distribution, merger or consolidation in the same manner and to the same extent as the Shares.

(c) Notice. Any notice required by the terms of this Agreement shall be given in writing and shall be deemed effective upon (i) personal delivery; (ii) [***] by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the [***]; (iii) [***] after deposit with a nationally recognized overnight courier, specifying [***] delivery, with written verification of receipt; or (iv) [***] after deposit with the United States Postal Service, by registered or certified mail, return receipt requested, with postage and fees prepaid. Notice shall be addressed to the Company at its principal executive office and to the University at the address that he or she most recently provided to the Company in writing.

(d) Entire Agreement. This Agreement, together with the Control Algorithm License Agreement, each entered into as of the date hereof (in either case, as the same may be amended or restated from time to time), constitutes the entire understanding between the parties hereto with regard to the subject matter hereof, and supersedes any other agreements, representations or understandings (whether oral or written and whether express or implied) which relate to the subject matter hereof.

(e) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties hereto.

(f) Choice of Law. This Agreement shall be governed by, and construed and enforced in accordance with, the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by, and construed and enforced in accordance with, the internal laws of the Commonwealth of Massachusetts without giving effect to the conflicts of laws principles thereof.

(g) Severability. The parties hereby agree that each provision herein shall be treated as a separate and independent clause, and the unenforceability of any one clause shall in no way impair the enforceability of any of the other clauses herein. In case any provisions (or portions thereof) contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, the parties agree that such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject so as to be unenforceable at law, University agrees that such provision or provisions shall be construed by the appropriate judicial body by limiting and reducing it or them, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

(h) Amendments; Waivers. This Agreement may only be amended or modified in writing signed by the University and the Company. No party shall be deemed to waive any rights hereunder unless such waiver is in writing and signed by such party. A waiver in writing on or more occasions shall not be deemed to be a waiver for any future occasions.

(i) Counterparts. This Agreement may be executed in counterparts, each of which when executed and delivered shall constitute a duplicate original, but all counterparts together shall constitute one and the same instrument.

(j) Captions. Captions are for convenience only and are not deemed to be part of this Agreement.

(k) Authority. Company acknowledges and agrees that the University, as the record holder of the Shares, shall have the right to exercise any rights granted hereunder and any other rights relating to the Shares pursuant to agreements by and between Company and University, whether with respect to Shares held for the University's own account or UIUC's account.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the Effective Date.

BETA BIONICS, INC.

TRUSTEES OF BOSTON UNIVERSITY

/s/ Ed Damiano
Name: Ed Damiano
Title: President

/s/ Martin J. Howard
Martin J. Howard
Senior VP, CFO & Treasurer

BETA BIONICS, INC.
22 Putnam Road
Acton, MA 01720

December 23, 2015

Re: Board Observer Rights for the Trustees of Boston University

Trustees of Boston University:

This letter will confirm our agreement made in connection with the issuance to Trustees of Boston University (“**BU**”) of shares of Class B common stock, no par value per share (“**Shares**”) of/by Beta Bionics, Inc. (the “**Company**”), pursuant to the terms of the Equity Agreement, effective as of December 23, 2015 (the “**Agreement**”), between BU and the Company. BU shall be entitled to the following board observer rights, in addition to any rights to non-public financial information, inspection rights, and other rights specifically provided to BU herein:

1. The Company shall invite an individual designated by BU and acceptable to the Company (the “**BU Observer**”), to attend all meetings of the Company’s Board of Directors (the “**Board**”) in a nonvoting observer capacity and, in this respect, the Company shall give the BU Observer copies of all notices, minutes, consents, and other materials that it provides to the Company’s directors at the same time and in the same manner as provided to such directors; provided, however, that the BU Observer shall agree to hold in trust and confidence all information so provided; and provided, further, that the Company reserves the right to withhold any information and to exclude the BU Observer from any meeting or portion thereof if access to such information or attendance at such meeting or portion thereof could either (a) adversely affect the attorney-client privilege between the Company and its counsel, or (b) likely result in a conflict of interest between the Company and BU. Upon reasonable notice and at a scheduled meeting of the Board or such other time, if any, as the Board may determine in its sole discretion, the BU Observer may address the Board with respect to BU’s concerns regarding significant business issues facing the Company.
2. BU shall be entitled to discuss with management of the Company significant business issues, including management’s proposed annual operating plans, and management will meet with representatives from BU regularly during each year at the Company’s facilities, outside of the Board meetings, at mutually agreeable times for such discussion and advice and to review progress in achieving said plans.

3. BU may examine the books and records of the Company and inspect its facilities and may request information at reasonable times and intervals concerning the general status of the Company's financial condition and operations, provided that access to highly confidential proprietary information and facilities need not be provided.

The rights granted herein shall terminate and be of no further force or effect upon the earliest of (i) the consummation of the sale of the Company's securities pursuant to a registration statement filed by the Company under the Securities Act of 1933, as amended, in connection with the firm commitment underwritten offering of its securities to the general public, and (ii) the later date of (a) the date any component of the Licensed Product is approved for sale by the FDA or similar regulatory agency outside of the United States or (b) [***] after the effective date of the Agreement. The confidentiality provisions hereof will survive any such termination.

Very truly yours,

BETA BIONICS, INC.

By: /s/ Ed Damiano

Name: Ed Damiano

Title: President

Agreed to and Acknowledged by:

TRUSTEES OF BOSTON UNIVERSITY

By: /s/ Martin J. Howard

Martin J. Howard

Senior VP, CFO & Treasurer

First Amendment to Control Algorithm License Agreement
between
Trustees of Boston University and Beta Bionics, Inc.

This First Amendment (“**First Amendment**”) effective as of December 11, 2017 (the “**Effective Date**”) amends that certain Control Algorithm License Agreement (“**Agreement**”) dated as of December 23, 2015 by and between Trustees of Boston University (the “**University**”) and Beta Bionics, Inc. (“**Licensee**”). University and Licensee may hereafter be referred to as the “**Parties**”.

WHEREAS, in support of Licensee seeking a Series B funding round, the Parties wish to amend the Milestones as defined in said Agreement in order to reflect Licensee’s current development plans;

NOW THEREFORE, in accordance with Section 11.02 of the Agreement and for good and valuable consideration, including the mutual obligations undertaken in the Agreement and this First Amendment, the receipt and sufficiency of which are hereby acknowledged, the parties agree to amend the Agreement as of the Effective Date as follows:

1. The list of Milestones set forth in the Principal Terms & Milestones List shall be deleted and the following list of Milestones shall be inserted in its place:

Milestones	Due Date
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***

This First Amendment shall become effective as of the Effective Date upon execution by an authorized officer of each party. Except as expressly amended by this First Amendment, capitalized terms used in this First Amendment which are defined in the Agreement shall have the meanings set forth in the Agreement.

This Agreement may be executed electronically/digitally in compliance with the Massachusetts Uniform Electronic Transactions Act (MUETA) Mass. Gen. Laws ch. 110G and/or The Electronic Signatures In Global And National Commerce Act (ESIGN) 15 USC ch. 96. Persons signing this document agree that, if used, electronic/digital signatures are intended to authenticate this writing and to have the same force and effect as the use of manual signatures.

IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to be executed by their respective duly authorized officers, and have duly delivered and executed this First Amendment under seal as of the date first set forth above.

TRUSTEES OF BOSTON UNIVERSITY

BETA BIONICS, INC.

By: /s/ Martin J. Howard
Name: Martin J. Howard
Title: Senior V.P., Treasurer & CFO
Date: Dec 18, 2017

By: /s/ Edward R. Damiano
Name: Edward R. Damiano
Title: President and CEO
Date: Dec 18, 2017

Second Amendment to Control Algorithm License Agreement
Between
Trustees of Boston University and Beta Bionics, Inc.

This Second Amendment (“**Second Amendment**”) effective as of September 21, 2020 (the “**Effective Date**”) amends that certain Control Algorithm License Agreement (“**Agreement**”) dated as of December 23, 2015 as amended by the First Amendment thereto effective as of December 11, 2017 by and between the Trustees of Boston University (the “**University**”) and Beta Bionics, Inc. (“**Licensee**”). University and Licensee may hereafter be referred to as the “**Parties**”.

WHEREAS, the Parties wish to amend certain terms as defined in said Agreement in order to update the Patent List, reflect Licensee’s current development plans, and clarify the agreement between the Parties regarding calculation of Royalties;

NOW THEREFORE, in accordance with Section 11.02 of the Agreement and for good and valuable consideration, including the mutual obligations undertaken in the Agreement and this Second Amendment, the receipt and sufficiency of which are hereby acknowledged, the parties agree to amend the Agreement as of the Effective Date as follows:

1. The Commercial Activity Reference Date set forth in the Principal Terms & Milestones List shall be changed from [***], to [***].
2. The list of Milestones set forth in the Principal Terms & Milestones List shall be deleted, and the following list of Milestones shall be inserted in its place:

Milestone	Due Date
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

3. EXHIBIT A and EXHIBIT B shall be deleted and replaced with the revised EXHIBIT A and EXHIBIT B that are attached hereto.

4. On Page 4, prior to the last clause beginning with “WHEREAS”, the following paragraph shall be added:

WHEREAS, University and Licensee are also parties to that certain Device License Agreement (“Device Agreement”) dated as of December 16, 2015; and

5. Section 4.01(E) shall be amended to read as follows:

(E) **Running Royalties.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to:

i. **Net Sales by Licensee.** The Running Royalty Amount for such Calendar Quarter (if any); plus

ii. **Net Sales by Sublicensee.** The Sublicensee Running Royalty Amount for such Calendar Quarter (if any) (collectively, 4.01(E)(i) and (ii) refer to the “**Running Royalties**”);

provided that amounts payable under 4.01(E)(i-ii) with respect to any Calendar Year are fully creditable against the Minimum Royalty Amount paid by Licensee to University in said Calendar Year such that Licensee need only make payments to University when the cumulative amount payable under this Section 4.01(E)(i-ii) exceeds the Minimum Royalty Amount and further provided that any available credit not taken against the Minimum Royalty Amount in any Calendar Year will be forfeited and thus not available as an offset in any subsequent Calendar Year. [***]

6. Section 4.01(F) shall be amended to read as follows:

(F) **Sublicense Lump Sum.** Within [***] after the end of each Calendar Quarter during the Term, Licensee will pay to the University an amount equal to the Sublicense Lump Sum for such Calendar Quarter. [***].

7. Section 4.01(G) shall be amended to read as follows:

(G) **Combination Product.** If a Licensed Product is sold as part of a Combination Product, Net Sales will be calculated by [***] Net Sales [***].

8. Section 5.02(B)(i) shall be amended to read as follows:

- (i) the number of each type of: 1) Licensed Product and/or Software-Based Product made, used, leased, sold, offered for sale or imported; and/or 2) Licensed Process and/or Software-Based Process (as appropriate) practiced by Licensee and/or a Sublicensee during such quarter, including identification of which items reported in 1) and 2) above also qualify as Licensed Products and/or Licensed Processes under the Device Agreement;

9. The final paragraph of Section 5.02(B) shall be amended to read as follows:

All Quarterly Reports shall provide a breakdown of the data specified in 5.02(B)(ii – vi) above identifying the portion of Net Sales or Running Royalty Amount reported that is due to sales to MGH and/or their Affiliates, as well as identifying the portion of Net Sales or Running Royalty Amount reported that is due to sales of products and/or processes that also qualify as Licensed Products and/or Licensed Processes under the Device Agreement. The reports described in this Section 5.02 are each referred to herein as a “**Quarterly Report**.” Each Quarterly Report will [***], or be sent to University [***], the payment under Sections 4.01(E) and 4.01(F). If Licensee elects to wire transfer payments to University, the Quarterly Report will be transmitted to University in accordance with Section 11.07 [***] that the wire transfer is made.

This Second Amendment shall become effective as of the Effective Date upon execution by an authorized officer of each party. Except as expressly amended by this Second Amendment, capitalized terms used in this Second Amendment which are defined in the Agreement shall have the meanings set forth in the Agreement.

This Agreement may be executed electronically/digitally in compliance with the Massachusetts Uniform Electronic Transactions Act (MUETA) Mass. Gen. Laws ch. 110G and/or The Electronic Signatures In Global And National Commerce Act (ESIGN) 15 USC ch. 96. Persons signing this document agree that, if used, electronic/digital signatures are intended to authenticate this writing and to have the same force and effect as the use of manual signatures.

IN WITNESS WHEREOF, the parties hereto have caused this Second Amendment to be executed by their respective duly authorized officers, and have duly delivered and executed this Second Amendment under seal as of the date first set forth above.

TRUSTEES OF BOSTON UNIVERSITY

By: /s/ Martin J. Howard
Name: Martin J. Howard
Title: Treasurer
Date: Dec 10, 2020

BETA BIONICS, INC.

/s/ Ed Damiano
Ed Damiano
President & CEO
Dec 11, 2020

EXHIBIT A

	BU Docket No.	Knobbe Docket No.	USSN / PCT / Patent No.	Title	Priority case (line #)	Owner	Filed / Issued
1.	BU-2004-0083-01	BETAB.020PR	60/681128	A Fully-Automated Closed-Loop Control System For Type 1 Diabetes			05/13/05
2.	BU-2004-0083-02	BETAB.020PR2	60/735568	A Fully-Automated Closed-Loop Control System For Type 1 Diabetes			11/10/05
3.	BU-2004-0083-03	BETAB.020WO	PCT/US2006/018620	Fully Automated Control System For Type I Diabetes	1, 2	BU	05/15/06
4.	BU-2004-0083-06	BETAB.020NP	7806854	Fully Automated Control System For Type I Diabetes	1, 2, 3	BU / U of I	10/05/10
5.	BU-2004-0083-08	BETAB.020C1	8273052	Fully Automated Control System For Type I Diabetes	1, 2, 3, 4	BU	09/25/12
6.	BU-2010-0345-01	BETAB.021PR	61/408639	Modulation Of Automated Glucagon Delivery Based On Estimated Effect Of Exogenous Insulin Accumulation			10/31/10
7.	BU-2010-0376-01	BETAB.021PR2	61/470210	Short- And Long-Time Adaptation Of Sensor-Driven Autonomous Glucose Control Systems			03/31/11
8.	BU-2010-0376-02	BETAB.021WO	PCT/US2011/058688	Blood Glucose Control System	6, 7	BU / GHC	10/31/11
9.	BU-2010-0376-03	BETAB.021C1	9833570	Blood Glucose Control System	6, 7, 8	BU / GHC	12/05/17
10.	BU-2010-0376-10	BETAB.021D1	10188795	Blood Glucose Control System	6, 7, 8, 9	BU / GHC	01/29/19
11.	BU-2013-0031-01	BETAB.022PR	61/933996	Offline Glucose Level Control Based On Preceding Periods Of Online Glucose Level Control			01/31/14
12.	BU-2013-0031-02	BETAB.022WO	PCT/US2015/012861	Offline Glucose Control Based On Preceding Periods	11	BU	01/26/15

13. BU-2013-0031-05	BETAB.022C1	10543313	Glucose Level Control System With Offline Control Based On Preceding Periods Of Online Control	11, 12	BU	01/28/20
14. BU-2015-0053-01	BETAB.023PR	62/202505	Offline Control System With Automatic Adaptation Of Glucose Target		BU / GHC	08/07/15
15. BU-2015-0053-02	BETAB.023WO	PCT/US2016/046008	Glucose Control System With Automatic Adaptation Of Glucose Target	14	BU / GHC	08/08/16
16. BU-2015-0053-03	BETAB.023NP	15/748333	Glucose Control System With Automatic Adaptation Of Glucose Target	14, 15	BU / GHC	01/29/18
17. 2020-018-01	BETAB.053PR	62/987440	Integrated User-Defined Input Into A Closed-Loop Control System		BU / Beta	March 2020

EXHIBIT B
FOREIGN PATENT RIGHTS

	<u>BU Docket No.</u>	<u>Knobbe Docket No.</u>	<u>PCT / App / Patent No.</u>	<u>Country</u>	<u>Title</u>	<u>Owner</u>	<u>Filed / Priority / Issued</u>
18.	BU-2004-0083-03	BETAB.020WO	PCT/US2006/018620	PCT	Fully Automated Control System For Type I Diabetes	BU	05/15/06
19.	BU-2004-0083-05	BETAB.020CA	2612714	CA	Fully Automated Control System For Type I Diabetes	BU	Priority to case in line 1
20.	BU-2004-0083-14	BETAB.020DE	06752536.0	GER	Fully Automated Control System For Type I Diabetes	BU	Priority to case in line 1
21.	BU-2004-0083-07	BETAB.020EP	1881786	EP	Fully Automated Control System For Type I Diabetes	BU	Priority to case in line 1
22.	BU-2004-0083-13	BETAB.020FR	1881786	FR	Fully Automated Control System For Type I Diabetes	BU	Priority to case in line 1
23.	BU-2004-0083-04	BETAB.020JP	5037496	JP	Fully Automated Control System For Type I Diabetes	BU	Priority to case in line 1
24.	BU-2004-0083-09	BETAB.020JPD1	5389147	JP	Fully Automated Control System For Type I Diabetes	BU	Priority to case in line 1
25.	BU-2010-0376-02	BETAB.021WO	PCT/US2011/058688	PCT	Blood Glucose Control System	BU / GHC	10/31/11
26.	BU-2010-0376-04	BETAB.021CA	2816314	CA	Blood Glucose Control System	BU / GHC	Priority to case in line 8
27.	BU-2010-0376-12	BETAB.021DE	602011061812.1	DE	Blood Glucose Control System	BU / GHC	Priority to case in line 8
29.	BU-2010-0376-	BETAB.021EPD1	11785841.5	EP	Blood Glucose Control System	BU / GHC	Priority to case in line 8
30.	BU-2010-0376-16	BETAB.021ES	2633456	ES	Blood Glucose Control System	BU / GHC	Priority to case in line 8

31. BU-2010-0376-13	BETAB.021FR	2633456	FR	Blood Glucose Control System	BU / GHC	Priority to case in line 8
32. BU-2010-0376-14	BETAB.021GB	2633456	GB	Blood Glucose Control System	BU / GHC	Priority to case in line 8
33. BU-2010-0376-15	BETAB.021IT	502019000098451	IT	Blood Glucose Control System	BU / GHC	Priority to case in line 8
34. BU-2010-0376-05	BETAB.021JP	6047097	JP	Blood Glucose Control System	BU / GHC	Priority to case in line 8
35. BU-2010-0376-09	BETAB.021JPD1	6378164	JP	Blood Glucose Control System	BU / GHC	Priority to case in line 8
36. BU-2013-0031-02	BETAB.022WO	PCT/US2015/012861	PCT	Offline Glucose Control Based On Preceding Periods	BU	01/26/15
37. BU-2013-0031-06	BETAB.022AU	2015211258	AU	Offline Glucose Control Based On Preceding Periods	BU	Priority to case in line 19
38. BU-2013-0031-14	BETAB.022AUD1	2017251868	AU	Offline Glucose Control Based On Preceding Periods Of Online Glucose Level Control	BU	Priority to case in line 19
39. BU-2013-0031-07	BETAB.022CA	2938078	CA	Offline Glucose Control Based On Preceding Periods	BU	Priority to case in line 19
40. BU-2013-0031-08	BETAB.022CN	20158001718	CN	Offline Glucose Control Based On Preceding Periods	BU	Priority to case in line 19
41. BU-2013-0031-09	BETAB.022EP	15744078.5	EP	Offline Glucose Control Based On Preceding Periods	BU	Priority to case in line 19
42. BU-2013-0031-13	BETAB.022HK	17104144.8	HK	Offline Glucose Control Based On Preceding Periods	BU	Priority to case in line 19
43. BU-2013-0031-10	BETAB.022IL	246934	IL	Glucose Off-Line Control Based On Previous Glucose-Level Control	BU	Priority to case in line 19
44. BU-2013-0031-11	BETAB.022JP	2016-548643	JP	Offline Glucose Control Based On Preceding Periods	BU	Priority to case in line 19
45. BU-2013-0031-12	BETAB.022MX	MX/A/16/009787	MX	Offline Glucose Control Based On Preceding Periods Of Online Glucose Level Control	BU	Priority to case in line 19
46. BU-2013-0031-15	BETAB.022MXD1	MX/a/2020/004660	MX	Offline Glucose Control Based On Preceding Periods Of Online Glucose Level Control	BU	Priority to case in line 19

47.	BU-2015-0053-02	BETAB.023WO	PCT/US2016/046008	PCT	Glucose Control System With Automatic Adaptation Of Glucose Target	BU / GHC	08/08/16
48.	BU-2015-0053-04	BETAB.023CA	2993830	CA	Glucose Control System With Automatic Adaptation Of Glucose Target	BU / GHC	Priority to case in line 30
49.	BU-2015-0053-05	BETAB.023EP	16835748.1	EP	Glucose Control System With Automatic Adaptation Of Glucose Target	BU / GHC	Priority to case in line 30
50.	BU-2015-0053-06	BETAB.023JP	2018-506198	JP	Glucose Control System With Automatic Adaptation Of Glucose Target	BU / GHC	Priority to case in line 30
51.	BU-2015-0053-07	BETAB.023JPD1	2020-090703	JP	Glucose Control System With Automatic Adaptation Of Glucose Target	BU / GHC	Priority to case in line 30

**Amendment to Control Algorithm License Agreement
Between
Trustees of Boston University and Beta Bionics, Inc.**

This Amendment (“**Amendment**”) effective as of February 14, 2022 (the “**Effective Date**”) amends that certain Control Algorithm License Agreement (“**Agreement**”) effective as of December 23, 2015 and last amended as of September 21, 2020 by and between the Trustees of Boston University (the “**University**”) and Beta Bionics, Inc. (“**Licensee**”). University and Licensee may hereafter be referred to as the “**Parties**”.

WHEREAS, the Parties wish to amend certain terms as defined in said Agreement in order to reflect Licensee’s current development plans;

NOW THEREFORE, in accordance with Section 11.02 of the Agreement and for good and valuable consideration, including the mutual obligations undertaken in the Agreement and this Amendment, the receipt and sufficiency of which are hereby acknowledged, the parties agree to amend the Agreement as of the Effective Date as follows:

1. The list of Milestones set forth in the Principal Terms & Milestones List shall be deleted, and the following list of Milestones shall be inserted in its place:

Milestone	Due Date
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***

This Amendment shall become effective as of the Effective Date upon execution by an authorized officer of each party. Except as expressly amended by this Amendment, capitalized terms used in this Amendment which are defined in the Agreement shall have the meanings set forth in the Agreement.

This Agreement may be executed electronically/digitally in compliance with the Massachusetts Uniform Electronic Transactions Act (MUETA) Mass. Gen. Laws ch. 110G and/or The Electronic Signatures In Global And National Commerce Act (ESIGN) 15 USC ch. 96. Persons signing this document agree that, if used, electronic/digital signatures are intended to authenticate this writing and to have the same force and effect as the use of manual signatures.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective duly authorized officers and have duly delivered and executed this Amendment under seal as of the date first set forth above.

TRUSTEES OF BOSTON UNIVERSITY

By: /s/ Gary W. Nicksa
Name: Gary W. Nicksa
Title: SVP and Treasurer
Date: Apr-22-2022

BETA BIONICS, INC.

/s/ Martha Goldberg Aronson
Martha Goldberg Aronson
Interim Chief Executive Officer
May-11-2022

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

CONFIDENTIAL

Execution Version

COLLABORATION AND LICENSE AGREEMENT

This **Collaboration and License Agreement** (this “**Agreement**”), effective as of May 2, 2024 (the “**Effective Date**”) is made by and between **Xeris Pharmaceuticals, Inc.**, having a principal place of business at 1375 W. Fulton Street, Suite 1300, Chicago, IL 60607 (“**Xeris**”), and **Beta Bionics, Inc.**, having a principal place of business at 11 Hughes, Irvine, CA 92618 (“**Beta**”). Each of Beta and Xeris may be referred to in this Agreement individually as a “**Party**” or together as the “**Parties**.”

RECITALS

WHEREAS, Xeris owns or otherwise controls certain intellectual property related to the Reformulated Glucagon (as defined below);

WHEREAS, Beta owns or otherwise controls certain intellectual property related to the Beta Product (as defined below);

WHEREAS, Xeris desires to grant to Beta, and Beta wishes to obtain from Xeris, an exclusive license under the Xeris Technology (as defined below) to develop and commercialize the Glucagon Product (as defined below) in accordance with the terms and conditions set forth below; and

WHEREAS, Beta desires to develop and commercialize the Glucagon Product as Beta’s exclusive glucagon product for use with a Pump System.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and conditions contained in this Agreement, the Parties hereby agree as follows:

AGREEMENT

1. DEFINITIONS.

- 1.1. “**Accounting Standards**” means (a) International Financial Reporting Standards or (b) GAAP, in each case ((a) or (b)), consistently applied throughout the applicable Party’s organization.
- 1.2. “**Acquired Entity**” has the meaning set forth in Section 2.4.3 (Acquisition of a Third Party).
- 1.3. “**Acquirer**” has the meaning set forth in Section 2.4.2 (Change of Control of Beta).
- 1.4. “**Adverse Event**” means any untoward medical occurrence or the deterioration of a pre-existing medical condition in a patient or clinical study subject to whom a pharmaceutical or biologic product has been administered and which does not necessarily have to have a causal relationship with the administration of such pharmaceutical or biologic product. An adverse event includes any unfavorable and unintended sign (*e.g.*, an abnormal laboratory finding, etc.), symptom, or disease temporally associated with the use of such pharmaceutical or biologic product, whether or not considered related to this pharmaceutical or biologic product together, in relation to pharmacovigilance standards, policies, and procedures, with all medical device events, (including incidents, near-incidents, serious injuries, malfunctions and failures) or untoward medical events and events such as suicide, overdose, abuse, misuse, medication errors and other events that may reasonably be related to a pharmaceutical or biologic product.

- 1.5. “**Affiliate**” means, with respect to a Party, any Person, that controls, is controlled by or is under common control with such Party, only for as long as such control exists. For such purpose the term “**control**” means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by holding of 50% or more of the common voting stock or ordinary shares, the right to appoint 50% or more of the directors of, said corporation, company, partnership, joint venture or entity, or by contract or otherwise. [***].
- 1.6. “**Agreement**” has the meaning set forth in the preamble.
- 1.7. “**Alliance Manager**” has the meaning set forth in Section 3.1 (Alliance Managers).
- 1.8. “**Anti-Corruption Laws**” means the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. Travel Act, the U.S. Domestic Bribery Statute (18 U.S.C. 201), and all other Applicable Laws in jurisdictions in which either Party engages in business that govern corruption, bribery, kickbacks, ethical business conduct, fraud, money laundering, and similar matters.
- 1.9. “**Applicable Laws**” means any and all applicable federal, state, local, foreign, or multinational laws, statutes, regulations, judgments, decrees, directives, injunctions, orders, permits of or from any Governmental Authority, including any applicable rules, regulations, guidelines, and requirements of any Regulatory Authority, that are, in any case, in effect from time to time and that govern or otherwise apply to the subject item, including any ordinance, code, resolution, or order having the force or effect of law.
- 1.10. “**Approved Labeling**” means: (a) the Regulatory Authority-approved full prescribing information for a Glucagon Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert (or other Regulatory Authority-approved material provided to patients) that is used with or for a Glucagon Product.
- 1.11. “**Audited Party**” has the meaning set forth in Section 8.7.1 (Audit Right).
- 1.12. “**Auditing Party**” has the meaning set forth in Section 8.7.1 (Audit Right).
- 1.13. “**Bankrupt Party**” has the meaning set forth in Section 2.5 (Bankruptcy).
- 1.14. “**Bankruptcy Code**” means Title 11, United States Code, as amended, and any analogous provisions of the Applicable Laws of any country outside the United States.
- 1.15. “**Beta**” has the meaning set forth in the preamble.
- 1.16. “**Beta Background Know-How**” means any and all Know-How, other than Collaboration Know-How, that is Controlled by Beta or its Affiliates as of the Effective Date or during the Term.
- 1.17. “**Beta Background Patent Rights**” means any and all Patent Rights that are Controlled by Beta or its Affiliates as of the Effective Date or during the Term that disclose or claim any Beta Background Know-How.
- 1.18. “**Beta Background Technology**” means, collectively, Beta Background Know-How and Beta Background Patent Rights.

- 1.19. “**Beta Collaboration Know-How**” means any and all (a) Collaboration Know-How that (i) incorporates or specifically relates to any Beta Background Technology (including all improvements, enhancements or derivatives of any Beta Background Technology) and (ii) (A) does not also incorporate or specifically relate to any Xeris Background Technology, and (B) is not specifically related to a Glucagon Product or the use of a Glucagon Product, and (b) other Collaboration Know-How conceived, generated, created or, in the case of a patentable invention, invented solely by or on behalf of one or more employees, agents, or independent contractors of Beta or its Affiliates or Subcontractors that (i) is not Joint Collaboration Know-How or (ii) within clause (a) of the definition of Xeris Collaboration Know-How.
- 1.20. “**Beta Collaboration Patent Rights**” means any and all Collaboration Patent Rights to the extent claiming Beta Collaboration Know-How.
- 1.21. “**Beta Collaboration Technology**” means, collectively, Beta Collaboration Know-How and Beta Collaboration Patent Rights.
- 1.22. “**Beta Development Activities**” has the meaning set forth in Section 4.4 (Beta Development Activities).
- 1.23. “**Beta Indemnitees**” has the meaning set forth in Section 12.2 (Indemnification by Xeris).
- 1.24. “**Beta Materials**” means the tangible materials provided by or on behalf of Beta to Xeris [***] set forth in the Development Plan, the Clinical Supply Agreement, or the Commercial Supply Agreement, as applicable.
- 1.25. “**Beta Patent Rights**” means the Beta Collaboration Patent Rights and the Beta Background Patent Rights.
- 1.26. “**Beta Product**” means (a) (i) a [***] product [***] that is proprietary to Beta, including [***] as of the Effective Date and (ii) [***] product [***], and (b) [***] of any of the foregoing. The Beta Product excludes the Glucagon Product.
- 1.27. “**Beta Technology**” means, collectively, the Beta Collaboration Technology, the Beta Background Technology, and Beta’s interest in the Joint Collaboration Technology.
- 1.28. “**Breaching Party**” has the meaning set forth in Section 11.3.1 (Material Breach).
- 1.29. “**Business Day**” means a day other than a Saturday, Sunday, or a bank or other public holiday in Chicago, Illinois or Irvine, California, and is not a day on which banking institutions are required by Applicable Law to be closed.
- 1.30. “**Buyer**” has the meaning set forth in Section 1.92 (Net Sales).
- 1.31. “**Calendar Quarter**” means three consecutive calendar months ending on March 31, June 30, September 30, or December 31 during the Term, or the applicable part thereof during the first or last calendar quarter of the Term.

- 1.32. “**Calendar Year**” means each successive period of 12 calendar months commencing on January 1 and ending on December 31 during the Term, or the applicable part thereof during the first or last calendar year of the Term.
- 1.33. “**Change of Control**” means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) any merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning 50% or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction or (c) the sale or transfer to any Third Party, in one or more related transactions, of all or substantially all of such Party’s consolidated assets taken as a whole. For clarity, for purposes of clause (a) of this definition, with respect to a Party, each reference to “Third Party” means a Third Party that is not the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party immediately prior to such acquisition or increase in percentage ownership.
- 1.34. “**Clinical Supply Agreement**” has the meaning set forth in Section 5.1.1 (Clinical Supply Agreement).
- 1.35. “**Clinical Trial**” means any clinical trial in humans, including clinical trials designed to generate data to address a commitment or requirement under a Regulatory Approval.
- 1.36. “**CMO**” means a Third Party contract manufacturing organization.
- 1.37. “**Collaboration Know-How**” means any and all Know-How that is: (a) conceived, generated, created or, in the case of a patentable invention, invented by or on behalf of one or more employees, agents, or independent contractors of a Party or its Affiliates or Subcontractors, either alone or jointly with one or more employees, agents, or independent contractors of the other Party or its Affiliates or Subcontractors, in the conduct of Development Activities under the Development Plan, the planning or preparation for such Development Activities during the Term; or (b) otherwise conceived, generated, created or, in the case of a patentable invention, invented during the Term by or on behalf of either Party, whether solely or jointly, in the performance of activities under this Agreement.
- 1.38. “**Collaboration Patent Rights**” means any and all Patent Rights that claim any Collaboration Know-How. Collaboration Patent Rights do not include any Beta Background Patent Rights or any Xeris Background Patent Rights.
- 1.39. “**Collaboration Technology**” means, collectively, all Collaboration Know-How and all Collaboration Patent Rights. Collaboration Technology does not include any Beta Background Technology or any Xeris Background Technology.
- 1.40. “**Combination Product**” means a Glucagon Product that is sold in the form of a combination containing or comprising such Glucagon Product together with (a) one or more other therapeutically active pharmaceutical agents [***], or (b) any other product, [***] in each case ((a) and (b)) that is [***] (such other [***], “**Other Product**”).

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- 1.41. “**Commercial License**” has the meaning set forth in Section 2.2 (License Grants to Beta).
- 1.42. “**Commercial Supply Agreement**” has the meaning set forth in Section 5.2 (Commercial Supply).
- 1.43. “**Commercial Supply Cost**” has the meaning set forth in Section 5.2 (Commercial Supply).
- 1.44. “**Commercialize**” or “**Commercialization**” means, with respect to any product, any and all activities directed to the marketing, promotion, Packaging and Labeling, distribution, pricing, reimbursement, import, export, offering for sale, and sale of such product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such product regarding the foregoing, including seeking and maintaining any required Pricing Approval, but excluding any activities directed to Manufacturing or Development. “**Commercializing**,” and “**Commercialized**” will be construed accordingly.
- 1.45. “**Commercially Reasonable Efforts**” means with respect to a Party’s obligations under this Agreement, the carrying out of such obligations or tasks with a level of effort and resources consistent with the level of efforts and resources typically used by other similarly situated companies of similar size and similar resources in the Development and Commercialization of a therapeutic product with similar commercial potential and at a similar stage in its research, development or commercial life as the relevant Glucagon Product, taking into account [***].
- 1.46. “[***]” has the meaning set forth in [***].
- 1.47. “[***]” means [***].
- 1.48. “**Confidential Information**” has the meaning set forth in Section 9.1 (Confidential Information).
- 1.49. “**Confidentiality Agreement**” has the meaning set forth in Section 9.2 (Duty of Confidence).
- 1.50. “**Control**,” “**Controls**,” or “**Controlled by**” means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of: (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein; or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Materials, intangible Know-How, or other Intellectual Property, the legal authority or right to grant a license, sublicense,

access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Materials, intangible Know-How or other Intellectual Property on the terms set forth herein, in each case (clauses (a) and (b)) without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense. Notwithstanding the foregoing, a Party will not be deemed to “Control” any Patent Rights, Regulatory Approvals, Regulatory Materials, Know-How, or other Intellectual Property that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of such Change of Control unless (i) immediately prior to the consummation of such Change of Control, such Party or any of its Affiliates also Controlled such Patent Rights, Regulatory Approvals, Regulatory Materials, Know-How, or other Intellectual Property or (ii) after the consummation of such Change of Control, such Party or any of its Affiliates determines to use or uses any such Patent Rights, Regulatory Approvals, Regulatory Materials, Know-How, or other Intellectual Property in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases (clauses (i) and (ii)) such Patent Rights, Regulatory Approvals, Regulatory Materials, Know-How, or other Intellectual Property will be “Controlled” by such Party for purposes of this Agreement.

- 1.51. “**Corporate Mark**” means, with respect to Xeris, the corporate names, trademarks, or logos of Xeris set forth on Schedule 1.51 (Corporate Marks) or otherwise provided by Xeris to Beta from time to time during the Term, in each case, to be used in connection with the Development, Packaging and Labeling, or Commercialization of Glucagon Products in the Field.
- 1.52. “**Covers**” means, with respect to a given Glucagon Product in a given country and a Xeris Background Patent Right or Xeris Collaboration Patent Right that (a) such Patent Right has a Valid Claim in such country that claims such Glucagon Product in the Field and (b) absent ownership of, or a license to, such Patent Right, the sale of such Glucagon Product in the Field in such country would infringe such Valid Claim.
- 1.53. “**CREATE Act**” means the Cooperative Research and Technology Enhancement Act of 2004, 35 U.S.C. § 102(c).
- 1.54. “**Deliverables**” means any and all deliverables specified in the Development Plan to be generated and provided by one Party to the other Party in connection with the performance of the Development Activities, including the development updates prepared and shared by the Parties under Section 4.7.2 (Development Updates).
- 1.55. “**Develop**” or “**Development**” means, with respect to any product, any and all internal and external research, development or regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, nonclinical and preclinical activities, preclinical testing, toxicity studies, and Clinical Trials, and (b) the preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials or to obtain, support, or maintain Regulatory Approval of such product, but excluding any activities directed to Packaging and Labeling, Manufacturing, or Commercialization. Development will include development and regulatory activities (including interacting with Regulatory Authorities) for additional forms, formulations, or indications for a product after receipt of Regulatory Approval of such product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or indication (such as post-marketing studies, observational studies, implementation and management of registries and analysis thereof, in each case if required by any Regulatory Authority in any region in the Territory to support or maintain Regulatory Approval for a product in such region). “**Developing**” and “**Developed**” will be construed accordingly.

- 1.56. “**Development Activities**” has the meaning set forth in Section 4.4 (Beta Development Activities).
- 1.57. “**Development Plan**” has the meaning set forth in Section 4.2 (Development Plan).
- 1.58. “**Development Results**” means any and all (a) data and information generated in the performance of Development Activities under the Development Plan or other Development of the Glucagon Product conducted pursuant to this Agreement; and (b) updates furnished by either Party to the other Party under the Development Plan or related to the Development Activities or other Development of the Glucagon Product conducted pursuant to this Agreement, including any and all descriptions of experiments conducted under the Development Plan or pursuant to this Agreement and corresponding analyses and conclusions.
- 1.59. “**Development Term**” means the time period beginning on the Effective Date and continuing until the date of completion of the Development Activities.
- 1.60. “**Disclosing Party**” has the meaning set forth in Section 9.1 (Confidential Information).
- 1.61. “**Dispute**” has the meaning set forth in Section 13.10.1 (Exclusive Dispute Resolution Mechanism).
- 1.62. “**Dollar**” means the U.S. dollar, and “\$” will be interpreted accordingly.
- 1.63. “**Effective Date**” has the meaning set forth in the preamble.
- 1.64. “**Embargoed Countries**” has the meaning set forth in Section 10.4.3 (Compliance with Laws).
- 1.65. “**Executive Officers**” means, for Beta, [***] or his/her designee, and for Xeris, [***] or his/her designee.
- 1.66. “**Exploit**” means to Develop, have Developed, make, have made, use, have used, perform medical affairs, have performed medical affairs, offer for sale, have offered for sale, sell, have sold, export, have exported, import, have imported, Manufacture, have Manufactured, Commercialize, have Commercialized, or otherwise exploit. “**Exploitation**” and “**Exploiting**” will be construed accordingly.
- 1.67. “**Export Control Laws**” means all Applicable Laws of the United States and applicable jurisdictions, including jurisdictions in which either Party conducts business, which govern exports of controlled commodities, software or technology, embargoes, sanctions and boycotts, including, but not limited to, the Export Administration Regulations, the International Traffic in Arms Regulations, regulations administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury, and International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code.
- 1.68. “**Field**” means chronic glycemic control in diabetes mellitus (*i.e.*, the treatment of hypoglycemia in diabetes mellitus) through the use of a Pump System, excluding single-dose, one-time use form for treatment of severe hypoglycemia and diagnostic uses.

- 1.69. “**First Commercial Sale**” means, with respect to a Glucagon Product in a given country in the Territory, the first commercial sale of such Glucagon Product by Beta, its Affiliate, or Sublicensee to a non-sublicensee Third Party for end use or consumption of such Glucagon Product in the Field in such country following Regulatory Approval of such Glucagon Product in such country. First Commercial Sale of a Glucagon Product in a given country will not include any distribution or other sale prior to the receipt of Regulatory Approval for such Glucagon Product in such country, including Glucagon Product supplied solely for patient assistance, named patient use, compassionate use or other patient access programs, or test marketing programs or non-registrational studies or similar programs or studies, in each case, where the Glucagon Product is [***].
- 1.70. “**Force Majeure**” has the meaning set forth in Section 13.2 (Force Majeure).
- 1.71. “**FTE**” means the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of [***] hours per year) carrying out activities under this Agreement. [***].
- 1.72. “**FTE Rate**” means the amount for an FTE per Calendar Year, which for the Calendar Year ending on December 31, 2024 will be [***] per FTE, pro-rated for the period beginning on the Effective Date and ending on December 31, 2024. [***].
- 1.73. “**GAAP**” means the generally accepted accounting principles in the United States, consistently applied.
- 1.74. “**Generic Product**” means, with respect to a Glucagon Product and on a country-by-country basis, a product whose approval or marketing authorization relies in whole or in part on (a) a prior Regulatory Approval granted to such Glucagon Product, or (b) any data contained or incorporated by reference in a prior Regulatory Approval granted to such Glucagon Product, including a product authorized for sale in the United States pursuant to Section 505(b)(2) or Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), or analogous versions of such Applicable Law in the applicable country, including any amendments and successor law with respect thereto.
- 1.75. “**Glucagon Product**” means a drug product comprising the Reformulated Glucagon for use in a Pump System (and excluding single-dose, one-time use form for treatment of severe hypoglycemia, including [***]).

For clarity, Glucagon Product in finished form shall include its Packaging and Labeling (including any cartridges and vials included in such Packaging and Labeling that are not proprietary to Beta or any of its Affiliates), but shall not include any component of any Beta Product.

- 1.76. **“Governmental Authority”** means any applicable (a) government of any country or territory, (b) any nation, state, province, county, city, or other political subdivision thereof, or (c) any arbitral or supranational body or (d) government authority, court, tribunal, arbitrator, agency, department, legislative body, commission, or other instrumentality of any of the foregoing.
- 1.77. **“Indemnified Party”** has the meaning set forth in Section 12.3.1 (Notice).
- 1.78. **“Indemnifying Party”** has the meaning set forth in Section 12.3.1 (Notice).
- 1.79. **“Infringement”** has the meaning set forth in Section 7.4.1 (Notification).
- 1.80. **“Infringement Action”** has the meaning set forth in Section 7.4.2 (Xeris Right to Enforce).
- 1.81. **“Intellectual Property”** means all Patent Rights, rights to inventions, copyrights, design rights, trademarks, trade secrets, Know-How, and all other intellectual property (whether registered or unregistered) and all applications and rights to apply for any of the foregoing, anywhere in the world.
- 1.82. **“Joint Collaboration Know-How”** means any and all Collaboration Know-How that (a) is solely related to (i) a Glucagon Product or (ii) the use of a Glucagon Product or (b) incorporates or relates to both the (i) Beta Background Technology (including all improvements, enhancements or derivatives of any Beta Background Technology) and (ii) Xeris Background Technology (including all improvements, enhancements or derivatives of any Xeris Background Technology).
- 1.83. **“Joint Collaboration Patent Rights”** means any and all Collaboration Patent Rights to the extent claiming Joint Collaboration Know-How.
- 1.84. **“Joint Collaboration Technology”** means all Joint Collaboration Know-How and Joint Collaboration Patent Rights.
- 1.85. **“JSC”** has the meaning set forth in Section 3.2 (Joint Steering Committee).
- 1.86. **“Know-How”** means any invention, conception, discovery, creation, improvement, or modification, whether or not patentable, including processes, methods, formulas, technical information, materials, compositions, formulas, skills, ideas, designs, drawings, procedures, biological materials, assays, compounds, techniques, computer software and documentation, specifications, results, Development Results, data and know-how (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data, and know-how, including study designs and protocols), in written, electronic, or any other form, including all laboratory notebooks and other written materials containing or comprising the same; *provided* that Know-How does not include Patent Rights.
- 1.87. **“Knowledge”** means [***] of
(a) [***] and (b) [***].

- 1.88. “**Late Stage Xeris Development Activities**” means the Xeris Development Activities set forth in the Development Plan following the Stage 1 Xeris Development Activities.
- 1.89. “**Liabilities**” has the meaning set forth in Section 12.1 (Indemnification by Beta).
- 1.90. “**Losses**” means liability, damage, loss, or expense (including reasonable attorneys’ fees and expenses).
- 1.91. “**Manufacture**” means activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostic), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding activities directed to Development, Packaging and Labeling, or Commercialization. “**Manufacturing**” and “**Manufactured**” will be construed accordingly.
- 1.92. “**Manufacturing Transfer Date**” has the meaning set forth in Section 5.2.2 (Commercial Supply Agreement).
- 1.93. “**Minimally Acceptable Results**” has the meaning set forth in Section 8.2 (Milestone Payments).
- 1.94. “**Net Sales**” means the gross amount invoiced or received by Beta and its Affiliates and Sublicensees (each of the foregoing, a “**Seller**”) to independent, unrelated persons (including Third Party distributors) (“**Buyers**”) in *bona fide* arm’s length transactions with respect to a Glucagon Product, less the following deductions, in each case, to the extent [***].
- 1.95. “**Non-Bankrupt Party**” has the meaning set forth in Section 2.5 (Bankruptcy).

- 1.96. “**Non-Breaching Party**” has the meaning set forth in Section 11.3.1 (Material Breach).
- 1.97. “**Non-Publishing Party**” has the meaning set forth in Section 9.5 (Publication).
- 1.98. “**Other Product**” has the meaning set forth in Section 1.40 (Combination Product).
- 1.99. “**Out-of-Pocket Costs**” means, with respect to activities to be performed under the Development Plan or otherwise under this Agreement, the [***].
- 1.100. “**Packaging and Labeling**” means primary, secondary, or tertiary packaging and labeling of a Glucagon Product (in its commercial packaging presentation) for sale or use in a country, including the Approved Labeling and insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed, or graphic materials accompanying such Glucagon Product and any brand security or anti-counterfeiting measures included in the packaging elements for such Glucagon Product considered to be part of the finished packaged Glucagon Product, and all testing and release thereof.
- 1.101. “**Party**” and “**Parties**” have the meaning set forth in the preamble.
- 1.102. “**Patent Challenge**” has the meaning set forth in Section 11.3.3 (Patent Challenge).
- 1.103. “**Patent Rights**” means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor’s certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing, and (f) United States and foreign counterparts of any of the foregoing.
- 1.104. “**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.
- 1.105. “**Pharmacovigilance Agreement**” means the pharmacovigilance agreement for the Glucagon Product to be entered into pursuant to Section 6.1.2 (Pharmacovigilance Agreement).
- 1.106. “**Phase 2 Clinical Trial**” means any Clinical Trial for a pharmaceutical or biologic product that would satisfy the requirements of 21 C.F.R. § 312.21(b), or its foreign equivalent, as may be amended from time to time, or any analogous Clinical Trial described or defined in Applicable Laws.
- 1.107. “**Phase 2 Supply Cost**” has the meaning set forth in Section 5.1.2(a) (Phase 2 Supply).
- 1.108. “**Phase 3 Clinical Trial**” means any Clinical Trial for a pharmaceutical or biologic product that would satisfy the requirements of 21 C.F.R. § 312.21(c), or its foreign equivalent, as may be amended from time to time, or any analogous Clinical Trial described or defined in Applicable Laws.

- 1.109. “**Phase 3 Supply Cost**” has the meaning set forth in Section 5.1.2(b) (Phase 3 Supply).
- 1.110. “**Pricing Approval**” means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical or biologic products, the receipt (or, if required to make such authorization, approval or determination effective, the publication) of such reimbursement authorization or pricing approval or determination (as the case may be).
- 1.111. “**Prohibited Party Lists**” has the meaning set forth in Section 10.4.3 (Compliance with Laws).
- 1.112. “**Prosecution**” or “**Prosecute**” means the preparation, filing, prosecution, maintenance, and defense of any Patent Rights and any proceeding before the United States Patent and Trademark Office (including the Patent Trial and Appeal Board) and foreign patent offices in connection with Patent Rights, including reissues, reexaminations, *inter partes* review, supplemental examination, appeals, interferences, derivation proceedings, oppositions, post grant reviews and any judicial or other appeals of the foregoing.
- 1.113. “**Publishing Party**” has the meaning set forth in Section 9.5 (Publication).
- 1.114. “**Pump System**” means a bihormonal pump product or system for glycemic control, including a Beta Product, or a single hormonal pump product or system for glycemic control.
- 1.115. “**Receiving Party**” has the meaning set forth in Section 9.1 (Confidential Information).
- 1.116. “**Reformulated Glucagon**” means any glucagon product that is (a) reformulated [***].
- 1.117. “**Regulatory Approval**” means any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority, in each case that are necessary for the marketing and sale of a pharmaceutical or biologic product in a country or group of countries (including all Pricing Approvals required for sale of a product in such country or group of countries), or for pharmacovigilance of such pharmaceutical or biologic products, in a country or group of countries.
- 1.118. “**Regulatory Authority**” means any applicable government regulatory authority involved in granting Regulatory Approvals or any other approvals for the Exploitation of products, including the United States Food and Drug Administration and the European Medicines Agency.
- 1.119. “**Regulatory Exclusivity**” means, with respect to any country in the Territory and a Glucagon Product, an exclusive marketing protection, other than Patent Right protection, granted by a Regulatory Authority for such Glucagon Product in such country which confers an exclusive Commercialization period during which period Beta or its Affiliates or Sublicensees have the exclusive right to market and sell such Glucagon Product in the Field in such country through a regulatory exclusivity right.
- 1.120. “**Regulatory Materials**” means all regulatory applications, submissions, notifications, communications, correspondences, registrations, approvals, and other filings made to, received from, or otherwise conducted with a Regulatory Authority in order to Develop, Manufacture, Commercialize, or otherwise Exploit a product in a particular country or jurisdiction, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority.

- 1.121. **“Royalties”** has the meaning set forth in Section 8.3.1 (Royalty Rates).
- 1.122. **“Royalty Report”** has the meaning set forth in Section 8.3.3 (Royalty Reports; Royalty Payments).
- 1.123. **“Royalty Term”** has the meaning set forth in Section 8.3.2 (Royalty Term).
- 1.124. **“Sell-Off Period”** has the meaning set forth in Section 11.4.6 (Return or Destruction of Materials).
- 1.125. **“Seller”** has the meaning set forth in Section 1.92 (Net Sales).
- 1.126. **“Stage 1 Xeris Development Activities”** means the Xeris Development Activities set forth in the section of the Development Plan entitled “Stage 1.”
- 1.127. **“Subcontractor”** means a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement, and with respect to Xeris, solely for the performance of Development Activities, other Development activities, and Manufacturing activities under this Agreement.
- 1.128. **“Sublicensee”** means a Third Party, other than a Subcontractor, that is granted a sublicense by Beta under the license grants in Section 2.2 (License Grants to Beta).
- 1.129. **“Term”** has the meaning set forth in Section 11.1 (Term).
- 1.130. **“Terminated Region”** means (a) [***], as applicable, by Beta pursuant to Section 11.2 (Termination for Convenience), or (b) all countries in the Territory if this Agreement is terminated (i) in its entirety or for [***] by Beta pursuant to Section 11.2 (Termination for Convenience) or (ii) in its entirety by Xeris pursuant to Section 11.3.3 (Patent Challenge) or by either Party pursuant to Section 11.3.1 (Termination for Cause) or Section 11.3.4 (Insolvency).
- 1.131. **“Territory”** means worldwide, excluding any Terminated Region.
- 1.132. **“Third Party”** means any Person other than Xeris, Beta, and their respective Affiliates.
- 1.133. **“Upfront Payment”** has the meaning set forth in Section 8.1 (Upfront Payment).
- 1.134. **“Valid Claim”** means (a) a claim of any issued and unexpired Patent Right whose validity, enforceability, or patentability has not been revoked or otherwise affected by: (i) irretrievable lapse, abandonment, revocation, dedication to the public, disclaimer or other admission of invalidity, unenforceability or non-patentability; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, government authority, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a pending claim of an unissued, pending patent application that has been filed and continues to be prosecuted in good faith and that has not been (i) cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken and (ii) pending for more than [***] from its earliest priority date. For clarity, a holding, finding, or decision being final and unappealable means a holding, finding or decision from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari or a similar appeal the consideration of which is subject to the discretion of the higher court) can be or has been taken.

- 1.135. “**VAT**” means value added tax, sales taxes, consumption taxes and other similar taxes imposed or required by Applicable Law.
- 1.136. “**Withholding Taxes**” has the meaning set forth in Section 8.8.3 (Withholding Tax; Cooperation).
- 1.137. “**Xeris**” has the meaning set forth in the preamble.
- 1.138. “**Xeris Background Know-How**” means any and all Know-How, other than Collaboration Know-How, that is Controlled by Xeris or its Affiliates as of the Effective Date or during the Term.
- 1.139. “**Xeris Background Patent Rights**” means any and all Patent Rights that are Controlled by Xeris or its Affiliates as of the Effective Date or during the Term that disclose or claim any Xeris Background Know-How, including the Xeris Formulation Patents.
- 1.140. “**Xeris Background Technology**” means, collectively, Xeris Background Know-How and Xeris Background Patent Rights. For clarity, the Xeris Background Technology includes the Xeris Technology.
- 1.141. “**Xeris Collaboration Know-How**” means any and all (a) Collaboration Know-How, other than Joint Collaboration Know-How, that (i) incorporates or specifically relates to any Xeris Background Technology (including all improvements, enhancements or derivatives of any Xeris Background Technology) and (ii) does not also incorporate or specifically relate to any Beta Background Technology, and (b) other Collaboration Know-How conceived, generated, created or, in the case of a patentable invention, invented solely by or on behalf of one or more employees, agents, or independent contractors of Xeris or its Affiliates or Subcontractors that (i) is not Joint Collaboration Know-How or (ii) within clause (a) of the definition of Beta Collaboration Know-How.
- 1.142. “**Xeris Collaboration Patent Rights**” means any and all Collaboration Patent Rights to the extent claiming Xeris Collaboration Know-How.
- 1.143. “**Xeris Collaboration Technology**” means, collectively, Xeris Collaboration Know-How and Xeris Collaboration Patent Rights.
- 1.144. “**Xeris Development Activities**” has the meaning set forth in Section 4.3 (Xeris Development Activities).
- 1.145. “**Xeris Formulation Patents**” means [***].
- 1.146. “**Xeris Indemnitees**” has the meaning set forth in Section 12.1 (Indemnification by Beta).
- 1.147. “**Xeris Patent Rights**” means the Xeris Background Patent Rights and the Xeris Collaboration Patent Rights.
- 1.148. “**Xeris Technology**” means, collectively, the Xeris Background Technology and any and all Xeris Collaboration Technology, and Xeris’ interest in the Joint Collaboration Technology.

2. LICENSE GRANTS.

2.1. License Grant to Xeris. Subject to the terms and conditions of this Agreement, Beta, on behalf of itself and its Affiliates, hereby grants and agrees to grant to Xeris and its Affiliates a non-exclusive, fully paid, royalty-free, non-transferrable (except to the extent permitted under Section 13.1 (Assignment)), license, with the right to grant sublicenses only to Subcontractors engaged in accordance with Section 4.10 (Subcontractors), under the Beta Technology that is necessary or reasonably useful for the conduct of the Xeris Development Activities or other Development activities pursuant to this Agreement in the Field in the Territory, solely to conduct such Xeris Development Activities and such other Development in the Field in the Territory.

2.2. License Grants to Beta.

2.2.1. Development and Commercialization. Subject to the terms and conditions of this Agreement, Xeris, on behalf of itself and its Affiliates, hereby grants to Beta an exclusive (even as to Xeris and its Affiliates, subject to Section 2.6 (Retained Rights)), non-transferrable (except to the extent permitted under Section 13.1 (Assignment)) license under the Xeris Technology that is necessary or reasonably useful for (a) the conduct of the Development Activities and other Development of the Glucagon Products in the Field in the Territory during the Development Term solely to conduct such Development Activities and such other Development in the Field in the Territory, and (b) following the Development Term, the Development and Commercialization of the Glucagon Products in the Field in the Territory to Develop and Commercialize the Glucagon Products in the Field in the Territory. The license set forth in the foregoing (a) is sublicensable only to [***], and the license set forth in the foregoing (b) is sublicensable through multiple tiers in accordance with Section 2.3 (Sublicensing).

2.2.2. Manufacturing. Subject to the terms and conditions of this Agreement, commencing upon the Manufacturing Transfer Date, Xeris, on behalf of itself and its Affiliates, hereby grants to Beta an exclusive, non-transferrable (except to the extent permitted under Section 13.1 (Assignment)) license under the Xeris Technology that is necessary or reasonably useful for the Manufacture of the Glucagon Products in the Field in the Territory solely to Manufacture the Glucagon Products in the Field in the Territory. The license set forth in this Section 2.2.2 (Manufacturing) is sublicensable through multiple tiers in accordance with Section 2.3 (Sublicensing).

2.2.3. Corporate Marks. Subject to the terms and conditions of this Agreement, Xeris hereby grants to Beta a non-exclusive, royalty-free, sublicensable in accordance with Section 2.3 (Sublicensing), license under the Corporate Marks of Xeris (a) during the Term, solely for the Development, Packaging and Labeling, and Commercialization of the Glucagon Products in the Field in the Territory and (b) commencing upon the Manufacturing Transfer Date and continuing throughout the Term, solely for the Manufacture of the Glucagon Products in the Field in the Territory, in each case ((a) or (b)), to the extent permitted under Applicable Law. In the exercise of the license set forth in this Section 2.2.3 (Corporate Marks) (a) Beta shall, and shall require its Affiliates and any Sublicensee to, use the Corporate Marks of Xeris in a manner consistent with Xeris' reasonable trademark usage policy and guidelines that are provided to Beta in writing from time to time, and in a manner that does not otherwise diminish the value of or dilute such Corporate Marks of Xeris; (b) Beta shall, upon Xeris' reasonable request from time to time, provide samples of the Packaging and Labeling, advertising or promotional materials that use such Corporate

Marks; and (c) Beta shall promptly notify Xeris if it becomes aware of an actual or threatened (in writing) infringement of the Corporate Marks of Xeris in connection with activities contemplated under this Agreement. All goodwill arising from the use by Beta, its Affiliates and Sublicensees of the Corporate Marks of Xeris belongs to and will inure to Xeris or its applicable Affiliate.

2.3. Sublicensing.

- 2.3.1. Right to Sublicense.** Subject to the terms of Section 2.3.2 (Sublicense Requirements) and Section 2.2 (License Grants to Beta), Beta may not grant sublicenses (including the right to grant further sublicenses in multiple tiers) under the licenses it receives under Section 2.2 (License Grants to Beta) to any of its Affiliates or any Sublicensee without [***].
- 2.3.2. Sublicense Requirements.** Beta will ensure that all sublicenses granted to Affiliate and Sublicensees pursuant to Section 2.3.1 (Right to Sublicense) (a) are consistent with the applicable terms of this Agreement, including (i) [***], (ii) [***], (iii) to the extent [***], and (iv) [***]. Beta will remain responsible and liable for the performance of all Sublicensees under their respective sublicensed rights to the same extent as if such activities were conducted by Beta. In no event will any sublicense relieve Beta of any of its obligations under this Agreement. No later than [***] following the execution of any sublicense agreement by Beta of the licenses Beta receives under Section 2.2 (License Grants to Beta), which sublicense grants Commercialization rights for a Glucagon Product to a Third Party (but excluding agreements with any distributors, contract sales forces or other subcontractors, even if such agreements contain a sublicense), Beta will deliver to Xeris a copy of any executed sublicense agreement (redacted as necessary to protect confidential information that is not necessary for Xeris to confirm compliance with this Agreement).

2.4. Exclusivity.

- 2.4.1. Non-Compete Covenant.** From the Effective Date until the expiration or termination of this Agreement in its entirety, except as set forth in Section 2.4.2 (Change of Control of a Party), neither Party nor its Affiliates will (either alone or with, for or on behalf of any Third Parties, including granting any license or other right to any Third Parties), directly or indirectly, Develop, Commercialize, or otherwise Exploit any Competing Product in the Field in the Territory.
- 2.4.2.** [***]

2.4.3. [***]

- 2.5. **Bankruptcy.** All rights and licenses to Intellectual Property granted under or pursuant to this Agreement by a Party to the other are and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the Bankruptcy Code. The Parties agree that the Parties and their respective sublicensees, as sublicensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the Bankruptcy Code and any foreign counterpart thereto. The Parties further agree that upon commencement of a bankruptcy proceeding by or against a Party (the “**Bankrupt Party**”) under the Bankruptcy Code, the other Party (the “**Non-Bankrupt Party**”) will be entitled to a complete duplicate of, or complete access to (as the Non-Bankrupt Party deems appropriate), all such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments of such intellectual property will be promptly delivered to the Non-Bankrupt Party (a) upon any such commencement of a bankruptcy proceeding and upon

written request by the Non-Bankrupt Party, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, upon the rejection of this Agreement by or on behalf of the Bankrupt Party and upon written request by the Non-Bankrupt Party. The Bankrupt Party (in any capacity, including debtor in possession) and its successors and assigns (including any trustee) agree not to interfere with the exercise by the Non-Bankrupt Party or its Affiliates of its rights and licenses to such intellectual property and such embodiments of intellectual property in accordance with this Agreement, and agrees to assist the Non-Bankrupt Party and its Affiliates in reasonable respects in obtaining such intellectual property and such embodiments of intellectual property in the possession or control of Third Parties as are reasonably necessary or desirable for the Non-Bankrupt Party to exercise such rights and licenses in accordance with this Agreement. The foregoing provisions are without prejudice to any rights the Non-Bankrupt Party may have arising under the Bankruptcy Code or other Applicable Laws.

- 2.6. Retained Rights.** All rights not expressly granted by a Party to the other Party under this Agreement are retained by such Party and may be used by such Party for any purpose that does not violate the terms of this Agreement. Without limiting the foregoing, Xeris hereby expressly retains the right under the Xeris Technology to (a) perform the Xeris Development Activities for the Glucagon Products in the Territory in accordance with the Development Plan, (b) Manufacture the Glucagon Products in the Territory until the Manufacturing Transfer Date, (c) Manufacture the Reformulated Glucagon for use outside the Field, and (d) perform Xeris' other obligations under this Agreement.
- 2.7. No Implied License.** Neither Party grants to the other Party any rights or licenses in any Patent Rights, Know-How, copyrights, or other intellectual property or other proprietary rights of such Party, except as specifically set forth in this Agreement.

3. GOVERNANCE.

- 3.1. Alliance Managers.** Promptly after the Effective Date, each Party will appoint a representative to act as its alliance manager under this Agreement (each, an "**Alliance Manager**") by providing written notification to the other Party. The Alliance Managers will serve as representatives of their respective Party on the JSC and assist the JSC in performing its oversight responsibilities. In particular, each Alliance Manager will (a) identify and bring disputes to the attention of the JSC (or the Parties, as applicable) in a timely manner and be the point of first referral in all matters of conflict resolution; (b) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties regarding issues that arise in the performance of the Development Activities; (c) plan and coordinate cooperative efforts and internal and external communications; and (d) take responsibility for ensuring that governance activities, such as the conduct of JSC meetings and drafting and securing approval of meeting minutes, occur as set forth in this Agreement and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed. Each Party's Alliance Manager will have appropriate experience, knowledge and authority within such Party's organization with respect to the responsibilities allocated to Alliance Managers under this Agreement. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.
- 3.2. Joint Steering Committee.**
- 3.2.1. Establishment.** [***] the Parties will establish a joint steering committee ("**JSC**") to oversee the activities of the Parties under this Agreement, as further described in Section 3.2.2 (Responsibilities).

- 3.2.2. Responsibilities.** The JSC will oversee and monitor the Parties' collaboration on the Development of the Glucagon Product under the Development Plan and Xeris' supply of the Glucagon Products to Beta under this Agreement. Within such scope the JSC will, subject to Section 3.3 (JSC Decision; Dispute Resolution of JSC Matters) and Section 3.4 (Limits on Decision Making Authority):
- (a) oversee the research and Development the Glucagon Product under the Development Plan;
 - (b) review, discuss and approve amendment to the Development Plan in accordance with Section 4.2.2 (Amendments to the Development Plan);
 - (c) review and discuss the status, progress, and results of the Parties' Development Activities;
 - (d) review Development Results and other updates submitted to the JSC pursuant to this Agreement;
 - (e) oversee Xeris' Manufacturing of the Glucagon Product under this Agreement; and
 - (f) discuss and attempt to resolve Manufacturing-related issues [***]
- 3.2.3. Composition.** The JSC will consist of an equal number of Xeris representatives and Beta representatives, in each case including the Alliance Manager of such Party, with such number of representatives to be agreed by the Parties. Each Party will designate its non-Alliance Manager JSC representatives within [***] after the Effective Date. A Party may change one or more of its JSC representatives from time to time in its sole discretion, effective upon written notice to the other Party of such change. A Party's representatives to the JSC will have appropriate experience, knowledge and authority within such Party's organization with respect to the responsibilities allocated to the JSC under this Agreement.
- 3.2.4. Meetings.**
- (a) The JSC will meet at least once every Calendar Quarter during the Development Term (or such other frequency as agreed to by the Parties) in accordance with a schedule agreed to by the Parties. No later than [***] prior to any meeting of the JSC, the Alliance Managers will jointly prepare and circulate an agenda for such meeting; *provided, however,* that either Party may propose additional topics to be included on such agenda, prior to such meeting so long as the other Party consents to such later additional of such agenda items. The JSC may meet in person or by means of teleconference, internet conference, videoconference, or other similar communications equipment. Each Party will bear its own travel, lodging and telecommunication expenses related to participation in and attendance at such meetings by its JSC representatives.
 - (b) Each Party may invite non-voting observers to attend any JSC meeting; *provided* that any such observers who are not employees of either Party or its Affiliates may only attend with the prior written consent of the other Party, which consent will not be unreasonably withheld. All such observers will be bound by confidentiality and non-use obligations similar to those contained in Article 9 (Confidentiality; Publication), or which are otherwise acceptable to both Parties.

- (c) Xeris' Alliance Manager and Beta's Alliance Manager will alternate responsibility for preparing written reasonably detailed draft minutes of each meeting of the JSC, and will provide the draft minutes to the Alliance Manager of the other Party within [***] after such meeting to coordinate review and approval by such other Party's JSC members, which such JSC members will provide any comments within [***] of receipt of such written draft minutes. The Parties will limit the content of such minutes to factual statements regarding any actions proposed or decisions made by the JSC. The Parties will refrain from including any opinions or other extraneous content in such minutes. The JSC minutes will become official when approved by the JSC at the next regularly scheduled JSC meeting, it being understood that actionable items approved and directed by the JSC during any meeting of the JSC will commence notwithstanding the timing of formal approval of JSC minutes for such meeting. Any discrepancies or disputes with respect to the content of JSC minutes will be resolved by the JSC.

3.3. JSC Decision; Dispute Resolution of JSC Matters. All JSC decisions shall be made by unanimous vote, with each Party's representatives collectively having one vote. The presence of at least one of each Party's JSC representatives constitutes a quorum for the conduct of business at any JSC meeting, and no vote of the JSC may be taken without a quorum present. If, after reasonable discussion and good faith consideration of each Party's view on a particular matter within the purview of the JSC, the JSC representatives of the Parties cannot reach agreement on such matter, then such matter will be escalated to the Executive Officers of each Party. The Executive Officers will meet promptly after referral of a matter to them and will negotiate in good faith to resolve such matter during a period of up to [***] following such referral. In the event that such Executive Officers are unable to resolve such matter, [***].

3.4. Limitations on Decision-Making. Notwithstanding any provision to the contrary set forth in this Agreement, [***] will have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with the terms and conditions of under this Agreement; or (c) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement. In addition, notwithstanding any provision to the contrary set forth in this Agreement, [***].

4. DEVELOPMENT.

- 4.1. Development Rights.** Except for the Development Activities allocated to Xeris in the Development Plan or requested to be conducted by Beta pursuant to the Development Plan, Beta, either itself or with or through Affiliates or Third Party(ies), will have the sole right to Develop (and will control all aspects of the Development of) Glucagon Products in the Field in the Territory, subject to the terms of this Agreement. For the avoidance of doubt, during the applicable Development Term, Beta will not conduct any material Development of the Glucagon Products other than the Beta Development Activities set forth in the Development Plan, unless mutually agreed by the Parties.
- 4.2. Development Plan.**
- 4.2.1. Initial Development Plan.** During the Development Term, the Parties will perform development activities in accordance with a written plan prepared by the Parties, together with estimated timelines for each of the foregoing activities (such plan, as amended pursuant to this Agreement the “**Development Plan**”). The initial Development Plan is attached hereto as Schedule 4.2 (Initial Development Plan). Xeris will have the right to make operational decisions with respect to the Xeris Development Activities and Beta will have the right to make operational decisions with respect to the Beta Development Activities, in each case to be performed under the Development Plan and in accordance with the terms of this Agreement. Each Party will discuss any of its operational decisions with respect to the Development Activities that may impact the estimated timelines in the Development Plan with the other Party. In the event of any conflict between the terms of the Development Plan and the terms of this Agreement, the terms of this Agreement will control.
- 4.2.2. Amendments to the Development Plan.** Either Party may propose to the JSC amendments to the then-current Development Plan from time to time, as such Party deems appropriate; *provided* that if Beta proposes any amendment that includes Xeris activities not contemplated by the then-current Development Plan, then such proposed amendment will also include financial terms for Xeris’ conduct of such proposed activities. If approved by the JSC, the amended Development Plan will become effective for the applicable period on the date approved by the JSC (or such other date as the JSC will specify). Any JSC-approved amended Development Plan will supersede the then-current Development Plan for the applicable period.
- 4.3. Xeris Development Activities.** During the Development Term, Xeris, itself or with or through a Subcontractor engaged in accordance with Section 4.10 (Subcontractors), will use Commercially Reasonable Efforts to (a) perform all activities allocated to it under the Development Plan, (b) prepare and deliver all Deliverables in accordance with the Development Plan, and (c) prepare and deliver all reports in accordance with Section 4.7.2 (Development Updates) (collectively, the “**Xeris Development Activities**”). Without limiting the foregoing, Xeris shall provide to Beta all Know-How within the Xeris Technology that is necessary to enable Beta to exercise the licenses set forth in Section 2.2 (License Grants to Beta), which Know-How will be mutually agreed upon by the Parties in a tech transfer plan [***].

Xeris will perform all Xeris Development Activities in accordance with the Development Plan and otherwise in accordance with this Agreement and will [***] to meet the estimated timelines for such Xeris Development Activities specified therein. In the event of any anticipated material delay, Xeris will promptly notify Beta. Xeris will be responsible for all internal and Out-of-Pocket Costs incurred by Xeris in the performance of the Stage 1 Xeris Development Activities. With respect to the Late Stage Xeris Development Activities and any additional activities set forth on Schedule 4.3 (Additional Xeris Development Activities), Beta will reimburse Xeris for its and its Affiliates' documented and reasonable internal expenses at the FTE Rate and its or its Affiliates' documented and reasonable Out-of-Pocket Costs incurred in the performance of such activities on a pass-through basis, *provided* that any Out-of-Pocket Cost that [***]. For the avoidance of doubt, any Phase 2 Supply Costs and Phase 3 Supply Costs will not be deemed Xeris Development Activities for purposes of such reimbursement. Xeris may perform any of the Xeris Development Activities itself or through an Affiliate or a Subcontractor engaged in accordance with Section 4.10 (Subcontractors), but subject to Section 4.9 (Beta Materials) with respect to transfer of Beta Materials. Xeris will not be required to perform any obligation that is not set forth in the Development Plan or in this Agreement.

- 4.4. Beta Development Activities.** During the Development Term, Beta, itself or with or through a Subcontractor engaged in accordance with Section 4.10 (Subcontractors), will use Commercially Reasonable Efforts to (a) perform all activities allocated to it under the Development Plan; (b) prepare and deliver all Deliverables in accordance with the Development Plan, and (c) prepare and deliver all reports in accordance with Section 4.7.2 (Development Updates) (collectively, the “**Beta Development Activities**” and, together with the Xeris Development Activities, the “**Development Activities**”). Beta will perform all Beta Development Activities in accordance with the Development Plan and otherwise in accordance with this Agreement and will [***] to meet the estimated timelines for such Beta Development Activities specified therein. Beta will be responsible for all internal and external costs and expenses incurred by Beta in the performance of the Beta Development Activities. Beta may perform any of the Beta Development Activities itself or through an Affiliate or a Subcontractor engaged in accordance with Section 4.10 (Subcontractors). Beta will not be required to perform any obligation that is not set forth in the Development Plan or in this Agreement.
- 4.5. Diligence.** Beta, either itself or with or through Affiliates or Third Party(ies), will use Commercially Reasonable Efforts to Develop, and to seek Regulatory Approval for, one Glucagon Product in each of [***].
- 4.6. Additional Work by Xeris.** To the extent not otherwise set forth in this Agreement or in the Development Plan, at the reasonable request of Beta, Xeris will provide to Beta any of the services set forth in Schedule 4.6 (Additional Work) in connection with Beta's Development of the Glucagon Product and Beta will pay to Xeris the amounts set forth on Schedule 4.6 (Additional Work) for such activities. For all such additional services where such fees are not captured on Schedule 4.6 (Additional Work) (and excluding the Phase 2 Supply Costs and Phase 3 Supply Costs), [***].

4.7. Development Records and Reports.

4.7.1. Records. During the Development Term and for [***] thereafter, the Parties will maintain written and electronic records of all Development Activities or other Development of the Glucagon Product performed by or on behalf of such Party, including the Development Results, in sufficient detail and in good scientific manner, appropriate for scientific, patent, and regulatory purposes and in compliance with Applicable Laws with respect to activities intended to be submitted in Regulatory Materials, which records will be complete and properly reflect all work done and results achieved in the performance of its Development Activities or other Development of the Glucagon Product by or on behalf of such Party.

4.7.2. Development Updates.

- (a) **Xeris Development Updates.** Xeris will keep Beta reasonably informed on the status, progress, and results of all Xeris Development Activities by providing the JSC with a report containing summaries of the Development Results each Calendar Quarter in the format specified in the Development Plan or other format to be agreed by the Parties. Following the end of the Development Term or in the event of any termination of this Agreement during the Development Term after Xeris has commenced the Xeris Development Activities, Xeris will promptly provide to Beta a final report of all data and other results generated pursuant to the Xeris Development Activities.
- (b) **Beta Development Updates.** Beta will keep Xeris reasonably informed on the status, progress, and results of all Beta Development Activities and other Development of the Glucagon Product conducted pursuant to this Agreement by providing the JSC with a report containing summaries of the Development Results each Calendar Quarter in the format specified in the Development Plan or other format to be agreed by the Parties. In the event of any termination of this Agreement during the Development Term after Beta has commenced the Beta Development Activities, Beta will promptly provide to Xeris a final report of all data and other results generated pursuant to the Beta Development Activities and other Development of the Glucagon Product conducted pursuant to this Agreement.
- (c) **Development Reports.** On a country-by-country basis, following [***] and until [***], promptly following the end of each Calendar Quarter, Beta will provide Xeris with a high-level written summary of any Development activities or interactions with Regulatory Authorities resulting from Beta's, its Affiliate's, or its Sublicensee's (a) [***] and (b) [***], in each case ((a) and (b)), (i) since the last written summary and (ii) that are planned for the next Calendar Quarter. Each high-level summary will provide sufficient detail for Xeris to assess Beta's compliance with its diligence obligations under this Agreement.
- (d) **Access to Data.** Upon the reasonable written request of either Party, the other Party will grant such Party access at a mutually convenient time during normal business hours and subject to appropriate confidentiality protocols to applicable databases or records maintained by the other Party in order for such requesting Party to review the raw data underlying any Development Results; provided that, such request includes a detailed description explaining why such access is necessary.

- 4.8. Performance of Development Activities.** Each Party will perform all of its Development Activities (a) with reasonable care and skill consistent with industry standards, (b) in accordance with all Applicable Laws and (c) in accordance with the terms of this Agreement (including the Development Plan). Each Party will use suitably qualified and trained employees and research assistants to perform its Development Activities in a professional manner and will provide or procure all necessary materials and facilities reasonably required to conduct such Development Activities.
- 4.9. Beta Materials.** To facilitate the conduct of the Development Activities, Beta will provide the agreed quantity of Beta Materials to be used for the performance of the Xeris Development Activities [***]. The quantity of Beta Materials and related activities will be described in the Development Plan. Beta may perform its obligations set forth under this Section 4.9 (Beta Materials) itself or through a Subcontractor, including a CMO, *provided* that the terms of Section 4.10 (Subcontractors) will apply to any such Subcontractor retained by Beta. Except as set forth in the foregoing, Xeris shall not transfer any Beta Materials provided by Beta to any Third Party without Beta's prior written consent. The Beta Materials will remain the sole property of Beta, will be used only in the performance of the Xeris Development Activities in accordance with the Development Plan or as otherwise agreed in writing by the Parties, may not be transferred or permitted to be transferred to any Third Party (other than Subcontractors) without Beta's prior written consent, and, in any case, will not be used in research or testing involving human subjects. Xeris shall not make or attempt to make any derivatives of or modifications to the Beta Materials. Xeris shall not, and shall cause any transferees not to, copy, disassemble, reverse engineer, deconstruct, or attempt to disassemble, reverse engineer or deconstruct, or in any way determine the structure of the Beta Materials for any purpose whatsoever, other than as necessary for the conduct of the Xeris Development Activities.
- 4.10. Subcontractors.** Each Party will have the right to engage Subcontractors to perform its obligations under the Development Plan or other Development of the Glucagon Product conducted pursuant to this Agreement to the extent such Subcontractors are specified in the Development Plan or otherwise agreed to in writing by the other Party (such agreement not to be unreasonably withheld, delayed or conditioned); *provided* that, in each case any such permitted Subcontractor is bound by written obligations of confidentiality and non-use at least as restrictive with the obligations in this Agreement and has agreed to assign to such Party (or exclusively license to such Party, with the right to grant sublicenses through multiple tiers) all inventions or other Intellectual Property developed or invented by such Subcontractor in the course of performing such subcontracted work. Each Party will remain responsible and primarily and fully liable for the performance of any subcontracted activities in accordance with this Agreement and for each Subcontractor's compliance with the terms of this Agreement.

5. MANUFACTURE AND SUPPLY.

5.1. Clinical Supply.

- 5.1.1. Clinical Supply Agreement.** [***] the Parties will negotiate in good faith and enter into a clinical supply agreement for the supply to Beta of Glucagon Products (together with the corresponding quality agreement, the "**Clinical Supply Agreement**"), pursuant to which Beta will purchase from Xeris Beta's (and its Affiliates' and Sublicensees') requirements of the Glucagon Products as necessary for Beta

to fulfill its obligations or exercise its rights under this Agreement related to the Development of the Glucagon Product in the Field in the Territory. The terms of the Clinical Supply Agreement will (a) be consistent with the terms of this Agreement, (b) incorporate customary supply terms including remedies in the event of supply shortfalls, shipment and delivery terms for the Glucagon Products, and (c) [***], to the extent applicable to the supply of Glucagon Products for use in the Field in the Territory for Development purposes. Pursuant to the Clinical Supply Agreement and subject to Beta satisfying its obligations set forth in Section 5.3 (Beta Supply Obligations), Xeris or its Affiliates will supply Glucagon Products to Beta [***].

5.1.2. Clinical Supply Costs. The Clinical Supply Agreement shall contain, among other terms, the following terms [***]

(a) [***]

(b) [***]

5.2. Commercial Supply.

5.2.1. Manufacture of Glucagon Product by Beta. Upon the Manufacturing Transfer Date, Beta may Manufacture or have Manufactured the Glucagon Products for its and its Affiliates' and Sublicensees' requirements for Commercialization in the Field in the Territory in accordance with the terms and conditions set forth in the Commercial Supply Agreement.

5.2.2. Commercial Supply Agreement. At a time to be agreed by the Parties, the Parties will negotiate in good faith and enter into a commercial supply agreement (together with the corresponding quality agreement, the "**Commercial Supply Agreement**"). The Commercial Supply Agreement will incorporate customary terms and conditions for such agreements, including: (a) the circumstances under which the Parties may agree to transfer the right and obligation to Manufacture or have Manufactured Glucagon Products for Commercialization by Beta in the Field and the Territory (the date upon which such transfer is agreed to, the "**Manufacturing Transfer Date**"); (b) Xeris' transfer, and a

timeline for such transfer, to Beta (or an Affiliate or a CMO selected by Beta) of all Know-How within Xeris Technology that is necessary to enable Beta to Manufacture or have Manufactured the Glucagon Product for Commercialization in the Field in the Territory, such transfer to be initiated upon the Manufacturing Transfer Date; (c) the cost of the Glucagon Product Manufactured by or on behalf of Xeris and provided to Beta, [***] (the “**Commercial Supply Cost**”); and (d) shipment and delivery terms for the Glucagon Product. The terms of the Commercial Supply Agreement will be consistent with the terms of this Agreement, and will not [***], to the extent applicable to the supply of Glucagon Products for use in the Field in the Territory for Commercial purposes.

- 5.3. Beta Supply Obligations.** Beta will supply the necessary quantity of Beta Materials to be used in the Manufacture of Glucagon Products in accordance with the Clinical Supply Agreement and the Commercial Supply Agreement. The quantity of supply and related activities will be described in the Clinical Supply Agreement or the Commercial Supply Agreement, as applicable. Beta may perform its obligations set forth under this Section 5.3 (Beta Supply Obligations) itself or through a CMO, *provided* that the terms of Section 4.10 (Subcontractors) will apply to any such CMO retained by Beta.
- 6. REGULATORY; COMMERCIALIZATION.**
- 6.1. Regulatory.**
- 6.1.1. Regulatory Responsibility.** Beta will have sole responsibility for and control of the preparation, submission, and maintenance of all Regulatory Materials and obtaining Regulatory Approvals with respect to the Glucagon Products in the Field in the Territory and will have sole control over all interactions with the applicable Regulatory Authority with respect thereto; *provided*, that Xeris will maintain a Drug Master File for the Glucagon Product at the United States Food and Drug Administration in accordance with 21 C.F.R. § 314.420, and will provide a Letter of Authorization to Beta that permits Beta to reference such Drug Master File. Xeris will reasonably cooperate with Beta, at Beta’s reasonable request and at Beta’s cost to the extent such cooperation is not otherwise included in the services set forth in Schedule 4.6 (Additional Work) and provided by Xeris to Beta in accordance with Section 4.6 (Additional Work), with respect to any regulatory matters related to the Glucagon Products. [***]. Beta will own all rights, title, and interests in and to any and all Regulatory Materials and Regulatory Approvals for Glucagon Products and, as between the Parties, all such Regulatory Materials and Regulatory Approvals will be held in the name of Beta.
- 6.1.2. Pharmacovigilance Agreement.** Beta and Xeris shall enter into a Pharmacovigilance Agreement for each country in the Territory or, if the Parties mutually agree, one Pharmacovigilance Agreement for all countries in the Territory [***] to ensure that an appropriate system for pharmacovigilance activities is in place to assume responsibility and liability for the Glucagon Product in accordance with all Applicable Laws. Beta and Xeris shall observe the procedures and notification requirements as set out in the applicable Pharmacovigilance Agreement with respect to Adverse Events and to any other regulatory and reporting matters.

- 6.1.3. Responsibilities of the Qualified Person.** Each Party shall designate a suitably qualified person responsible for compliance with its pharmacovigilance obligations. The qualified person of each Party shall be responsible for: (a) the collection of Adverse Event reports for the Glucagon Product reported to the other Party and their respective Affiliates; (b) notification to other Party of such reports in accordance with the terms of the Pharmacovigilance Agreement; (c) the timely submission of individual written reports to the relevant Regulatory Authority in compliance with Applicable Laws; (d) answering pharmacovigilance related questions; and (e) all notifications and communications with any Regulatory Authority related to pharmacovigilance, as appropriate or required by each Party, as applicable.
- 6.2. Commercialization.**
- 6.2.1. General.** Beta, either itself or with or through Affiliates or Third Party(ies), will have the sole right to Commercialize (and will control all aspects of the Commercialization of) Glucagon Products in the Field in the Territory, subject to the terms of this Agreement.
- 6.2.2. Diligence.** Beta, either itself or with or through Affiliates or Third Party(ies), will use Commercially Reasonable Efforts to Commercialize each Glucagon Product in the Field in [***]
- 7. INTELLECTUAL PROPERTY.**
- 7.1. Inventorship of Intellectual Property.** All determinations of inventorship under this Agreement will be in accordance with U.S. patent law. Ownership will follow inventorship, except as otherwise provided in Section 7.2 (Ownership).
- 7.2. Ownership.**
- 7.2.1. Xeris Ownership.** As between the Parties, Xeris owns (or will own to the extent arising after the Effective Date) all rights, title, and interest in and to the Xeris Background Technology and the Xeris Collaboration Technology. Beta (for itself and its Affiliates) hereby assigns to Xeris (or, to the extent assignment is not permissible, grants to Xeris an exclusive, irrevocable, fully paid-up, sublicensable license or right to practice under) any rights, title, and interest of Beta or its Affiliates in any Xeris Collaboration Technology conceived, generated, created or, in the case of a patentable invention, invented by or on behalf of one or more employees, agents, or independent contractors of Beta or its Affiliates. Beta will provide Xeris all reasonable assistance and cooperation, at Xeris' request and expense, to perfect and enforce Xeris' rights in any and all countries, in and to Xeris Collaboration Technology.
- 7.2.2. Beta Ownership.** As between the Parties, Beta owns (or will own to the extent arising after the Effective Date) all rights, title, and interest in and to the Beta Background Technology and the Beta Collaboration Technology. Xeris (for itself and its Affiliates) hereby assigns to Beta (or, to the extent assignment is not permissible, grants to Beta an exclusive, irrevocable, fully paid-up, sublicensable license or right to practice under) any rights, title,

and interest of Xeris or its Affiliates in any Beta Collaboration Technology conceived, generated, created or, in the case of a patentable invention, invented by or on behalf of one or more employees, agents, or independent contractors of Xeris or its Affiliates. Xeris will provide Beta all reasonable assistance and cooperation, at Beta's request and expense, to perfect and enforce Beta's rights in any and all countries, in and to Beta Collaboration Technology.

- 7.2.3. Joint Ownership.** The Parties will jointly own all rights, title, and interest in and to the Joint Collaboration Technology. Each Party (for itself and its Affiliates) hereby assigns to the other Party (or, to the extent assignment is not permissible, grants to the other Party such license or right to practice under) such rights, title, and interest of such Party or its Affiliates in any Joint Collaboration Technology conceived, generated, created or, in the case of a patentable invention, invented by or on behalf of one or more employees, agents, or independent contractors of such Party or its Affiliates as necessary or appropriate to vest joint ownership of the Joint Collaboration Technology in Xeris and Beta. Each Party will provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in order to perfect and enforce such other Party's rights in any and all countries, in and to the Joint Collaboration Technology. Subject to the terms and conditions set forth in this Agreement including Article 2 (License Grants), each Party will have an equal, undivided interest in and to the Joint Collaboration Technology. The restrictions set forth in this Section 7.2.3 (Joint Ownership) will survive expiration or termination of this Agreement for any reason.
- 7.2.4. Disclosure of Inventions.** Each Party will promptly disclose to the other Party all potentially patentable Collaboration Know-How that it develops or invents, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such inventions), including all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating thereto. Each Party will also respond promptly to reasonable requests from the other Party for additional information relating to such inventions within the Collaboration Know-How.
- 7.2.5. Personnel Obligations.** Each employee, agent, or independent contractor of a Party or its respective Affiliates or Subcontractors performing activities under this Agreement will, prior to commencing such activities, be bound by invention assignment obligations: (a) promptly reporting any invention, discovery, process, or other Intellectual Property comprising Collaboration Know-How developed, invented, or filed during any performance under this Agreement; (b) presently assigning to the applicable Party all of his or her rights, title, and interests in and to such Collaboration Know-How; (c) cooperating in the preparation, filing, prosecution, maintenance, and enforcement of any Collaboration Patent Rights claiming such Collaboration Know-How; and (d) performing all acts (including good faith testimony by affidavit, declaration, in-person, or other proper means) and signing, executing, acknowledging, and delivering any and all documents required for effecting the obligations and purposes of this Agreement and to support any effort by a Party to establish, perfect, defend, or enforce its rights in and to any Collaboration Technology. It is understood and agreed that any such invention assignment agreement need not reference or be specific to this Agreement.

7.3. Patent Prosecution.

- 7.3.1. Beta Patent Rights.** As between the Parties, Beta will have the sole right, but not the obligation, to control the Prosecution of the Beta Patent Rights. Beta will be responsible for and pay all costs and expenses incurred in connection with the Prosecution of the Beta Patent Rights.
- 7.3.2. Xeris Patent Rights.** As between the Parties, Xeris will have the sole right, but not the obligation, to control the Prosecution of the Xeris Patent Rights. Xeris will be responsible for and pay all costs and expenses incurred in connection with the Prosecution of the Xeris Patent Rights. Xeris shall keep Beta reasonably and regularly informed of the status of the Xeris Patent Rights and shall promptly provide Beta with copies of all material correspondence received from any patent authority in connection therewith. In addition, Xeris shall promptly provide Beta with drafts of all proposed material filings and material correspondence to any patent authority with respect to the Xeris Patent Rights for Beta's review and comment prior to the submission of such proposed filings and correspondence, and shall reasonably consider Beta's comments in good faith.
- 7.3.3. Joint Collaboration Patent Rights.** During the Term, Beta will have the first right to Prosecute any Joint Collaboration Patent Rights, *provided* that Beta shall keep Xeris reasonably and regularly informed of the status of the Joint Collaboration Patent Rights and shall promptly provide Xeris with copies of all material correspondence received from any patent authority in connection therewith. In addition, Beta shall promptly provide Xeris with drafts of all proposed material filings and material correspondence to any patent authority with respect to the Joint Collaboration Patent Rights for Xeris' review and comment at least [***] prior to the submission of such proposed filings and correspondence, and shall reasonably incorporate Xeris' comments in good faith to the extent they relate to the Xeris Technology. Subject to the remainder of this Section 7.3.3 (Joint Collaboration Patent Rights), Beta will be responsible for and pay all costs and expenses incurred in connection with the Prosecution of the Joint Collaboration Patent Rights. If, during the Term, Beta decides that it is no longer interested in Prosecuting a particular Joint Collaboration Patent Right, then it will promptly provide written notice to Xeris of such decision at least [***] prior to any filing or payment due date or any other due date that requires action in order to avoid loss of rights in connection with such Patent Right. Xeris may, upon written notice to Beta, assume the responsibility Prosecuting such Patent Right. In such event, Xeris will be responsible for and pay all costs and expenses incurred in connection with such Joint Collaboration Patent Right. Notwithstanding the foregoing, each Party will have the right to exercise its full rights to Joint Collaboration Patent Rights upon expiration or termination of this Agreement.
- 7.3.4. Patent Term Extensions.**
- (a) Xeris shall cooperate with Beta, at Beta's request, in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available), supplemental protection certificates or any other Patent Right extensions that are now or become available in the future, wherever applicable in any country in the Territory for any Xeris Patent Rights with respect to Glucagon Products. If elections with respect to obtaining such patent term extensions are to be made, Beta shall have the right to make such elections with respect to the Glucagon Product.

- (b) Beta shall have the sole right to make decisions regarding, and to apply for, patent term extensions (including any pediatric exclusivity extensions as may be available), supplemental protection certificates or any other Patent Right extensions that are now or become available in the future, wherever applicable in any country in the Territory for Beta Patent Rights and Joint Collaboration Patent Rights with respect to Glucagon Products.

7.3.5. Cooperation. The non-prosecuting Party will (a) obtain and deliver to the prosecuting Party any necessary documents for the prosecuting Party to exercise its rights to prepare, prosecute, defend, and maintain all Patent Rights pursuant to this Section 7.3 (Patent Prosecution), (b) render all signatures that will be necessary in connection with all such patent filings, and (c) assist the prosecuting Party in all other reasonable ways that are necessary for the issuance of those Patent Rights for which such prosecuting Party is responsible, as well as for the preparation, prosecution, defense, and maintenance of such Patent Rights.

7.4. Patent Enforcement.

7.4.1. Notification. Each Party will promptly notify the other in the event of any actual, potential, or suspected infringement of any Joint Collaboration Patent Right, Xeris Patent Right or Beta Patent Right through the making, having made, using, selling, offering for sale or importing of any product that would reasonably be expected to compete with any Glucagon Product in the Field, or any alleged or threatened assertion of non-infringement, invalidity or unenforceability of any such Patent Right in connection with such activities (an “**Infringement**”) of which it becomes aware. Each Party will provide any available evidence of such Infringement with such notification.

7.4.2. Xeris Right to Enforce. Xeris will have the sole right, but not the obligation, to initiate an infringement, misappropriation, or other appropriate suit (an “**Infringement Action**”) against any Infringement with respect to any Xeris Patent Rights at Xeris’ sole discretion and at Xeris’ sole cost and expense.

7.4.3. Beta Right to Enforce. Beta will have the sole right, but not the obligation, to initiate an Infringement Action against any Infringement with respect to any Beta Patent Rights at Beta’s sole discretion and at Beta’s sole cost and expense. In addition, Beta will have the first right, but not the obligation, to initiate an Infringement Action against any Infringement with respect to any Joint Collaboration Patent Rights at Beta’s sole discretion and at Beta’s sole cost and expense. During the Term, if Beta fails to initiate an Infringement Action against any Infringement with respect to any Joint Collaboration Patent Right within [***] after written notice of such Infringement is first provided by a Party under Section 7.4.1 (Notification), then Xeris will have the right to initiate and control an Infringement Action with respect to such Infringement at Xeris’ sole discretion and at Xeris’ sole cost and expense.

7.4.4. Collaboration. Each Party will provide to the enforcing Party reasonable assistance with respect to any Infringement Action brought under this Section 7.4 (Patent Enforcement), at such enforcing Party’s request and expense, including to be named in such action if required by Applicable Laws to pursue such action. The enforcing Party will not settle any claim, suit, or action that is brought under this Section 7.4 (Patent Enforcement) in any manner that would (a) impose any liability or obligation on, or admit fault of, such other Party, (b) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the rights and licenses granted to the other Party under this Agreement, or (c) otherwise materially adversely affect the applicable Patent Rights, including the licenses or other rights granted to such other Party hereunder, in each case without the prior written consent of the other Party (which consent will not be unreasonably withheld, delayed, or conditioned).

- 7.4.5. Expenses and Recoveries.** Except as expressly provided otherwise in this Section 7.4 (Patent Enforcement), the enforcing Party bringing a claim, suit, or action under this Section 7.4 (Patent Enforcement) will be solely responsible for any expenses incurred by such Party as a result of such claim, suit, or action. Each Party shall keep the other informed of developments in any Infringement Action with respect to any Infringement, including, to the extent permissible by Applicable Law, the status of any settlement negotiations and the terms of any offer related thereto. If such Party recovers monetary damages in such claim, suit, or action, then such recovery will be allocated (a) first to the reimbursement of any expenses incurred by the enforcing Party, (b) second to the reimbursement of any expenses incurred by the other Party, and (c) third, any remaining amounts will be retained by the enforcing Party.
- 7.5. Defense Against Claims of Infringement of Third Party Patents.** Each Party will give the other Party written notice in the event such Party has knowledge of any actual or potential infringement of any Third Party Patent Rights through the making, having made, using, selling, offering for sale, or importing of any Glucagon Product in the Field. If a Third Party asserts that a Patent Right or other right owned or otherwise controlled by it is or has been infringed by the manufacture, use, sale, offer for sale or import of a Glucagon Product in the Field, then the Party first obtaining knowledge of such a claim will promptly provide the other Party written notice of such claim along with the related facts in reasonable detail. In such event, unless the Parties otherwise agree, as between the Parties, notwithstanding any right of the Indemnifying Party to control the defense of a Third Party claim as set forth in Section 12.3, [***] will have the first right, but not the obligation, at its expense, to control the defense of such claim with respect to such Glucagon Product in the Field. If [***] does not wish to defend such claim, or wishes to cease defending such claim, it will notify [***] of such decision at least [***] before any deadline for any action or filing that is required in order to preserve any rights. Thereafter, [***] will have the right, but not the obligation, at its expense, to control the defense of such claim. Each Party will cooperate with the defending Party, at the defending Party's reasonable request and expense, and will have the right to be represented separately by counsel of its own choice, but at its own expense. The defending Party will also control settlement of such claim; *provided, however*, that no settlement will be entered into without the prior consent of the other Party if such settlement would adversely affect the rights and benefits of, or impose or adversely affect any obligations on, the other Party, such consent not to be unreasonably withheld, delayed, or conditioned.
- 7.6. Trademarks.** Beta will have the right to select, and will be free, in its sole discretion, to use and to register in any trademark office in the Territory, any trademark for use with a Glucagon Product in the Field (other than the Corporate Marks, for which Xeris will retain the registration rights). As between the Parties, Beta will own all right, title and interest in and to any such trademarks adopted by Beta for use with Glucagon Products in the Field (other than the Corporate Marks), and will have sole authority and responsibility (as between the Parties) for the registration, filing, maintenance and enforcement thereof.
- 7.7. CREATE Act.** Notwithstanding any provision to the contrary in this Article 6 (Intellectual Property), neither Party will have the right to make an election under the CREATE Act when exercising its rights under this Article 6 (Intellectual Property) without the prior written consent of the other Party. In the event such consent is provided, the Parties will use reasonable efforts to cooperate and coordinate their activities with respect to any submissions, filings, or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

8. FINANCIAL TERMS.

- 8.1. **Upfront Payment.** Within [***] following the Effective Date, Beta will pay Xeris a non-refundable, non-creditable, one-time payment of \$500,000 (the “**Upfront Payment**”).
- 8.2. **Milestone Payment.** Within [***] following the earlier of (i) [***] and (ii) [***], Beta shall be obligated to pay to Xeris a non-refundable, non-creditable, one-time milestone payment of \$3,000,000 (the “**Milestone Payment**”).
- 8.3. **Royalties.**

- 8.3.1. **Royalty Rates.** As further consideration for the rights granted to Beta under this Agreement, during the applicable Royalty Term, Beta will pay to Xeris, for each Calendar Year, a tiered royalty (the “**Royalties**”) based on cumulative Net Sales of the Glucagon Products in the Field in the Territory, at the royalty rates set forth in the table below:

	[***]		[***]
	[***]		[***]
	[***]		[***]
	[***]		[***]

For clarity, following the First Commercial Sale of the first Glucagon Product in the Field in the Territory, once the cumulative Net Sales of all Glucagon Products in the Field in the Territory reach [***], the royalty rate for all Glucagon Products in the Field in the Territory shall be [***] for the remainder of the Royalty Term, subject to any reductions set forth in Section 8.3.3 (Royalty Reductions; Royalty Floor).

- 8.3.2. **Royalty Term.** On a Glucagon Product-by-Glucagon Product and country-by-country basis, Beta’s royalty payment obligation will commence beginning on the date of the First Commercial Sale of such Glucagon Product in such country and expire on the later of: (a) [***] after the First Commercial Sale of such Glucagon Product in such country; (b) the date on which there is no longer a Valid Claim of (i) a Xeris Patent Right or (ii) Joint Collaboration Patent Right, in each case ((i) and (ii)), that Covers such Glucagon Product in such country and (c) the expiration or termination of Regulatory Exclusivity for such Glucagon Product in such country (such period, the “**Royalty Term**”). After expiration of the Royalty Term, no further Royalties will be payable in respect of sales of such Glucagon Product in such country and thereafter all licenses and rights granted by Xeris to Beta under this Agreement with respect to such Glucagon Product in such country will automatically become fully paid-up, royalty-free, perpetual, and irrevocable licenses.

8.3.3. Royalty Reductions; Royalty Floor.

- (a) **Lack of Valid Claim.** Subject to Section 8.3.3(d) (Cumulative Royalty Reductions), if at any time during the Royalty Term of a Glucagon Product in a country in the Territory, there is no Valid Claim of any Xeris Patent Right or Joint Collaboration Patent Right that Covers the composition of matter of such Glucagon Product in such country, then the applicable royalty rates in effect with respect to such Glucagon Product in such country as specified in Section 8.3.1 (Royalty Rates) for such Glucagon Product in such country shall be [***] for the remainder of the Royalty Term.
- (b) **Generic Product.** On a Glucagon Product-by-Glucagon Product and country-by-country basis, if, during any [***] Calendar Quarters during the Royalty Term for such Glucagon Product in such country, [***] Generic Products are being marketed or sold in such country and such Generic Products, by unit equivalent volume, exceed [***] of the aggregate market share of such Glucagon Product together with all such Generic Products (based on the number of units of such glucagon Product and such Generic Products in the aggregate sold in such country prior to such [***] Calendar Quarters, as reported by a well-known reporting service mutually agreed by the Parties), then, subject to Section 8.3.3(d) (Cumulative Royalty Reductions), the royalty rate with respect to such Glucagon Product in such country will be [***] of the applicable rate set forth in Section 8.3 (Royalties) for the remainder of the Royalty Term.
- (c) **Third Party Rights.** If Beta enters into any agreement with a Third Party to obtain a license or other rights to [***] from such Third Party that is necessary for the Commercialization or, [***], the Manufacture of a Glucagon Product in the Field in a country, including any such license or other agreement entered into by Beta in connection with any settlement pursuant to Section 7.5 (Defense Against Claims of Infringement of Third Party Patents), then, subject to subject to Section 8.3.3(d) (Cumulative Royalty Reductions), Beta may reduce royalties otherwise payable to Xeris for Net Sales of such Glucagon Product in the Field in such country by [***] of the [***] paid to such Third Party pursuant to such agreement in such Calendar Quarter.
- (d) **Cumulative Royalty Reductions.** In no event will the royalties due to Xeris in any Calendar Quarter with respect to any Glucagon Product in the Field in the Territory be [***] as a result of the operation of the reductions contemplated by Section 8.3.3(a) (Lack of Valid Claim), Section 8.3.3(b) (Generic Product), and Section 8.3.3(c) (Third Party Rights); [***].

- 8.3.4. Royalty Reports; Royalty Payments.** During the Royalty Term, following the First Commercial Sale of a Glucagon Product, Beta will, within [***] following the end of each Calendar Quarter, provide to Xeris a written report for such Calendar Quarter setting forth, on a Glucagon Product-by-Glucagon Product and country-by-country basis, (i) the amount of Net Sales and gross sales of each Glucagon Product made by Beta and its Affiliates and Sublicensees during such Calendar Quarter for which Royalties are payable, (ii) the number of Glucagon Products sold, (iii) Royalties (in Dollars) due on Net Sales for such Calendar Quarter, and (iv) the exchange rate used to calculate the Royalty amount (“**Royalty Report**”). Beta will pay all Royalties due under this Agreement with respect to a Calendar Quarter [***].
- 8.4. Payment Date.** Any payments that are not paid on or before the date such payments are due under this Agreement will bear interest at an annual rate equal to [***] except that, with respect to any disputed payments, no interest payment will be due on the disputed amount until such dispute is resolved and the interest that will be payable thereon will be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.
- 8.5. No Refunds.** Except as expressly provided herein, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.
- 8.6. Payment Method and Exchange Rate.** All amounts payable under this Agreement will be in Dollars. Each payment to be made to Xeris under this Agreement will be made by bank wire transfer in immediately available funds to the bank account designated in writing by Xeris. In the case of sales outside the United States, payments received by Beta in a currency other than Dollars will be converted to their Dollar equivalent using a rate of exchange which corresponds to the rate of exchange for such currency reported in *The Wall Street Journal*, Internet U.S. Edition at www.wsj.com as of the last day of the applicable reporting period (or, if unavailable on such date, the first date thereafter on which such rate is available).
- 8.7. Audits.**
- 8.7.1. Audit Right.** Each Party (the “**Auditing Party**”) may, upon the Auditing Party’s request and at the Auditing Party’s expense (except as provided for herein), audit, during ordinary business hours, the books and records of the other Party (the “**Audited Party**”) and its Affiliates and the correctness of any payment made or required to be made (including (a) with respect to Xeris as the Audited Party, any costs in connection with Xeris Development Activities or any additional work to be reimbursed by Beta, the Phase 2 Supply Costs, the Phase 3 Supply Costs, and transfer prices for supply of the Glucagon Product as set forth in the Commercial Supply Agreement and Commercial Supply Costs, and (b) with respect to Beta as the Audited Party, the royalties payable under Section 8.3 (Royalties)), and any report underlying any such payment (or lack thereof), pursuant to the terms of this Agreement, and any other payments due by Beta to Xeris under this Agreement. Such audit shall be performed by an independent certified public accounting firm of internationally recognized standing selected by the Auditing Party and reasonably acceptable to the Audited Party. The accounting firm will enter a confidentiality agreement

reasonably acceptable to the Audited Party governing the use and disclosure of the Audited Party's information disclosed to such firm, and such firm will disclose to the Auditing Party only whether information provided by the Audited Party was accurate and not the specific details concerning any discrepancies.

- 8.7.2. Limitations.** In respect of each audit of the Audited Party's and its Affiliates' books and records: (a) the Audited Party and each of its Affiliates may be audited only [***] per Calendar Year, (b) no books and records for any given Calendar Year may be audited more than [***], but the Audited Party's and its Affiliates' books and records will still be made available if such records impact another Calendar Year being audited, and (c) the Auditing Party will only be entitled to audit books and records of the Audited Party and its Affiliates from the [***] Calendar Years prior to the Calendar Year in which the audit request is made.
- 8.7.3. Audit Notice.** In order to initiate an audit for a particular Calendar Year, the Auditing Party will provide to the Audited Party at least [***] prior written notice of such audit. The Audited Party will, and will ensure that its Affiliates, reasonably accommodate the scheduling of such audit. The Audited Party will, and will ensure that its Affiliates, provide the Auditing Party with full access to the applicable books and records and otherwise reasonably cooperate with such audit.
- 8.7.4. Payments.** If the final result of the audit shows any under-reporting or underpayment, or overpayment by Beta, that under-reporting, underpayment or overpayment will be reported to Xeris, and (a) Beta will remit any underpayment (together with interest at the rate set forth in Section 8.4 (Payment Date)) to Xeris within [***] after receiving the audit report and (b) Beta may credit any overpayment to Xeris against future payments owed by Beta to Xeris under this Agreement (and if no further payments are due, such overpayment will be refunded by Xeris at the request of Beta within [***] of the receipt of the request). Further, if the audit for any Calendar Year shows an under-reporting or underpayment by Beta, or any over-reporting by Xeris, for that Calendar Year in excess of [***] of the amounts properly determined, the Audited Party will reimburse the Auditing Party for its documented and reasonable internal expenses at the FTE Rate and its documented and reasonable Out-of-Pocket Costs in connection with such audit, which reimbursement will be made within [***] after receiving appropriate invoices and other support for such audit-related costs.

8.8. Taxes.

- 8.8.1. Taxes on Income.** Each Party will be liable for any and all taxes, duties, and other levies applied by a Governmental Authority of any country or territory on payments made to such Party by the other Party under this Agreement.
- 8.8.2. VAT on Payments.** All payments due under this Agreement are exclusive of VAT. If any VAT is chargeable in respect of amounts payable pursuant to this Agreement, VAT will be charged at the applicable rate required by Applicable Law and the Party making such payment will pay the VAT amount on receipt of a VAT invoice in the appropriate form. Beta shall only be responsible for any VAT not recoverable by Xeris (or the principal or representative member of any VAT group of which it forms part), subject to Xeris (or the representative member) taking all reasonable steps to recover such VAT as may be practicable.

8.8.3. Withholding Tax; Cooperation. In the event that any payments due to a Party are subject to any taxes, duties, levies, imposts, assessments, deductions, fees, or other similar charges required by Applicable Laws to be paid to a Governmental Authority (“**Withholding Taxes**”), the paying Party may deduct the amount of such Withholding Taxes from the applicable payment otherwise payable to the other Party. In such event, the paying Party will pay the taxes to the proper taxing authority and send evidence of the payment of such obligation to the other Party following that payment. Any amount of Withholding Taxes withheld and remitted by a paying Party to a relevant Governmental Authority constitutes payment to the other Party in satisfaction of the paying Party’s obligations under this Article 8 (Financial Terms), as if the amount were paid directly to the other Party. For the avoidance of doubt, in the event that any payment due to a Party is subject to such Withholding Tax, the paying Party will not have any obligation to pay to such Party any amount exceeding the amount of such payment minus the amount of such Withholding Tax. Xeris will provide Beta any tax forms (including an Internal Revenue Service Form W-9) that may be reasonably necessary in order for Beta to determine whether to withhold tax on any such payments or to withhold tax on any such payments at a reduced rate under an applicable bilateral income tax treaty. Each Party will use reasonable efforts to assist the other Party in claiming exemptions from, or reductions in, such deductions or withholdings as permitted by Applicable Laws, including any treaty in effect. The paying Party will be responsible for withholding and remitting Withholding Taxes to Governmental Authorities in accordance with this Section 8.8 (Taxes) and Applicable Laws.

9. CONFIDENTIALITY; PUBLICATION.

- 9.1. Confidential Information.** As used herein, the term “**Confidential Information**” means any non-public or proprietary technical, scientific, business or other information that is disclosed by one Party (the “**Disclosing Party**”) to the other Party (the “**Receiving Party**”) in connection with this Agreement, including any such information that is disclosed by or on behalf of the Disclosing Party or any of its Affiliates or otherwise made available to the Receiving Party or any of its Affiliates or permitted recipients, including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in oral, written, electronic or other form. Additionally, Confidential Information includes:
- 9.1.1.** the terms and conditions of this Agreement, the Deliverables, the Development Results, the Joint Collaboration Know-How, the Joint Collaboration Patent Rights, and the Development Plan, which will be considered Confidential Information of both Parties;
 - 9.1.2.** all Beta Background Technology and Beta Collaboration Technology, which will be considered the Confidential Information of Beta; and
 - 9.1.3.** all Xeris Background Technology and Xeris Collaboration Technology, which will be considered the Confidential Information of Xeris.
- 9.2. Duty of Confidence.** Subject to Section 9.3 (Exceptions) and Section 9.4 (Authorized Disclosures), the Receiving Party will (a) hold in confidence the Confidential Information of the Disclosing Party and refrain from disclosing the Confidential Information of the Disclosing Party to any Third Party without the express written consent of the Disclosing Party, (b) will safeguard the Disclosing Party’s Confidential Information using at least the same degree of care with which the Receiving Party holds its own confidential information (but in no event less than a reasonable degree of care),

and (c) not use or disclose the Confidential Information of the Disclosing Party for any purpose other than to exercise the Receiving Party's rights and perform the Receiving Party's obligations under this Agreement or as expressly permitted by any other written agreement between the Parties. Without limiting the foregoing, each Receiving Party will permit only those employees, contractors, or authorized agents of the Receiving Party who (i) have a need to know the Disclosing Party's Confidential Information, (ii) are similarly bound by confidentiality, non-disclosure and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement, and (iii) who are informed of the confidential nature of such information access to such Confidential Information. The Receiving Party will be responsible for any breach by such employers, contractors, or agents of this Article 9 (Confidentiality; Publication). The Receiving Party's obligations under this Article 9 (Confidentiality; Publication) will continue throughout the Term and for [***] following the termination or expiration of this Agreement. The Mutual Nondisclosure Agreement by and between Beta and Xeris dated May 30, 2023 (the "**Confidentiality Agreement**") is hereby superseded and replaced by this Agreement, and all information disclosed pursuant to such Confidentiality Agreement prior to the Effective Date will be protected and governed by this Article 9 (Confidentiality; Publication). Each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

9.3. Exceptions. Information will not be Confidential Information of a Disclosing Party, and the confidentiality and non-use obligations set forth in Section 9.1 (Confidential Information) and Section 9.2 (Duty of Confidence) will not apply to such information, to the extent that the Receiving Party can demonstrate through competent evidence that such information:

- 9.3.1.** was lawfully known by the Receiving Party without restriction prior to disclosure under this Agreement or the Confidentiality Agreement;
- 9.3.2.** was lawfully disclosed to the Receiving Party by a Third Party without an obligation of confidentiality;
- 9.3.3.** was already in or subsequently entered the public domain through means other than an unauthorized disclosure or other breach of this Agreement or the Confidentiality Agreement by the Receiving Party; or
- 9.3.4.** was independently developed by the Receiving Party without knowledge or use of or access to the Confidential Information of the Disclosing Party.

Any combination of features or disclosures will not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

9.4. Authorized Disclosures. In addition to the exceptions contained in Section 9.2 (Duty of Confidence) and Section 9.3 (Exceptions), a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent that such disclosure is reasonably necessary in the following instances:

- 9.4.1.** the Prosecution of any Xeris Patent Rights, Joint Collaboration Patent Rights or Beta Patent Rights, in each case as contemplated by this Agreement;

9.4.2. in connection with Regulatory Materials to the extent necessary to obtain or maintain Regulatory Approval to Develop, Manufacture or Commercialize the Glucagon Products in the Field as contemplated by this Agreement;

9.4.3. disclosure of the existence and terms of this Agreement, Development Results, the status of the Development Activities, and the status of Development, Manufacture or Commercialization of Glucagon Products to actual or *bona fide* potential investors, acquirors, (sub)licensees, collaborators, lenders, and other financial or commercial partners (including in connection with a potential royalty monetization), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction or collaboration; *provided* that, in each such case, such Persons are bound by obligations of confidentiality, non-disclosure, and non-use at least as restrictive or protective of the Parties as those set forth in this Agreement, and no such disclosure by Xeris will be permitted to any entity that is developing or commercializing a product that is or is reasonably expected to be competitive with the Beta Product except with Beta's prior written consent;

9.4.4. to the extent such Confidential Information is required to be produced, disclosed, or announced under Applicable Laws (including disclosure of the existence and terms of this Agreement, or the achievement of milestones hereunder, in connection with any filing with the United States Securities and Exchange Commission or any other Governmental Authority) or the rules of any securities exchange; *provided*, that, to the extent permitted under Applicable Laws, in such case the Receiving Party will: (a) promptly notify the Disclosing Party in writing of the existence, terms, and circumstances of such required disclosure; (b) allow the Disclosing Party to offer its objections to the production of the applicable Confidential Information; (c) cooperate with the Disclosing Party to take legally available steps to limit such disclosure; (d) disclose only those portions of Confidential Information that the Receiving Party is, in the opinion of its counsel, legally obligated to disclose; and (e) seek confidential treatment for all Confidential Information so disclosed;

9.4.5. to prosecute or defend litigation so long as, to the extent reasonably practicable, there is [***] prior written notice given by the Receiving Party to the Disclosing Party before filing, and in connection with the Receiving Party's rights and obligations pursuant to this Agreement; *provided*, that the Receiving Party will: (a) cooperate with the Disclosing Party to take legally available steps to limit such disclosure; and (b) seek confidential treatment for all Confidential Information so disclosed; or

9.4.6. to allow the Receiving Party to exercise its rights and obligations hereunder; *provided* that such disclosure is covered by terms of confidentiality and non-use at least substantially as restrictive as those set forth herein.

- 9.5. **Publication.** Beta will have the right to publish manuscripts, abstracts, presentations or other articles in scientific journals or at scientific conferences relating to any Glucagon Product when combined with any Pump System without obtaining the prior written consent of Xeris. Xeris will have the right to publish manuscripts, abstracts, presentations or other articles in scientific journals or at scientific conferences relating to any Glucagon Product when combined with any Pump System solely upon obtaining the prior written consent of Beta, in each case subject to this Section 9.5 (Publication). Except as set forth in the first two sentences of this Section 9.5 (Publication), each Party (the "**Publishing Party**") will have the right to publish manuscripts, abstracts, presentations or other articles in scientific journals or at scientific conferences relating to any Glucagon Product without obtaining the prior written consent of the other Party (the

“Non-Publishing Party”); *provided, however*, that (a) if an employee of the Non-Publishing Party is also named as an author or (b) if such manuscripts, abstracts, presentations or other articles contain information relating to the Xeris Technology if Xeris is the Non-Publishing Party or to the Beta Technology if Beta is the Non-Publishing Party, then the Non-Publishing Party will have the right to review and comment upon each such manuscript, abstract, presentation or other article and the Publishing Party will consider such comments in good faith. If the Publishing Party desires to make a publication pursuant to this Section 9.5 (Publications) for which the Non-Publishing Party has the right to comment, then the Publishing Party will provide a copy of the proposed publication (including abstracts, or presentation to a journal, editor, meeting, seminar or other third party) to the Non-Publishing Party for at least [***] prior to submission of such proposed manuscript for publication; the object being to prevent either the endangerment of applications for the protection of property rights by premature publications detrimental to their novelty or the disclosure of Confidential Information. If, during the [***] specified above the Non-Publishing Party notifies the Publishing Party that a proposed publication contains patentable subject matter directed to Xeris Background Know-How or Xeris Collaboration Know-How if Xeris is the Non-Publishing Party or to the Beta Background Know-How or Beta Collaboration Know-How if Beta is the Non-Publishing Party that requires protection, the Non-Publishing Party may by written notice delay the publication for a period of time not to exceed [***] from the date of such written notice to seek appropriate patent protection for any subject matter in such publication that it reasonably believes may be patentable. The Publishing Party will delete from the proposed publication prior to submission all Confidential Information of the Non-Publishing Party that the Non-Publishing Party identifies in good faith and requests to be deleted.

- 9.6. Announcements.** [***] the Parties will issue the press release attached hereto as Schedule 9.6 (Initial Press Release). Except for such initial press release, or as may be expressly permitted under Section 9.4 (Authorized Disclosures), neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party; *provided* that each Party may, subject to and in accordance with Section 9.4 (Authorized Disclosures), issue a public announcement as required, in the reasonable judgment of such Party, by Applicable Laws, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity. For clarity, neither Party will be obligated to obtain consent to re-issue or reiterate information previously specifically disclosed with the consent of the other Party; *provided* that such information continues as of such time to be accurate.
- 9.7. Use of Names.** Each Party will have the right to use the other Party’s name and logo in presentations, its website, corporate overviews, and other informational materials to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to Section 9.6 (Announcements); *provided* that neither Party will use the other Party’s corporate name in such a manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of such other Party will not be impaired, and consistent with best practices used by such other Party for its other collaborators. Except as permitted under this Section 9.7 (Use of Names) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Applicable Law. Each Party will use the other Party’s corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases. Beta will include explanatory text such as “*Developed in partnership with Xeris Pharmaceuticals, Inc.*” in all branding and material promotional materials relating to Glucagon Product, or such other similar text provided by Xeris.

10. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

10.1. Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

- 10.1.1. Good Standing.** Such Party is duly organized, validly existing, and in good standing under the Applicable Laws of the jurisdiction of its incorporation or organization.
- 10.1.2. Corporate Power and Authority.** Such Party (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.
- 10.1.3. Binding Obligation.** This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation, enforceable against such Party in accordance with the terms hereof.
- 10.1.4. No Conflict.** The execution, delivery, and performance of this Agreement by such Party will not constitute a default under or conflict with any agreement, instrument, or understanding to which such Party is a party or by which such Party is bound, or violate any Applicable Laws of any Governmental Authority or administrative or other agency having jurisdiction over either Party.
- 10.1.5. Right to Grant Licenses.** Each Party has the full right, power, and authority to grant the rights, licenses, and option rights granted to the other Party under this Agreement, and neither Party has previously assigned, transferred, conveyed, or granted any license or other rights to any Third Party that would conflict with or limit the scope of any of the rights, options or licenses granted to the other Party hereunder.

10.2. Additional Representations and Warranties of Xeris. Xeris hereby represents and warrants to Beta, as of the Effective Date, that, except as provided on Schedule 10.2 (Exceptions to Xeris Representations and Warranties):

- 10.2.1. Xeris Patent Rights.** Schedule 10.2.1 sets forth a complete and accurate list of all Xeris Patent Rights Covering any Glucagon Product (including formulation thereof) existing as of the Effective Date. Xeris does not own or have rights to any other Patent Rights that would otherwise qualify as a Xeris Patent Right Covering any Glucagon Product (including formulation thereof) but for the fact that Xeris does not Control such Patent Right. Xeris exclusively owns all rights, title, and interests in and to the Xeris Patent Rights licensed to Beta hereunder, and, to Xeris' Knowledge, none of such Xeris Patent Rights are, or will be upon issuance, invalid or unenforceable. All Xeris Patent Rights licensed hereunder are being diligently prosecuted in the respective patent offices in accordance with Applicable Laws. There is no lien, encumbrance, or security interest (including in connection with any indebtedness) on or in the Xeris Patent Rights licensed hereunder that would conflict with any of the rights or licenses granted to Beta hereunder. Except as set forth in Schedule 10.2.1, Xeris's rights, title, and interests to all the Xeris Technology are free of any financial lien or security interest.

- 10.2.2. Infringement of Third Party Intellectual Property.** To Xeris' Knowledge, the use of the Xeris Technology in the performance of the Development Activities and other activities as contemplated under this Agreement, does not and will not infringe, misappropriate, or otherwise violate any intellectual property of any Third Party. There is no pending litigation, or litigation that has been threatened in writing, that alleges, or any written communication received by Xeris or any of its Affiliates alleging, that Xeris' practice of the Xeris Technology licensed hereunder has infringed, misappropriated, or otherwise violated the intellectual property of any Third Party. To Xeris' Knowledge, there are no Patent Rights owned by a Third Party that would be required to practice licenses granted to Beta hereunder.
- 10.2.3. Infringement by Third Parties.** To Xeris' Knowledge, no Third Party is infringing or misappropriating, or threatening in writing to infringe or misappropriate the Xeris Technology licensed hereunder.
- 10.2.4. Inventor Assignment.** To Xeris' Knowledge, Xeris has obtained, or caused its Affiliates, as applicable, to obtain, assignments from the inventors of all inventorship rights to the Xeris Patent Rights. All such assignments are valid and enforceable, and the inventorship of the Xeris Patent Rights is accurately identified on each issued patent or patent application in the Xeris Patent Rights.
- 10.2.5. Third Party Challenge.** Xeris has not received any written notice from any Third Party that challenges the ownership, scope, duration, validity, enforceability, priority, or right to use any Xeris Patent Rights (including, by way of example, through the institution of or written threat of institution of interference, *inter partes* review, reexamination, protest, opposition, nullity, or similar invalidity proceeding before the United States Patent and Trademark Office or any foreign patent authority or court).
- 10.2.6. Confidentiality.** Xeris and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality, and value of all Know-How within Xeris Technology that constitutes trade secrets under Applicable Law and to Xeris' Knowledge, such Know-How has not been used, disclosed to, or discovered by any Third Party except pursuant to such confidentiality agreements.
- 10.2.7. Third Party Funding.** The Xeris Technology has not been created pursuant to, and are not subject to, any funding agreement with any Governmental Authority or any Third Party, and are not subject to the requirements of Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. part 401.
- 10.3. Additional Representations and Warranties of Beta.** Beta hereby represents and warrants to Xeris, as of the Effective Date, that, except as provided on Schedule 10.3 (Exceptions to Beta Representations and Warranties):
- 10.3.1. Beta Patent Rights.** Beta exclusively owns all rights, title, and interests in and to the Beta Patent Rights licensed to Xeris hereunder, and, to Beta's Knowledge, none of such Beta Patent Rights are, or will be upon issuance, invalid or unenforceable. All Beta Patent Rights licensed hereunder are being diligently prosecuted in the respective patent offices in accordance with Applicable Laws. There is no lien, encumbrance, or security interest (including in connection with any indebtedness) on or in the Beta Patent Rights licensed hereunder that would conflict with any of the rights or licenses granted to Xeris hereunder.

10.3.2. Infringement of Third Party Intellectual Property. To Beta's Knowledge, the use of the Beta Technology in the performance of the Development Activities and other activities as contemplated under this Agreement, does not and will not infringe, misappropriate, or otherwise violate any intellectual property of any Third Party. There is no pending litigation, or litigation that has been threatened in writing, that alleges, or any written communication received by Beta or any of its Affiliates alleging, that Beta's practice of the Beta Technology licensed hereunder has infringed, misappropriated, or otherwise violated the intellectual property of any Third Party. To Beta's Knowledge, there are no Patent Rights owned by a Third Party that would be required to practice licenses granted to Xeris hereunder.

10.3.3. Infringement by Third Parties. To Beta's Knowledge, no Third Party is infringing or misappropriating, or threatening in writing to infringe or misappropriate the Beta Technology licensed hereunder.

10.4. Mutual Covenants.

10.4.1. Non-Contravention. During the Term, neither Party, nor its Affiliates, will grant any right to any Third Party that would conflict with this Agreement or with the rights granted by it to the other Party hereunder.

10.4.2. Adequate Resources. Each Party will maintain sufficient resources to perform the activities for which it is responsible under this Agreement in accordance herewith.

10.4.3. Compliance with Laws. Each Party will comply with all Applicable Laws and other legal requirements applicable to such Party in the performance of activities under this Agreement, including, but not limited to Anti-Corruption Laws and Export Control Laws. Each Party shall not, directly or indirectly, offer, promise, authorize, pay, provide, accept, or solicit any bribe, kickback, or other improper payment or thing of value to or from any person in violation of Anti-Corruption Laws. Each Party further agrees that, except as permitted by applicable government license or authorization, in performance of its obligations under the Agreement, it shall not engage in any direct or indirect transactions or dealings with any country or territory that is the subject of an embargo by the U.S. government (currently, Cuba, Iran, North Korea, Syria, and the Crimea, Donetsk People's Republic, and Luhansk People's Republic regions of Ukraine) (collectively, the "**Embargoed Countries**"), any person that is located in, acting on behalf of, or directly or indirectly owned or controlled by any governmental entity of, any Embargoed Country, or any person identified on, or 50% or more owned or otherwise controlled by persons identified on, any list of prohibited parties maintained by the government of the United States or other applicable jurisdiction ("**Prohibited Party Lists**"), including, but not limited to, the Specially Designated Nationals and Blocked Persons List or Foreign Sanctions Evaders List, which are maintained by the Office of Foreign Assets Control of the U.S. Treasury Department, or the Entity List, Denied Persons List, or Unverified List, which are maintained by the Bureau of Industry and Security of the U.S. Commerce Department.

10.4.4. Confidentiality. All employees of each Party and its Affiliates and Subcontractors working under this Agreement will be bound by appropriate confidentiality provisions at least as protective as those contained in Article 9 (Confidentiality; Publication).

- 10.4.5. Sanctions and Debarment.** Neither Xeris, Beta, nor any of their employees or, to the respective Knowledge of Xeris or Beta, their respective Affiliates or agents participating in the Development Activities (a) are presently debarred as such term is defined in 42 U.S.C. § 1320a – 7b(f); (b) has been listed by any federal or state agency as excluded, debarred, suspended, or otherwise ineligible to participate in any Federal Health Care Program, as such term is defined in 42 U.S.C. § 1320a – 7b(f); (c) has been convicted of any crime relating to any Federal Health Care Program. Each Party will not knowingly use in the performance of activities pursuant to this Agreement any employee or consultant who meets any criteria in (a) through (c) above. Each Party will promptly notify the other Party in writing in the event that the representation in this Section 10.4.5 (Sanctions and Debarment) no longer remains accurate. In such event, the other Party will have the right to terminate this Agreement immediately upon providing written notice of such termination to such Party.
- 10.5. DISCLAIMER.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES OR GIVES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY NATURE, EXPRESS OR IMPLIED, RELATING TO ANY INTELLECTUAL PROPERTY, PRODUCTS, GOODS, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT, INCLUDING WARRANTIES OF VALIDITY OR ENFORCEABILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, PERFORMANCE, AND NON-INFRINGEMENT OF ANY THIRD PARTY PATENT OR OTHER INTELLECTUAL PROPERTY RIGHT. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, THAT THE DEVELOPMENT ACTIVITIES OR RESULTS OR OTHER DELIVERABLES HEREUNDER WILL BE SUCCESSFUL OR THAT ANY PARTICULAR OUTCOME WILL BE ACHIEVED.
- 11. TERM AND TERMINATION.**
- 11.1. Term.** The term of this Agreement (the “**Term**”) shall commence on the Effective Date and, unless terminated earlier pursuant to this Article 11 (Term and Termination), shall expire (a) on a Glucagon Product-by-Glucagon Product and country-by-country basis upon the expiration of the Royalty Term for such Glucagon Product in such country and (b) in its entirety upon expiration of all applicable Royalty Terms under this Agreement with respect to all Glucagon Products in all countries in the Territory.
- 11.2. Termination for Convenience.** Beta may, at its election, terminate this Agreement (a) in its entirety, (b) with respect to [***], (c) with respect to [***] or (d) with respect to [***], in each case upon [***] prior written notice to Xeris.
- 11.3. Termination for Cause.**
- 11.3.1. Material Breach.** Either Party (the “**Non-Breaching Party**”) may terminate this Agreement in its entirety, effective upon written notice to the other Party, if the other Party (the “**Breaching Party**”) materially breaches this Agreement and after receiving written notice identifying such material breach in reasonable detail, fails to cure such breach within (a) [***] for all breaches other than as set forth in clause (b), or (b) [***] for a payment breach, *provided* that if any non-payment breach is reasonably capable of being cured but not reasonably capable of being cured within such [***] period, then the cure period may be extended by mutual agreement of the Parties as reasonably necessary to cure such breach (which extension in no event will be longer than an additional [***]). For clarity, in the event of a diligence breach by Beta, Xeris’ termination right pursuant to this Section 11.3.1 will be limited to the applicable region(s) or country(ies) (as applicable) in which such diligence breach occurred.

- 11.3.2. Disputes Regarding Material Breach.** If the Parties reasonably and in good faith disagree as to whether there has been a material breach of this Agreement, then the Breaching Party that disputes whether there has been a material breach may contest the allegation in accordance with the dispute resolution terms of this Agreement and the applicable cure period will toll upon the initiation of such dispute resolution procedures. If, as a result of such dispute resolution process, it is finally determined pursuant to the dispute resolution terms of Section 13.10 of this Agreement that the Breaching Party committed a material breach of this Agreement, then the applicable cure period will resume and unless such alleged breach was cured during the pendency of such cure period (once resumed), this Agreement will terminate effective as of the expiration of such cure period. If, as a result of such dispute resolution proceeding, it is determined that the Breaching Party did not commit such material breach (or such material breach was cured in accordance with Section 11.3 (Termination for Cause)), then no termination of this Agreement will be effective, and this Agreement will continue in full force and effect.
- 11.3.3. Patent Challenge.** Except to the extent unenforceable under Applicable Law, Xeris may terminate this Agreement in its entirety upon [***] written notice of termination to Beta if Beta, or any of its Affiliates or Sublicensees, commences (or knowingly assists a Third Party to commence) any interference, derivation, post-grant review, *inter partes* review, declaratory judgment or opposition proceeding with respect to the scope, validity, or enforceability of any Xeris Patent Rights in the Territory in any court, tribunal, arbitration proceeding, or other proceeding (a “**Patent Challenge**”); *provided* that, if Beta or its Affiliate or Sublicensee withdraws (or causes to be withdrawn) such Patent Challenge within [***] after being requested to do so by Xeris in writing (which termination notice will be deemed a request), then Xeris will have no right to terminate this Agreement pursuant to this Section 11.3.3 (Patent Challenge). If Xeris reasonably believes in good faith, based on the advice of Xeris’ external counsel, that [***], then in lieu of [***], Xeris may instead [***] by providing written notice of such election to Beta. If Xeris [***], then [***]. For the avoidance of doubt, Xeris may not terminate this Agreement pursuant to this Section 11.3.3 (Patent Challenge) if Beta or its Affiliate or Sublicensee is required by legal process to be joined as a party in any Patent Challenge by a Third Party. In addition, notwithstanding the foregoing, Xeris will have no right to terminate this Agreement pursuant to this Section 11.3.3 (Patent Challenge) with respect to: (a) any affirmative defense or other validity, enforceability, or non-infringement challenge, whether in the same action or in any other agency or forum of competent jurisdiction advanced by Beta, or any of its Affiliates or Sublicensees in response to any claim or action brought in the first instance by, on behalf of, Xeris or any of its Affiliates or licensees; (b) any Patent Challenge to the extent commenced by a Third Party that, after the Effective Date, acquires or is acquired by Beta or any of its Affiliates or its of their business or assets, whether by stock purchase, merger, asset purchase or otherwise; *provided* that such proceeding commenced prior to the closing of such acquisition; or (c) any Patent Challenge that is commenced by a Sublicensee; *provided* that Beta demands that such Sublicensee withdraw such Patent Challenge promptly after Beta becomes aware of such Patent Challenge and terminates the sublicense agreement with the applicable Sublicensee if such Sublicensee does not withdraw such Patent Challenge within [***] after receipt of notice from Beta.

- 11.3.4. Insolvency.** Either Party may terminate this Agreement in its entirety, [***] in the event of (a) the bankruptcy or dissolution of the other Party; (b) the other Party making a general assignment for the benefit of its creditors; (c) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] of its filing; or (d) the appointment of a trustee, conservator, receiver, or similar fiduciary for the other Party or substantially all of the assets of the other Party as a result of the other Party's insolvency.
- 11.4. Effects of Termination.** Upon any termination of this Agreement, the following provisions will apply with respect to the Terminated Regions:
- 11.4.1. Termination of License.** All of the licenses granted under this Agreement will terminate, except as necessary for Beta to sell remaining unused Glucagon Product during the Sell-Off Period in accordance with Section 11.4.6 (Return or Destruction of Materials) or as otherwise expressly provided in the License Agreement, as applicable.
- 11.4.2. Sublicenses.** Xeris shall grant to each Sublicensee of Beta with respect to the Terminated Region, at each such Sublicensee's written request to Xeris within [***] of the effective date of termination in such Terminated Region, a direct license, provided that such Sublicensee (a) is not then in default of its sublicense agreement or this Agreement, (b) agrees in writing to comply with the terms of this Agreement to the extent applicable to the rights originally sublicensed to such Sublicensee by Beta, and (c) agrees to pay directly to Xeris such Sublicensee's payments under such sublicense agreement. The scope of such direct license shall be no less than the scope of the license granted herein and sublicensed to such Sublicensee, and Xeris shall have no obligation to perform any task for such Sublicensee beyond the obligations owed to Beta hereunder.
- 11.4.3. Wind-Down.** Upon receipt of notice of termination from the other Party, each Party will cooperate, and will cease, to the extent permitted in accordance with Applicable Law, as promptly as practicable, all activities then being performed by such Party and its Affiliates and sublicensees (including Subcontractors and Sublicensees) hereunder in the Terminated Region, except as necessary to conduct any wind-down activities in accordance with Applicable Law and industry standard.
- 11.4.4. Payments.** Subject to Section 11.4.6 (Return or Destruction of Materials), Beta shall pay to Xeris all unpaid, undisputed amounts due and payable under the terms of this Agreement, including any costs incurred or committed (and non-cancellable) in accordance with this Agreement solely prior to the effective date of such termination, and any costs solely in connection with any such necessary wind-down activities.
- 11.4.5. Return or Destruction of Confidential Information.** Promptly after expiration or termination of this Agreement, each Receiving Party will return to the Disclosing Party or destroy, at the Disclosing Party's election, all Confidential Information of the Disclosing Party that is in the possession or control of the Receiving Party related to this Agreement. Nothing in this Agreement will prevent a Party retaining any records as required by Applicable Laws, any such retention to remain subject to surviving obligations pursuant to Section 11.5 (Survival).

- 11.4.6. Return or Destruction of Materials.** Promptly after expiration or termination of this Agreement, (a) Xeris will (i) destroy any remaining unused Beta Materials in its possession and provide Beta with written evidence of such destruction or return to Beta, at Beta's reasonable cost, any unused Beta Materials, and (ii) destroy any remaining Glucagon Products in its possession and provide Beta with written evidence of such destruction to Beta, and (b) Beta may sell any remaining unused Glucagon Product in its possession for [***] in the Terminated Region ("Sell-Off Period") and will continue to pay to Xeris all amounts due related to such sales in accordance with this Agreement. After the Sell-Off Period, Beta will destroy any remaining unused Glucagon Products in its possession in the Terminated Region and provide Xeris with written evidence of such destruction to Xeris, or transfer such Glucagon Products to other country(ies) or region(s) in the Territory.
- 11.5. Survival.** Termination or expiration of this Agreement will not affect the rights and obligations of the Parties accrued prior to the effectiveness of such termination or prior to expiration (including, by way of example, the delivery of reports in respect of Development Activities conducted prior to such termination or expiration). The following provisions, and the obligations of the Parties set forth therein, will survive such termination or expiration of this Agreement: Article 1 (Definitions); Section 4.7.1 (Records) (for the duration set forth therein); Section 7.2.3 (Joint Ownership); Section 8.2 (Milestone Payment) through Section 8.6 (Payment Method and Exchange Rate) (solely with respect to any payment obligations that have accrued prior to the effective date of termination or expiration of this Agreement); Section 8.7 (for the duration set forth therein); Section 8.8 (Taxes) (solely with respect to any payment obligations that have accrued prior to the effective date of termination or expiration of this Agreement); Section 9.2 (Duty of Confidence) (for the duration set forth therein); Section 11.4 (Effects of Termination); this Section 11.5 (Survival); Section 12.1 (Indemnification by Beta) through Section 12.4 (Mitigation of Loss); and Article 13 (General Provisions).
- 12. INDEMNIFICATION, LIABILITY, INSURANCE.**
- 12.1. Indemnification by Beta.** Beta will indemnify, defend, and hold harmless Xeris and its Affiliates, and each of their respective directors, officers, employees, and agents (collectively "**Xeris Indemnitees**"), from and against all Losses to the extent resulting from any claims, demands, actions, or other proceedings by any Third Party arising out of:
- 12.1.1. [***]
 - 12.1.2. [***]
 - 12.1.3. [***]
 - 12.1.4. [***]
 - 12.1.5. [***]
 - 12.1.6. [***]

except in each case (Section 12.1.1 through Section 12.1.6) to the extent such Losses arise from any Third Party claim for which Xeris is responsible for indemnifying Beta pursuant to Section 12.2 (Indemnification by Xeris).

- 12.2. Indemnification by Xeris.** Xeris will indemnify, defend, and hold harmless Beta and its Affiliates and each of their respective directors, officers, employees, and agents (collectively “**Beta Indemnitees**”), from and against all Losses to the extent resulting from any claims, demands, actions, or other proceedings by any Third Party arising out of:

12.2.1. [***]

12.2.2. [***]

12.2.3. [***]

except in each case (Section 12.2.1 through Section 12.2.3) to the extent such Losses arise from any Third Party claim for which Beta is responsible for indemnifying Xeris pursuant to Section 12.1 (Indemnification by Beta).

12.3. Indemnification Procedure.

12.3.1. Notice. If either Party is seeking indemnification under Section 12.1 (Indemnification by Beta) or Section 12.2 (Indemnification by Xeris) (the “**Indemnified Party**”), then such Indemnified Party will inform the other Party (the “**Indemnifying Party**”) of the Third Party claim giving rise to the obligation to indemnify pursuant to such Section within [***] after receiving notice of such Third Party claim, *provided, however*, that no delay or failure on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) such delay or failure is materially prejudicial to or otherwise adversely affects the Indemnifying Party’s ability to defend the Third Party claim.

12.3.2. Control. The Indemnifying Party will, and the Indemnified Party shall permit the Indemnifying Party to, assume the direction and control of the defense, litigation, settlement, appeal, or other disposition of any such claim for which it is obligated to indemnify the Indemnified Party (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party. The Indemnified Party will cooperate with the Indemnifying Party, and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the claim, including by furnishing such records, information, and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. The Indemnified Party will have the right to participate (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense and with counsel of its choice, in the defense of any claim that has been assumed by the Indemnified Party.

- 12.3.3. Settlement.** Notwithstanding any provision to the contrary in this Agreement, the Indemnifying Party will not enter into any settlement, consent judgment, or other voluntary final disposition of any claim that has an adverse effect on the rights of any Indemnified Party hereunder or on the Beta Technology, Xeris Technology, or admits any wrongdoing or fault by any Xeris Indemnitees or Beta Indemnitees, or imposes on any Xeris Indemnitees or Beta Indemnitees any payment or other liability, without the prior written consent of such Indemnified Party.
- 12.4. Mitigation of Loss.** Each Indemnified Party will take and will procure that its Affiliates take all such reasonable steps and actions as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article 12 (Indemnification, Liability, Insurance), at the Indemnifying Party's expense. Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.
- 12.5. Insurance.** Each Party will procure and maintain, during the Term, [***] to cover its obligations under this Agreement as is normal and customary in the pharmaceutical industry for similarly situated parties. Each Party will provide the other Party with evidence of such insurance by furnishing a certificate of insurance upon written request of the other Party. It is understood that such insurance will not be construed to create a limit of either Party's liability, including with respect to its indemnification obligations under this Article 12 (Indemnification, Liability, Insurance). In addition, without limiting the foregoing, each Party will maintain, at its sole cost and expense, insurances of the following types at these minimum levels: [***]. Neither Party will not cancel any of such insurance coverage without providing the other Party [***] advance written notice. Any Subcontractor engaged by a Party pursuant to the terms of this Agreement to perform any Development Activities will be subject to all the requirements above, and such subcontracting Party will remain responsible for ensuring such Subcontractor's compliance with those requirements at all times.
- 13. GENERAL PROVISIONS.**
- 13.1. Assignment.** No rights hereunder may be assigned, and except as otherwise expressly provided herein no performance hereunder may be delegated, by either Party, directly or by merger or other operation of law, without the express prior written consent of the other Party; *provided* that, notwithstanding the foregoing, either Party may assign this Agreement without the other Party's prior written consent, (i) to an Affiliate, *provided* that such assigning Party will remain responsible for such Affiliate's conduct or (ii) to a Third Party in connection with (or by operation of law resulting from) a merger, acquisition, Change of Control, or sale of all or substantially all of its stock or assets to which this Agreement relates. Any prohibited assignment of this Agreement or assignment or delegation of the rights or obligations in violation of the terms of this Section 13.1 (Assignment) hereunder will be null and void. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party.

- 13.2. LIMITATION OF LIABILITY.** NOTWITHSTANDING ANY PROVISION TO THE CONTRARY SET FORTH IN THIS AGREEMENT, NEITHER PARTY, OR ITS DIRECTORS, OFFICERS, EMPLOYEES, OR AGENTS, WILL BE LIABLE TO THE OTHER PARTY FOR ANY LIABILITIES ARISING UNDER OR IN CONNECTION WITH ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES, INCLUDING INCIDENTAL DAMAGES, ECONOMIC DAMAGES, OR LOST PROFITS, EVEN IF SUCH PARTY HAS BEEN INFORMED, SHOULD HAVE KNOWN OR IN FACT KNEW OF THE POSSIBILITY OF SUCH DAMAGES; *PROVIDED* THAT THIS SECTION 13.2 (LIMITATION OF LIABILITY) WILL NOT APPLY TO THE PARTIES' INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 12.1 (INDEMNIFICATION BY BETA) AND SECTION 12.2 (INDEMNIFICATION BY XERIS) OR ANY PARTY'S BREACH OF ARTICLE 9 (CONFIDENTIALITY; PUBLICATION).
- 13.3. Force Majeure.** Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, epidemics, pandemics, or quarantines, or like catastrophe ("Force Majeure") and for so long as such failure or delay continues to be caused by or result from such Force Majeure event. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder due to any such Force Majeure circumstances affecting such Party for as long as the other Party is continuing to perform its obligations. The affected Party will (i) promptly notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement, (ii) provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and (iii) undertake reasonable efforts to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then the affected Party will update such notice to the other Party on a weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume. In any event, if a Party's failure to perform its obligations under this Agreement as a result of a Force Majeure event continues for longer than [***], then the unaffected Party may terminate this Agreement by providing written notice to the Party affected by the Force Majeure event.
- 13.4. Amendments.** No change, modification, addition, or amendment to this Agreement will be valid or enforceable unless in writing and signed and dated by authorized representatives of the Parties.
- 13.5. Performance by Affiliates.** Each Party will have the right to engage Affiliates to perform its obligations under this Agreement, including under the Development Plan. Each Party will remain responsible and primarily and fully liable for the performance of any activities performed by such Party's Affiliates as contemplated by this Agreement and for such Affiliates' compliance with the terms of this Agreement.
- 13.6. No Waiver.** A waiver by either Party of a breach or violation of any provision of this Agreement will not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision of this Agreement, except with respect to an express written and signed waiver (signed by the Party providing such waiver) relating to a particular matter for a particular time.

- 13.7. Enforceability.** If any provision of this Agreement is found by a court of competent jurisdiction to be invalid or unenforceable, then the provision will be considered severed from this Agreement, so as not to affect the validity or enforceability of the remainder of this Agreement and the Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one to reflect as nearly as possible the intent of the Parties as of the Effective Date.
- 13.8. Relationship between the Parties; No Third Party Beneficiaries.** Each Party will act solely as an independent contractor, and nothing in this Agreement will be construed to give either Party the power or authority, to act for, bind, or commit the other Party in any way. Nothing herein will be deemed to establish a relationship of principal and agent between Beta and Xeris, nor any of their agents or employees, nor will this Agreement be construed as creating any form of legal association or arrangement which would impose liability upon one Party for the act or failure to act of the other Party. Nothing in this Agreement, express or implied, is intended to confer benefits, rights or remedies on any person other than the Parties or their permitted assigns, except for the Beta Indemnitees and Xeris Indemnitees expressly entitled to indemnification as provided in Article 12 (Indemnification, Liability, Insurance) and only in accordance with the terms of such Article 12 (Indemnification, Liability, Insurance). Neither Party will treat or report the relationship arising under this Agreement as a partnership for United States tax purposes unless required pursuant to a determination under Section 1313 of the Internal Revenue Code of 1986, as amended.
- 13.9. Notices.** All communications hereunder will be in writing, including by electronic mail, and will be deemed to have been duly given (a) upon personal delivery, (b) [***] with a recognized courier with [***] delivery instructions, (c) [***] after sending, if sent by electronic mail with receipt confirmed by reply email, or (d) [***] after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested:

If to Beta:

Beta Bionics, Inc.
11 Hughes
Irvine, CA 92618
[***]
[***]

With a copy (which will not constitute notice) to:

Cooley LLP
10265 Science Center Drive
San Diego, CA 92121-1117
[***]
[***]

If to Xeris:

Xeris Pharmaceuticals, Inc.
1375 West Fulton Street, Suite 1300
Chicago, IL 60607
[***]
[***]

With a copy (which will not constitute notice) to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199
[***]
[***]

13.10. Dispute Resolution.

13.10.1. Exclusive Dispute Resolution Mechanism. The Parties agree that, except as expressly set forth in this Agreement, the procedures set forth in this Section 13.10 (Dispute Resolution) will be the exclusive mechanism for resolving any dispute, controversy, or claim between the Parties arising out of or relating to this Agreement (whether based on contract, tort or otherwise) (each, a “**Dispute**”). For the avoidance of doubt, this Section 13.10 (Dispute Resolution) will not apply with respect to resolution of any matter set forth in Section 3.3 (JSC Decision; Dispute Resolution of JSC Matters), except as set forth in Section 13.10.7 (Dispute Regarding Achievement of Minimally Acceptable Results).

13.10.2. Resolution by Executive Officers. Except as otherwise provided in this Section 13.10.2 (Resolution by Executive Officers) or as provided in Section 13.10.5 (Preliminary Injunctions), in the event of any Dispute regarding the construction or interpretation of this Agreement, or the rights, duties, or liabilities of either Party hereunder, the Parties will first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within [***], either Party may, by written notice to the other Party, refer the Dispute to the Executive Officer of the other Party for attempted resolution by good faith negotiation within [***] after such notice is received. Each Party may, in its sole discretion, seek resolution of any and all Disputes that are not resolved under this Section 13.10.2 (Resolution by Executive Officers) in accordance with Section 13.10.4 (Arbitration).

13.10.3. Governing Law. This Agreement and all Disputes arising out of or related to this Agreement, or the performance, enforcement, breach, or termination hereof, and any remedies relating thereto, will be construed, governed, interpreted, and applied in accordance with the laws of [***], without regard to its conflict of laws principles.

13.10.4. Arbitration.

(a) [***]

-
- (b) [***]
 - (c) [***]
 - (d) [***].

- 13.10.5. Preliminary Injunctions.** Notwithstanding any provision to the contrary set forth in this Agreement, if a Party reasonably requires relief on a more expedited basis than would be possible pursuant to the procedure set forth in Section 13.10.2 (Resolution by Executive Officers) or Section 13.10.4 (Arbitration), a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis.
- 13.10.6. Patent Disputes.** Notwithstanding any provision to the contrary set forth in this Agreement, any and all issues regarding the scope, construction, validity, and enforceability of any Patent Rights licensed or created under this Agreement will be finally determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent laws.
- 13.10.7. Dispute Regarding Achievement of Minimally Acceptable Results.** Notwithstanding any provision to the contrary set forth in this Section 13.10 (Dispute Resolution), if the Parties in good faith disputes whether Minimally Acceptable Results have been achieved following escalation to the Executive Officers under Section 13.10.2 (Resolution by Executive Officers), then either Party may submit such disagreement for final resolution [***].
- 13.10.8. Payment Tolling.** [***] any dispute resolution proceeding between the Parties under this Section 13.10 (Dispute Resolution) regarding the obligation to make any payment under this Agreement from one Party to the other Party (in whole or in part), the obligation to make such payment (solely with respect to any disputed amounts) will be tolled until the final outcome of such Dispute has been established. Except as set forth in the foregoing, during a pending dispute where this Agreement has not yet been terminated, each Party shall continue to perform in good faith its obligations under this Agreement.
- 13.10.9. Confidentiality.** Any and all activities conducted under this Section 13.10 (Dispute Resolution), including any and all proceedings and decisions hereunder, will be deemed Confidential Information of each of the Parties, and will be subject to Article 9 (Confidentiality; Publication), to the extent applicable and in accordance with Applicable Law.
- 13.11. Further Assurances.** From time to time after the Effective Date, each Party will execute, acknowledge, and deliver to each other any further documents, assurances, and other matters, and will take any other action consistent with the terms and conditions of this Agreement, that may reasonably be requested by a Party and necessary or desirable to carry out the purpose of this Agreement.
- 13.12. Entire Agreement.** This Agreement, including the Schedules and exhibits hereto embody the entire understanding between the Parties relating to the subject matter hereof and supersedes all prior understandings and agreements, whether written or oral. This Agreement may not be varied except by a written document signed by duly authorized representatives of both Parties.

13.13. Interpretation. Except where the context expressly requires otherwise: (a) the use of any gender herein will be deemed to encompass references to all genders, and the use of the singular will be deemed to include the plural (and vice versa); (b) the words “include,” “includes” and “including” will be deemed to be followed by the phrase “without limitation” and will not be interpreted to limit the provision to which it relates; (c) the word “will” will be construed to have the same meaning and effect as the word “shall”; (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein); (e) any reference herein to any Person will be construed to include the Person’s successors and assigns; (f) the words “herein,” “hereof” and “hereunder,” and words of similar import, will be construed to refer to this Agreement in each of their entirety, as the context requires, and not to any particular provision hereof; (g) all references herein to Sections, Schedules, or Exhibits will be construed to refer to Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto; (h) the word “notice” means notice in writing (whether or not specifically stated) and will include notices, consents, approvals, and other written communications contemplated under this Agreement; (i) references to any specific law, rule or regulation, article, Section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; and (j) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or.”

13.14. Construction. This Agreement has been prepared, examined, negotiated, and revised by each Party and their respective attorneys, and no implication will be drawn and no provision will be construed against any Party to this Agreement by virtue of the purported identity of the drafter of this Agreement or any portion thereof.

13.15. Counterparts. This Agreement may be executed in two or more counterparts, all of which taken together will be regarded as one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (PDF) or by DocuSign sent by electronic mail. PDF or DocuSign signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the duly authorized representatives of the Parties hereby execute this Agreement as of the Effective Date.

XERIS

BETA

Xeris Pharmaceuticals, Inc.

Beta Bionics, Inc.

By: /s/ Paul R. Edick
Name: Paul R. Edick
Title: Chairman and CEO

By: /s/ Sean Saint
Name: Sean Saint
Title: CEO

Signature Page to Collaboration and License Agreement

Schedule 1.51
Corporate Marks

[***]

Schedule 1.145
Xeris Formulation Patents

***]

Schedule 4.2
Initial Development Plan

Schedule 4.6
Additional Work

Schedule 8.2
Minimally Acceptable Results



XERIS ENTERS INTO AN EXCLUSIVE WORLDWIDE COLLABORATION AND LICENSE AGREEMENT WITH BETA BIONICS

For development and commercialization of a new and unique formulation of liquid stable glucagon for use in a bi-hormonal pump and pump systems

CHICAGO, IL; May x, 2024 – Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a growth-oriented biopharmaceutical company committed to improving patient lives by developing and commercializing innovative products across a range of therapies, today announced that it has entered into an exclusive worldwide collaboration and license agreement with Beta Bionics, Inc. for the development and commercialization of a glucagon product utilizing Xeris' XeriSol™ technology for use in Beta Bionics' proprietary bi-hormonal pump and pump systems.

"We're excited to be partnering with Beta Bionics by being the exclusive provider of the glucagon component that will facilitate their development of the first dual-hormone pump for people with diabetes," said Paul R. Edick, Chairman and CEO of Xeris. "We will move quickly to support Beta Bionics in this important development program."

"If insulin is like the gas pedal in your car, then glucagon is the brakes," said Sean Saint, CEO of Beta Bionics. "Beta Bionics has always felt that a bi-hormonal glucose control system has real advantages over insulin alone...just like the brakes in your car. Now with this partnership with Xeris, we are ready to take the next step in bringing this system to market."

Under the terms of the License Agreement, Xeris has the potential to receive development payments, plus low double-digit royalties based on future sales of the Xeris glucagon for pumps and pump systems.

About Xeris

Xeris (Nasdaq: XERS) is a growth-oriented biopharmaceutical company committed to improving patients' lives by developing and commercializing innovative products across a range of therapies. Xeris has three commercially available products; Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia, Keveyis®, for a proven therapy for primary periodic paralysis, and Recorlev® for the treatment of endogenous Cushing's syndrome. Xeris also has a pipeline of development programs to extend the current marketed products into important new indications and uses and bring new products forward using its proprietary formulation technology platforms, XeriSol™ and XeriJect®, supporting long-term product development and commercial success.

Xeris Biopharma Holdings is headquartered in Chicago, IL. For more information, visit www.xerispharma.com, or follow us on X, LinkedIn, or Instagram.

About Beta Bionics

Beta Bionics is a medical technology company focused on the design, development, and commercialization of its iLet Bionic Pancreas in both the single hormone and bi-hormonal configurations. The iLet Bionic Pancreas platform is designed to use adaptive, self-learning, control algorithms, together with continuous glucose monitoring and pump technology, to autonomously compute and administer doses of insulin and/or glucagon and mimic the body's natural ability to maintain tight glycemic control, relieving some of the burden of living with diabetes. To learn more, visit www.betabionics.com.

Beta Bionics is a for-profit, public benefit corporation and Certified B Corporation. Since its founding in 2015, its mission has been to help improve health outcomes and the quality of life of children and adults living with diabetes and other conditions of glycemic dysregulation.

Forward-Looking Statements

Any statements in this press release other than statements of historical fact are forward-looking statements. Forward-looking statements include, but are not limited to, statements about future expectations, plans and prospects for Xeris Biopharma Holdings, Inc., including the development and potential of a glucagon product utilizing Xeris' XeriSol™ technology, the expectations regarding future product development efforts between Xeris and Beta Bionics, Xeris' potential entitlements to milestone and royalty payments from Beta Bionics, the potential utility of its formulation platforms such as XeriSol™, the market and therapeutic potential of its products and product candidates, and other statements containing the words "will," "would," "continue," "expect," "should," "anticipate" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on numerous assumptions and assessments made in light of Xeris' experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, geopolitical factors and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The various factors that could cause Xeris' actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements, include, but are not limited to, its financial position and need for financing, including to fund its product development programs or commercialization efforts, whether its products will achieve and maintain market acceptance in a competitive business environment, its reliance on third-party suppliers, including single-source suppliers, its reliance on third parties to conduct clinical trials, the ability of its product candidates to compete successfully with existing and new drugs, and its and collaborators' ability to protect its intellectual property and proprietary technology. No assurance can be given that such expectations will be realized and persons reading this communication are, therefore, cautioned not to place undue reliance on these forward-looking statements. Additional risks and information about potential impacts of financial, operational, economic, competitive, regulatory, governmental, technological, and other factors that may affect Xeris can be found in Xeris' filings, including its most recently filed Annual Report on Form 10-K filed with the Securities and Exchange Commission, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Forward-looking statements in this communication are based on information available to us, as of the date of this communication and, while we believe our assumptions are reasonable, actual results may differ materially. Subject to any obligations under applicable law, we do not undertake any obligation to update any forward-looking statement whether as a result of new information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations.

Xeris Investor Contact

Allison Wey
Senior Vice President, Investor Relations and Corporate Communications
away@xerispharma.com

Beta Bionics Media Contact

Karen Hynes
Vice President, Marketing
(619) 206-9811
khynes@betabionics.com

Schedule 10.2
Exceptions to Xeris Representations and Warranties

[***]

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

EXECUTION VERSION
CONFIDENTIAL

DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

THIS DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the “*Agreement*”) is entered into as of April 2, 2024 (the “*Effective Date*”) by and between Abbott Diabetes Care Inc., a Delaware corporation having its principal place of business at 1420 Harbor Bay Parkway, Alameda, CA 94502 (“*ADC*”), and Beta Bionics, Inc., a Massachusetts public benefit corporation having a place of business at 11 Hughes, Irvine, CA 92618 (“*Beta*”), each of which is referred to as a “*Party*” and collectively referred to as the “*Parties*”.

RECITALS

WHEREAS, ADC has developed the CGM System and Beta has developed the Beta System;

WHEREAS, on March 21, 2023, the Parties entered into an Exploration Agreement to evaluate the feasibility of integrating ADC’s CGM System with the Beta System (as amended on June 13, 2023 and August 2, 2023, the “*Exploration Agreement*”); and

WHEREAS, the Parties desire to coordinate on the development and commercialization of the Libre-Beta System.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and promises contained in this Agreement, ADC and Beta agree as follows:

ARTICLE I DEFINITIONS

1.1 “*ADC Encoded Beta CID*” means the source code built by ADC from the Beta CID Documentation.

1.2 [***]

1.3 “*ADC Highly Confidential Information*” means [***] that is Confidential Information of ADC.

1.4 “*ADC Indemnitees*” means ADC, its Affiliates, and any directors, officers, agents, and employees of the foregoing.

1.5 “*ADC Licensed Background IP*” means ADC’s Background IP under its Control (including, the ADC Highly Confidential Information, but not including [***]). Notwithstanding the foregoing, in the event of a Merge Transaction involving ADC, any Intellectual Property Controlled by the Merged Third Party immediately before the consummation of such Merge Transaction shall be excluded from ADC Licensed Background IP.

1.6 “ADC Marks” means the Trademarks listed on Exhibit 1.6 and any other Trademarks as the Parties may stipulate in writing.

1.7 “Affiliate” of a Party (or other Person) means any Person which controls, is controlled by or is under common control with such Party (or other Person). For purposes of this definition, “control” shall mean (a) in the case of corporate Persons, direct or indirect ownership of at least fifty percent (50%) of the stock or shares entitled to vote for the election of directors; and (b) in the case of non-corporate Persons, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of the subject Person. [***]

1.8 “AID Algorithms” means [***].

1.9 “API” means application program interface.

1.10 “Applicable Law” means any national, international, supranational, multinational, provincial, federal, state or local law (in each case, whether United States or non-United States or otherwise, and whether statutory, common or otherwise), constitution, treaty, convention, ordinance, code, rule, statute, regulation or other similar requirement enacted, issued, adopted, promulgated, entered into or applied by an Authority that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.

1.11 “Approved Person” means:

(a) with respect to Beta, [***].

(b) with respect to ADC, [***].

1.12 “*Authority*” means (a) any government regulatory body responsible for granting approvals for the performance of services under this Agreement (if applicable); or (b) any national, international, supranational, federal, state, international, or local governing or competent body having jurisdiction over a Party with respect to the Party’s performance under this Agreement.

1.13 “*Beta Automated Dosing Sub-System*” means the subset of the Beta System, [***].

1.14 “*Beta CID*” means the [***].

1.15 “*Beta CID Documentation*” means written documentation, including any specifications, provided by or on behalf of Beta to ADC, [***].

1.16 “*Beta Companion App*” means [***].

1.17 “*Beta Cloud*” means any cloud-based data management platform used in conjunction with the Beta Companion App.

1.18 “*Beta Display Device*” means a device [***].

1.19 [***].

- 1.20 “**Beta Highly Confidential Information**” means [***] in each case that is Confidential Information of Beta.
- 1.21 “**Beta Indemnitees**” means Beta, its Affiliates, and any directors, officers, agents, and employees of the foregoing.
- 1.22 “**Beta Libre Code**” means any code [***].
- 1.23 “**Beta Infusion Pump**” means a subcutaneous infusion pump [***].
- 1.24 “**Beta Licensed Background IP**” means Beta’s Background IP under its Control (including the Beta CID and Beta CID Documentation, but not including GUI IP). Notwithstanding the foregoing, in the event of a Merge Transaction involving Beta, any Intellectual Property Controlled by the Merged Third Party immediately before the consummation of such Merge Transaction shall be excluded from Beta Licensed Background IP.
- 1.25 “**Beta Marks**” means the Trademarks listed on Exhibit 1.25, and any other Trademarks as the Parties may stipulate in writing.
- 1.26 “**Beta System**” means a subcutaneous insulin infusion delivery system [***]. The Beta System expressly excludes the CGM System.
- 1.27 “**Beta System Data**” means all data generated by the Beta System that is part of the Libre-Beta System, and made available to ADC through the Beta CID.
- 1.28 “**Bilateral CDA**” means the Confidential Disclosure Agreement – Bilateral by and between the Parties effective [***]
- 1.29 “**CGM Data**” means all data generated by the FreeStyle Libre 3 Plus Sensor when combined with or used as part of the Libre-Beta System. “**CGM Data**” shall include: [***].
- 1.30 “**CGM Matters**” means matters relating to [***].

1.31 “CGM System” means a glucose monitoring system [***].

1.32 “Change of Control” means with respect to a Party, (a) the sale of all or substantially all of such Party’s assets or business relating to this Agreement; or (b) a merger, reorganization, consolidation or similar transaction in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least 50% of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or similar transaction; or (c) a Person, or group of Persons, acting in concert acquiring, directly or indirectly, more than 50% of the voting equity securities of, or the power to control the management of, such Party.

1.33 “Claim” means any and all Third Party claims, defenses, demands, causes of action, suits, choses in action, controversies, actions, judgments, liens, indebtedness, damages, losses, attorney’s fees, expert’s fees, expenses, liabilities, and proceedings of whatever kind and character.

1.34 “Commercially Reasonable Efforts” means carrying out those obligations and tasks that comprise a level of effort and expenditure of resources (including appropriate allocation of resources) [***] in connection with the development, testing, protection of intellectual property, pursuit of regulatory approvals and commercialization of a product owned or controlled by Party, which are, at the time of measurement of such level of effort and expenditure of resources, similarly situated to (including with respect to market and sales potential), at a stage of development similar to a Party’s applicable device under this Agreement [***].

1.35 “Confidential Information” means all information, including information relating to products (including development or production), customers, suppliers, data, processes, prototypes, samples, plans, marketing plans, reports, forecasts, software (including source code), technical, financial, commercial or personal information or data, research, research results, strategies, and trade secrets that is disclosed by or on behalf of one Party (“**Disclosing Party**”) to the other Party (“**Receiving Party**”) in writing, orally, visually or in another form, [***].

Confidential Information does not include [***] any information that is:

(a) already known to the Receiving Party, as evidenced by its written records, prior to receipt thereof under this Agreement, the Exploration Agreement or the Bilateral CDA;

(b) disclosed to the Receiving Party by a Third Party who has no obligations of confidentiality to the Disclosing Party;

(c) in the public domain at the time of disclosure, or becomes part of the public domain other than through breach of this Agreement, the Exploration Agreement or the Bilateral CDA by the Receiving Party (in which instance, the Receiving Party's obligations and liabilities for treatment of such information prior to its entering the public domain shall not be affected or diminished); or

(d) independently developed by or for the Receiving Party as evidenced by its written records, without reference to Confidential Information received from the Disclosing Party.

1.36 “Consent” means a form of consent that is legally valid under applicable Data Protection Laws.

1.37 “Control” or “Controlled” means, with respect to any Intellectual Property rights that a Party has the legal authority or right, whether by ownership, license, covenant not to sue, or otherwise (other than by operation of the license and other grants in this Agreement) to grant to the other Party a license or sublicense under, or access or right to use, such Intellectual Property rights, on the terms and conditions set forth herein, in each case without breaching the terms of any agreement with a Third Party.

1.38 “CSII System” means a continuous subcutaneous insulin infusion delivery system.

1.39 “Data Protection Laws” means all Applicable Law, as well as all generally applicable industry or self-regulatory standards in each Launch Country relating to the Processing or release, transfer, provision of, providing access to, or divulging in any other manner of Personal Information, data protection, data security, and data privacy, including where applicable the guidance and codes of practice and decisions issued by any Authority, as amended or superseded from time to time, in each case, that are in effect as of the Effective Date, as they become effective, and as amended or superseded, from time to time. To the extent applicable to the Launch Country, such Data Protection Laws include Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended, (collectively, “**HIPAA**”); the CAN-SPAM Act of 2003; the Telephone Consumer Protection Act and similar laws and regulations governing telephone calls and text messages; and any other applicable U.S. state and federal data protection laws or regulations.

1.40 “Data Security Breach” means any actual or reasonably suspected (a) unauthorized access to, acquisition of, or use of Personal Information; (b) unauthorized or accidental loss, alteration, disclosure, or destruction of Personal Information; (c) compromise, intrusion, interference with, or unauthorized access to networks, systems, databases, servers, or electronic or other media on which Personal Information is Processed or from which Personal Information may be accessed, including those of an agent or subcontractor; or (d) other circumstance that actually or is reasonably suspected of compromising, or could compromise, the privacy, security, confidentiality, availability, or integrity of any Personal Information or the proper functioning of the network resources of ADC or Beta.

1.41 “Disclosure” (including “*Disclose*”) means the release, transfer, provision of, access to, or divulging in any other manner of Personal Information outside the Party maintaining such information (and its Affiliates) and not to the other Party.

1.42 [*]**

1.43 “Existing Users” means following regulatory approval of the Libre-Beta System and the JSC’s approval of the Commercialization Plan, users of the Libre-Beta System as of the date of termination of this Agreement.

1.44 “FDA” means the United States Food and Drug Administration or any successor entity thereto.

1.45 “First Commercial Sale” means the first sale for monetary value of the Libre-Beta System after regulatory approval has been obtained.

1.46 “FOSS” means any software (object code or source code) (i) which is distributed as free software or open source software (including under any license meeting the Open Source Initiative’s Open Source Definition as amended, revised or updated from time to time (<http://www.opensource.org/docs/osd>), or (ii) which is distributed with access to its source code (or any part thereof) and where the recipient could be placed under an obligation to ensure that any further distribution of such software (or source code of software derived from such software, if required by the applicable open source license) takes place on the same or similar terms, or (iii) which is distributed as free software or open source software on terms that could require or condition the use or distribution of any portion of such software, other material, or derivatives thereof, on (1) the distribution of any data or material therewith, or (2) the granting to licensees of the right to make derivative works or other modifications to such software or other material or portions thereof.

1.47 “FreeStyle Libre App” means the continuous glucose monitor application marketed by ADC for use with Freestyle Libre 3 Plus Sensor, including ADC’s LibreLink or FreeStyle Libre applications, as applicable.

1.48 “FreeStyle Libre 3 Plus Documentation” means the specifications, libraries or applications provided by or on behalf of ADC to Beta [***].

1.49 “*FreeStyle Libre 3 Plus Security Credentials*” means the security credentials provided by or on behalf of ADC to Beta and its Affiliates [***].

1.50 “*FreeStyle Libre 3 Plus Sensor*” means the on-body device [***] that is part of the system marketed by ADC as the “*FreeStyle Libre 3 Plus system*.”

1.51 “*FreeStyle Libre Technology*” means [***]

1.52 “*Glucose Metrics*” means [***].

1.53 “*GUF*” means the graphical user interface in a product.

1.54 “*GUI IP*” means the Intellectual Property that claims or covers a GUI and is Controlled by a Party.

1.55 “*Highly Confidential Information*” means the ADC Highly Confidential Information or the Beta Highly Confidential Information, as applicable.

1.56 “*Insulin Metrics*” means [***].

1.57 “*Intellectual Property*” means all patents, patent applications, continuations or continuations-in-part of patents or patent applications, divisionals of patents or patent applications, copyrights, works of authorship, copyrightable subject matter, moral rights, trade secrets, know-how, and all other proprietary and intellectual property rights in discoveries and inventions (whether or not patentable), but not including Trademarks.

1.58 “*Libre-Beta System*” means an automated insulin delivery system, combining the CGM System and Beta System, to be developed by the Parties pursuant to the Development Plan, [***].

1.59 “*Libre-Beta User Data*” means the Consent information and unique customer identifier specific to a Libre-Beta System that is Processed by the Libre-Beta System, [***].

1.61 “**LibreView**” means the cloud-based data management platform that is marketed by ADC or its designee as “**LibreView**”.

1.62 “**Merge Transaction**” means the acquisition by a Third Party of a Party, or acquisition by a Party of a Third Party, or any transaction in which all or substantially all the assets of a Third Party merge with the assets of a Party or in which all or substantially all of the assets for a Party applicable to this Agreement merge with the assets of a Third Party.

1.63 “**Merged Third Party**” means a Third Party involved in a Merge Transaction, including any of such Third Party’s Affiliates existing immediately before the consummation of such Merge Transaction.

1.64 “**Person**” means an individual, corporation, partnership, limited liability company, association, company, joint venture, estate, trust, other entity or organization of any kind or nature, including an Authority.

1.65 “**Personal Information**” means any information or set of information relating to an identified or identifiable individual, directly or indirectly, Processed by either Party through the Libre-Beta System or provided or shared by or on behalf of one Party to the other Party under this Agreement (“**Shared Personal Information**”), regardless of the medium in which such information is displayed or contained, which shall include (a) all information that identifies that individual or could reasonably be used to identify such individual, (b) all “protected health information” as defined by HIPAA, (c) all information, “personal data” such as identification number, location data, an online identifier or one or more factors specific to the physical, physiological, genetic mental, economic, cultural or social identity of a natural individual, as defined by or to which any applicable Data Protection Laws apply, and (d) any information subject to an express written agreement of the Parties to treat such information not otherwise included by applicable Data Protection Laws as Personal Information. For the purposes of this Agreement, Personal Information includes: Libre-Beta User Data, CGM Data, and Beta System Data.

1.66 “**Processing**” (including “**Process**” and “**Processed**”) means any operation or set of operations that is performed on Personal Information within an entity that maintains such information, including use, collection, recording, maintaining, organization, storage, adaptation, modification, retrieval, consultation, retention, alteration, dissemination, transmission, access, transfer, combination, erasure, destruction, deidentification, or pseudonymization or as defined by applicable Data Protection Laws. Processing does not mean Disclosure.

1.67 “*Senior Officer*” means, in the case of ADC, [***] and, in the case of Beta, [***].

1.68 “*Service Provider*” means any Person that Processes or receives Personal Information for a business purpose pursuant to a written agreement.

1.69 “*Shared Data*” means the Libre-Beta User Data, CGM Data or Beta System Data, which may include Shared Personal Information to which a Party receives from the other Party in connection with this Agreement.

1.70 “*Third Party*” means any Person other than ADC or Beta or their respective Affiliates or Service Providers.

1.71 “*Trademarks*” means all trademarks, trade names, brand names, domain names, service marks, trade dress, logos, taglines, slogans, certification marks, Internet domain names, social media account or user names (including “handles”), corporate names, business names and all other source indicators, whether registered or unregistered, including all goodwill associated therewith and all applications, registrations and renewals in connection therewith throughout the world, and all rights therein provided by international treaties and conventions.

Additional Definitions. Each of the following definitions is set forth in the Section indicated below:

<u>Definition</u>	<u>Section</u>
“ <i>ADC</i> ”	Preamble
“ <i>ADR</i> ”	Exhibit 15.11
“ <i>Alliance Manager</i> ”	Section 2.7
“ <i>Alternate Devices</i> ”	Section 9.3(g)
“ <i>Applicable Device</i> ”	Section 1.34
“ <i>Approved GUF</i> ”	Section 6.1(c)
“ <i>Background IP</i> ”	Section 5.1
“ <i>Beta</i> ”	Preamble
“ <i>Beta Protection Technology</i> ”	Section 3.6(e)
“ <i>Caregiver</i> ”	Section 3.2(f)
[***]	[***]
“ <i>Caregiver Data</i> ”	Section 3.2(f)
“ <i>Commercialization Plan</i> ”	Section 7.1(a)

<u>Definition</u>	<u>Section</u>
<i>Critical Issues</i>	Section 10.3(b)
<i>“Development Plan”</i>	Section 3.1(a)
<i>“Disclosing Party”</i>	Section 1.35
<i>“Effective Date”</i>	Recitals
<i>“Exploration Agreement”</i>	Recitals
<i>“GDPR”</i>	Section 7.1(b)
<i>“HIPAA”</i>	Section 1.39
<i>“Initial Term”</i>	Section 12.1
<i>“Joint IP”</i>	Section 5.2(b)(i)
<i>“JSC”</i>	Section 2.1
<i>“Launch Country”</i>	Section 7.1(b)
<i>“Losses”</i>	Section 14.1
<i>“Mandatory Disclosure”</i>	Section 11.2(b)
<i>“Master Materials”</i>	Section 7.5(a)
<i>“Party”</i>	Preamble
<i>“Potentially Infringing Item”</i>	Section 14.4
<i>“Project Leader”</i>	Section 2.8
<i>“Quality Agreement”</i>	Section 8.1
<i>“Regulatory Plan”</i>	Section 3.4(a)
<i>“Renewal Term”</i>	Section 12.1
<i>“Restriction”</i>	Section 13.1(h)
<i>“Software Protection Provider”</i>	Section 3.6(e)
<i>“Sole IP”</i>	Section 5.2(a)
<i>“System Pen Testing”</i>	Section 10.3(a)
<i>“Target Launch Date”</i>	Section 7.3(a)
<i>“Term”</i>	Section 12.1

ARTICLE II GOVERNANCE

2.1 Joint Steering Committee. The Parties hereby form a joint steering committee (“**JSC**”) to facilitate communications between the Parties and to aid in long-range planning in connection with the development and commercialization of the Libre-Beta System. The JSC shall include [***] from each Party one of whom shall be designated as the lead member by such Party but who shall otherwise have no additional powers or rights beyond those held by other JSC members. Each Party shall provide the other Party with a list of its initial members of the JSC within [***] after the Effective Date. Each Party shall use commercially reasonable efforts to maintain the continuity of its representation, but may, if needed, (a) replace any or all of its representatives at any time by giving prior written notification to the other Party, or (b) appoint a proxy at any time by giving prior written notification to the other Party.

2.2 JSC Meetings. The JSC shall meet at least [***] during the Term, or more frequently as agreed to by the Parties. Such meetings alternating between locations designated by ADC and locations designated by Beta. Upon mutual agreement of the Parties, such meetings may take place telephonically or via video conference. [***]. If a representative of a Party is unable to attend a meeting, the Party may designate an alternate to attend such meeting in place of the absent representative. Each Party may, in its reasonable discretion, invite other employees of such Party to attend meetings of the JSC. Each Party shall provide advance notice of any additional attendees it will include at a meeting of the JSC and shall keep the JSC reasonably informed of its progress and activities under this Agreement. Each Party shall be responsible for calling meetings with reasonable advance notice. Any member of the JSC may make proposals for agenda items and shall provide all appropriate information with respect to such proposals reasonably in advance of the applicable meeting. The Parties shall alternate in preparing and circulating for review and approval of the other Party minutes of each meeting of the JSC within [***] after each such meeting. The Parties shall agree on the minutes of each meeting [***] thereafter.

2.3 JSC Responsibilities. The JSC shall provide oversight for the collaboration between the Parties under this Agreement, including (a) reviewing and approving the initial Development Plan and amendments thereto, (b) reviewing and approving the initial Regulatory Plan and amendments thereto, (c) reviewing and approving the initial Commercialization Plan and amendments thereto, (d) reviewing and approving the final architecture of the Libre-Beta System, and (e) monitoring the progress of activities under the Development Plan, Regulatory Plan, Commercialization Plan and Quality Agreement, and such other functions as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

2.4 Procedural Rules. The JSC shall have the right to adopt such standing rules as shall be necessary for its work to the extent that such rules are not inconsistent with this Agreement. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) member appointed by each Party, and a quorum shall be required for adoption of standing rules. Members of the JSC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants.

The JSC shall take actions [***].

2.5 Dispute Resolution. The JSC shall act in good faith to resolve all issues before it. If the JSC cannot, or does not, [***] on an issue, then the dispute shall be first referred to the Senior Officers of the Parties, who shall confer in good faith on a resolution of the issue. Any final decision mutually agreed to be the Senior Officers of the Parties shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within [***] after such issue was first referred to them, then, except as provided in Section 3.1(d)Error! Reference source not found., such dispute shall be resolved pursuant to Section 15.11. Disputes arising between the Parties under this Agreement that are outside of the responsibilities of the JSC, shall be resolved pursuant to Section 15.11.

2.6 No Binding Powers. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be given to the JSC beyond those in this Article II. [***].

2.7 Alliance Managers. Within [***] after the Effective Date, each Party shall appoint an individual, to act as the alliance manager for such Party (the “*Alliance Manager*”). Each non-member Alliance Manager of the Parties shall thereafter be permitted to attend meetings of the JSC and any subcommittee as an observer. The Alliance Managers shall be the point of contact for the parties regarding the contractual and business aspects of the collaboration during the Term. Each party may replace its Alliance Manager or appoint a proxy [***] by giving prior written notification to the other parties. Each party shall pay for its own Alliance Manager’s time and activities.

2.8 Project Leaders. Within [***] after the Effective Date, each Party shall appoint an individual as the project leader for such Party (the “*Project Leader*”). The Project Leaders shall meet [***] or as mutually agreed by the Parties at such locations or by such means as the Parties agree. The Project Leaders will jointly coordinate the day-to-day work of the Parties under this Agreement and jointly report progress to the JSC. Each Party may replace its Project Leader or appoint a proxy [***] by giving prior written notification to the other Party. [***]. Project Leaders may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participant. The Parties shall be free to appoint the Project Leader as a member of the JSC, but one person cannot act as Project Leader, Alliance Manager and member of the JSC at the same time.

**ARTICLE III
DEVELOPMENT PROGRAM**

3.1 Development Program Generally.

(a) Within [***] after the Effective Date, the Parties shall jointly prepare and submit to the JSC for approval a development plan covering each Party's responsibilities in developing the Libre-Beta System (the "***Development Plan***"), which plan shall be consistent with the terms of this Article III. Each Party shall keep the JSC informed and updated regarding its conduct of the Development Plan. The final architecture of the Libre-Beta System shall be mutually agreed by the Parties through the JSC.

(b) If the Parties are unable to reach agreement on the terms of the Development Plan within such [***] period, then either Party may refer the matter to the Senior Officers for resolution pursuant to Section 2.5. The Development Plan may be amended by the JSC to include or change roles, responsibilities and timelines for any technical work required for development of the Libre-Beta System. In the event the JSC is unable to reach agreement on any proposed update to the Development Plan, such dispute shall be resolved in accordance with the terms of Section 2.5.

(c) Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to complete the activities assigned to it in the Development Plan and will contribute reasonable time, resources, personnel and materials, including for purposes of clinical trials, as specifically set forth in the Development Plan. Notwithstanding anything to the contrary herein, neither Party shall be obligated to conduct any development activities related to the Libre-Beta System until the Development Plan has been approved by the Parties or their Senior Officers.

(d) If at any time prior to First Commercial Sale, a Party reasonably determines, after any change to the Development Plan that is not initiated by such Party or its designees, that its remaining obligations under the Development Plan are unduly burdensome it will notify the other Party's members of the JSC in writing of the need to discuss such concerns as an agenda item at the next JSC meeting. If the Parties are not able to come to an agreement at the JSC meeting on how to address such concerns, then the dispute shall be first referred to the Senior Officers of the Parties, who shall confer in good faith on a resolution of the issue. Any final decision mutually agreed to by the Senior Officers of the Parties shall be conclusive and binding on the Parties. If the Senior Officers of the Parties are unable to arrive to a mutually agreed decision, then the dispute shall be resolved in accordance with the terms of Section 2.5.

3.2 Beta Development Activities.

(a) Beta shall be responsible for developing the Libre-Beta System in accordance with the Development Plan; provided that use of the ADC Marks is subject to Section 6.2.

(b) Beta shall be responsible for all development and clinical trials, for the Libre-Beta System, [***].

(c) [***].

(d) Beta shall ensure that its Beta Cloud [***].

(e) Beta shall enable the Libre-Beta System to display and trigger alarms for the CGM System utilizing CGM Data collected [***].

(f) [***].

3.3 ADC Development Activities.

(a) ADC shall be responsible for all development for the CGM System, including any software that may be required to transmit data derived from the CGM System to the Libre-Beta System for interpretation.

(b) ADC shall provide reasonable assistance to Beta to the extent necessary for the design and development by Beta of the aspects of the Libre-Beta System that allow CGM Data to be displayed, interpreted and processed by the Libre-Beta System. In particular, subject to Section 3.6, ADC shall provide to Beta the FreeStyle Libre Technology. ADC shall also provide Beta with reasonable quantities of test sensors, ADC internally created development or testing tools, in each case as reasonably necessary for Beta to develop, test and conduct clinical trials for the Libre-Beta System.

3.4 Regulatory Matters.

(a) Within [***] after the Effective Date, the Parties shall jointly prepare and submit to the JSC for approval a regulatory plan (“**Regulatory Plan**”) for the Libre-Beta System, which plan shall be consistent with the terms of this Section 3.4 [***]. Subject to the terms of this Agreement, each Party shall use Commercially Reasonable Efforts to complete the activities assigned to it in the Regulatory Plan. If the Parties are unable to reach agreement on the Regulatory Plan within such [***] period, either Party may refer the matter to the JSC for resolution at its next meeting. If the JSC is unable to resolve the dispute within [***] after its next meeting, either Party may refer the matter to the Senior Officers for resolution pursuant to Section 2.5.

(b) The Parties agree to regularly present and discuss the status of their regulatory activities hereunder, and any proposed updates to the Regulatory Plan, at the JSC meetings, or more frequently as needed to keep each other reasonably informed of regulatory matters related to the Libre-Beta System.

(c) Beta shall provide ADC with summaries or copies, as appropriate, of (i) all filings for regulatory approvals for the Libre-Beta System contemporaneously with Beta’s submission of such filings and (ii) all CGM related written or electronic correspondence (other than filings for regulatory approvals) relating to the development of the Libre-Beta System received by or on behalf of Beta from, or sent by or on behalf of Beta to, Authorities. If Beta intends to update its regulatory filings or technical information or documentation necessary for Beta to obtain and maintain regulatory approvals for the Beta System or Libre-Beta System related to the CGM, Beta shall notify ADC in writing of any proposed updates no later than [***] prior to the filing or implementation, as applicable, so long as such notice doesn’t delay Beta’s response to FDA, to meet FDA deadlines.

(d) Beta shall be solely responsible for obtaining and maintaining regulatory approvals and ongoing communication with Authorities for the Libre-Beta System and performing all testing (including system, human factors, or clinical) required for such approval as contemplated by the Development Plan; provided that ADC shall have final decision-making authority with respect to any CGM Matters. When requested by Beta, ADC shall provide reasonable support, including participation in joint meetings with Authorities, necessary to assist in obtaining and maintaining regulatory approval of the Libre-Beta System.

(e) ADC shall be solely responsible for obtaining and maintaining regulatory approvals and ongoing communication with Authorities for the CGM System, and performing all testing (including system, human factors, or clinical) required for such approval. In addition, ADC shall be solely responsible for obtaining and maintaining integrated continuous glucose monitoring approval from the FDA for the CGM System for commercialization in the United States. When requested by ADC, Beta shall provide reasonable support, including (i) participation in joint meetings with Authorities to assist in obtaining and maintaining regulatory approval of the CGM System that can be used with the Libre-Beta System, and (ii) for testing and verification of the incorporation of the data generated by the CGM System into the Libre-Beta System.

(f) If any regulatory approval of the Libre-Beta System will involve joint approval of both the Beta System and CGM System, the Parties will work in good faith to coordinate their activities to secure such approval; provided that, in connection therewith, Beta shall have final decision-making authority with respect to Beta System and ADC shall have final decision-making authority with respect to the CGM System.

(g) Each Party shall provide the assistance described in this Section 3.4 and shall otherwise cooperate with the other Party as reasonably necessary to obtain or maintain regulatory approval of the Beta System and CGM System, as applicable, to the extent necessary for the Libre-Beta System, including providing reasonably requested information or documents. Any such information or documents that are non-public shall be used by the receiving Party solely for the purpose of obtaining or maintaining regulatory approval. If the disclosing Party determines in its reasonable discretion that any information or documents requested pursuant to this Section 3.4 contains information of a sensitive nature, the disclosing Party shall have the right to provide such information or documents in confidence directly to the applicable Authorities rather than to the other Party, provided that the disclosing Party timely provides the submission to the applicable Authorities and notifies the other Party of the submission.

3.5 Costs. Unless otherwise expressly provided for in this Agreement, the Development Plan or Regulatory Plan, [***].

3.6 Use of ADC Highly Confidential Information.

(a) Beta shall use the ADC Highly Confidential Information solely for (i) [***], (ii) [***] and (iii) [***]. Beta shall not use the ADC Highly Confidential Information for any other purpose and shall not modify or attempt to reverse-engineer the FreeStyle Libre Technology or any other ADC Highly Confidential Information.

(b) Beta shall not provide ADC Highly Confidential Information to any Third Parties (except in accordance with Section 3.6(e)) and shall ensure that only Approved Persons receive access to the ADC Highly Confidential Information. Beta shall maintain a written list of Approved Persons, [***] update the list with any additions or deletions, and provide a copy of the current list to ADC within [***] after ADC's request therefor. For clarity, such list shall be Beta's Confidential Information.

(c) Beta shall ensure that:

(i) the ADC Highly Confidential Information is [***];

(ii) [***];

(iii) the ADC Highly Confidential Information shall [***];

(iv) [***]; and

(v) [***].

(d) If ADC provides any [***] shall be ADC Highly Confidential Information and Beta shall write [***] with respect to the ADC Highly Confidential Information as may be set forth in the Development Plan.

(e) Beta represents and warrants that [***] (collectively, “**Beta Protection Technology**”). Before distribution of the Libre-Beta System (or any of its components) to any Third Party (excluding an Approved Person for development purposes hereunder), Beta shall take any steps that [***] to (i) [***], (ii) [***] and (iii) [***].

(f) Beta agrees that upon request, it shall certify in writing whether it is in compliance with the provisions of this Section 3.6. [***] (and in any event within [***]) after Beta becomes aware of any actual or expected noncompliance with this Section 3.6, Beta shall notify ADC in writing. Such written notice shall include the nature and period of existence of the noncompliance and what action Beta is taking or proposes to take to identify and cure such noncompliance. [***], Beta shall work in good faith with ADC to address and remediate such noncompliance.

(g) If ADC determines [***], in its reasonable discretion, that [***], ADC shall inform Beta of [***]. [***] but no more [***] after receipt of such notice, Beta shall [***] Beta will [***] provide ADC a written report of [***]. In the course of [***].

(h) [***].

(i) Beta acknowledges that any use or disclosure of the ADC Highly Confidential Information other than as permitted in this Agreement may cause ADC irreparable harm and significant injury to an extent that may be extremely difficult to ascertain. Accordingly, Beta agrees that ADC shall have, in addition to any other rights or remedies available to it at law or in equity, the right to seek a preliminary or permanent injunction to prevent unauthorized use or disclosure of the ADC Highly Confidential Information.

(j) The ADC Highly Confidential Information constitutes ADC's Confidential Information and shall be treated as such; provided, however, that to the extent this Section 3.6 conflicts with any other provision of the Agreement regarding the treatment of Confidential Information, this Section 3.6 shall control with regard to the ADC Highly Confidential Information.

3.7 Use of Beta Highly Confidential Information.

(a) Subject to the terms of this Agreement, ADC shall use the Beta Highly Confidential Information solely for development of capability to transfer Beta System Data, CGM Data, and Libre-Beta User Data into LibreView [***]. ADC shall not use the Beta Highly Confidential Information for any other purpose and shall not modify or attempt to reverse-engineer the Beta Highly Confidential Information.

(b) ADC shall ensure that:

(i) the Beta Highly Confidential Information is never checked into any source code management system such as [***]; provided that the foregoing shall not preclude ADC's use of a private source control system which is dedicated for ADC's exclusive use and not accessible by Third Parties;

(ii) all filenames relating to the Beta Highly Confidential Information are added to [***] of any source code management system (other than a private source control system allowed under foregoing clause (i)) [***];

(iii) the Beta Highly Confidential Information shall never be shared [***];

(iv) every computer with the Beta Highly Confidential Information on the disk drive has drive encryption and password-protection enabled; and

(v) the Beta Highly Confidential Information is never copied onto a USB or other external hard drive.

(c) ADC agrees that upon request, it shall certify in writing whether it is in compliance with the provisions of this Section 3.7. [***] (and in any event within [***]) after ADC becomes aware of any actual or expected noncompliance with this Section 3.7, ADC shall notify Beta in writing. Such written notice shall include the nature and period of existence of the noncompliance and what action ADC is taking or proposes to take to identify and cure such noncompliance. [***], ADC shall work in good faith with Beta to address and remediate such noncompliance.

(d) If Beta determines [***], in its reasonable discretion, that (i) ADC has failed to comply with the provisions of this Section 3.7 or has otherwise failed to sufficiently protect the Beta Highly Confidential Information and that such failure has resulted in or is imminently likely to result in unauthorized disclosure of the Beta Highly Confidential Information to a Third Party or unauthorized use of the Beta Highly Confidential Information by a Third Party, ADC shall inform Beta of ADC's reasons for believing that such actual or potential breach, unauthorized disclosure or use has occurred. [***] but no more [***] after receipt of such notice, ADC shall commence an investigation into such concerns and upon conclusion of its investigation Beta will [***] provide ADC a written report of the results of such investigation. In the course of the investigation ADC shall use commercially reasonable efforts to identify how the unauthorized disclosure or unauthorized use, if any, of such Beta Highly Confidential Information occurred. If Beta notifies ADC that it alleges in good faith that ADC is failing to sufficiently protect the Beta Highly Confidential Information despite compliance with this Section 3.7, then ADC and Beta shall in good faith negotiate reasonable additional policies and procedures for ADC to implement to sufficiently protect the Beta Highly Confidential Information, provided, however, that ADC shall during such negotiations use reasonable best efforts to mitigate any risk of unauthorized use or disclosure created by the issues reasonably identified by Beta in its written notice.

(e) A material failure by ADC to comply with its obligations under subsections through (d) above shall be a material breach of this Agreement.

(f) ADC acknowledges that any use or disclosure of the Beta Highly Confidential Information other than as permitted in this Agreement may cause Beta irreparable harm and significant injury to an extent that may be extremely difficult to ascertain. Accordingly, ADC agrees that Beta shall have, in addition to any other rights or remedies available to it at law or in equity, the right to seek a preliminary or permanent injunction to prevent unauthorized use or disclosure of the Beta Highly Confidential Information.

(g) The Beta Highly Confidential Information constitutes Beta Confidential Information and shall be treated as such; provided, however, that to the extent this Section 3.7 conflicts with any other provision of the Agreement regarding the treatment of Confidential Information, this Section 3.7 shall control with regard to the Beta Highly Confidential Information.

3.8 Pre-Production Environment. ADC shall provide a pre-production environment and any necessary support to facilitate Beta's testing and, if necessary, modification of the Beta System required for the conduct of the Development Plan. Beta shall provide a pre-production environment and any necessary support to facilitate ADC's testing and, if necessary, modification of any CGM System required for the conduct of the Development Plan.

3.9 Technical Team Meetings. During the conduct of the development activities pursuant to the Development Plan, the relevant technical representatives from each Party will meet as reasonably requested by either Party to discuss the development of the Libre-Beta System.

3.10 Use of FOSS and Third Party Software.

(a) Beta represents and warrants to ADC: (i) that it has satisfied all its obligations to any third parties with respect to all applicable FOSS licenses; (ii) that the FOSS, in the form included in the Beta-Libre System, is suitable for the intent and purposes furnished hereunder; (iii) that use of the FOSS in such form for such intent and purposes in no manner creates any added obligation on the part of ADC, or diminishes, conditions or eliminates any of the rights, title, or interest that Beta grants ADC under this Agreement; and (iv) that use of the FOSS in such form for such intent and purposes, with any software of ADC, does not subject ADC to any obligation of disclosure or distribution to any third party or to the public of any such proprietary software, or otherwise make such software subject to the terms of any FOSS license or impair ADC's rights, title, or interest in or to such software.

(b) Beta represents and warrants to ADC that it has obtained all necessary licenses for any third-party software that is not FOSS but is incorporated into the Libre-Beta System or used in the development of the same.

**ARTICLE IV
NEW PRODUCTS AND PRODUCT UPDATES**

4.1 Update Notices. Each Party shall keep the other Party reasonably informed of planned Beta System or CGM System updates or any planned cloud-to-cloud data API interface updates, as applicable (whether software updates or hardware modifications), if such updates will or could reasonably be expected to impact the integration, features, functions or capabilities of the Libre-Beta System [***].

4.2 Change Management.

(a) ADC and its (sub)contractors shall use Commercially Reasonable Efforts to ensure continued functionality of the Libre-Beta System with the CGM System. Beta shall use Commercially Reasonable Efforts to provide any reasonable assistance requested by ADC for evaluation testing, design verification, and validation testing necessary to implement any changes ADC anticipates making to the CGM System related to the Libre-Beta System in accordance with ADC's product development timeline. ADC shall provide Beta with an estimation of resource type, timing and duration for the requested assistance reasonably in advance.

(b) Beta shall use Commercially Reasonable Efforts to ensure continued functionality of the Libre-Beta System with the Beta System. ADC shall use Commercially Reasonable Efforts to provide any reasonable assistance requested by Beta for evaluation testing, design verification, and validation testing necessary to implement any changes Beta anticipates making to the Beta System related to the Libre-Beta System in accordance with Beta's product development timeline. Beta shall provide ADC with an estimation of resource type, timing and duration for the requested assistance reasonably in advance.

ARTICLE V INTELLECTUAL PROPERTY RIGHTS

5.1 Background IP. Each Party shall retain all right, title, and interest in any Intellectual Property (a) owned or Controlled by the Party prior to the Effective Date, or (b) developed or acquired solely by or for the Party independently of this Agreement without use of the other Party's Confidential Information or Intellectual Property, whether before or after the Effective Date (collectively, "**Background IP**").

5.2 Program Intellectual Property.

(a) Sole IP. As between the Parties, each Party shall own all right, title, and interest in Intellectual Property invented, discovered, or created solely by one or more employees, contractors or agents of such Party or its Affiliates pursuant to and during the conduct of activities under this Agreement, and without the use of the other Party's Confidential Information (such Party's "**Sole IP**").

(b) Joint IP.

(i) The Parties shall jointly own all Intellectual Property invented, discovered, reduced to practice, or created jointly by one or more employees, contractors or agents of ADC and one or more employees, contractors or agents of Beta in connection with the conduct of activities under this Agreement ("**Joint IP**").

(ii) Each Party shall have full rights in the Joint IP as accorded to joint owners under U.S. intellectual property law, including the right to exploit the Joint IP and freely grant licenses to Affiliates or Third Parties in the Joint IP without the consent of or accounting to, the other Party; provided, however, that to the extent that the Joint IP includes a Party's copyrighted images, such Party's prior written consent shall be required prior to any exploitation or licensing of such Joint IP. The Joint IP shall be considered the Confidential Information of both Parties.

(iii) Each Party shall [***] disclose to the other Party in writing the making, conception or reduction to practice of any Joint IP.

5.3 Determination of Inventorship and Authorship. Inventorship and authorship of Intellectual Property invented, discovered, or created in relation to this Agreement shall be determined according to U.S. intellectual property law, regardless of the jurisdiction in which the Intellectual Property was invented, discovered, or created.

5.4 Documents and Assistance. Each Party shall execute and shall cause its employees, contractors and agents to execute all documents necessary to effectuate the Parties' rights set forth in this Article V. Each Party shall also provide the other Party with reasonable assistance necessary for the other Party to obtain or maintain protection of its Intellectual Property.

ARTICLE VI LICENSES

6.1 Intellectual Property Licenses for Activities Under Agreement.

(a) ADC Licenses to Beta. [***] and subject to the terms and conditions of this Agreement, ADC hereby grants to Beta and its Affiliates performing under this Agreement a [***] license under ADC Licensed Background IP and ADC's Sole IP solely for the purpose of and to the extent necessary for performing Beta's obligations under this Agreement.

(b) Beta License to ADC. [***] and subject to the terms and conditions of this Agreement, Beta hereby grants to ADC a [***] license under the Beta Licensed Background IP and Beta's Sole IP solely for the purpose of and to the extent necessary for performing ADC's obligations under this Agreement.

(c) Licenses to GUI. If under the Development Plan a Party proposes specific GUI formats and the other Party approves in writing such GUI format ("**Approved GUI**"), then solely in that event, the approving Party shall and does hereby grant to the other Party a [***] license under the approving Party's GUI IP only, to develop, make, have made, use, sell, have sold, offer for sale and import such Approved GUI (i) with respect to Beta's Approved GUIs only, for use with any component of the Libre-Beta System and, (ii) with respect to ADC's Approved GUIs only, in LibreView and FreeStyle Libre App, in each case of (i) and (ii), [***] and subject to the terms and conditions of this Agreement (including Section 15.16).

6.2 Trademark Licenses.

(a) Subject to compliance with Applicable Law and subject to, and in accordance with, the terms and conditions of this Agreement, ADC hereby grants to Beta a [***] license to use the ADC Marks for the sole and exclusive purpose of developing the Libre-Beta System and marketing, the Libre-Beta System in the Launch Country, in accordance with the Commercialization Plan. Beta may sublicense its right to use the ADC Marks with [***]. ADC shall provide Beta with copies of the ADC Marks in an appropriate form for the uses contemplated herein. ADC shall have the right to approve the appearance, placement and manner of use of the ADC Marks in advance of their use and to withhold approval of any ADC Marks uses in its sole and absolute discretion. Beta agrees to use the ADC Marks solely in the form provided or approved in writing by ADC and to comply with any standards or guidelines regarding the usage or presentation of the ADC Marks which ADC may communicate from time to time, with any revisions to be effective upon written notice to Beta. ADC or its Affiliate is the sole and exclusive owner of all right, title and interest in and the ADC Marks. ADC or its Affiliate shall retain all right, title, and interest in the ADC Marks, and all goodwill derived from the use of the ADC Marks shall inure solely to the benefit of ADC or its Affiliates. To the extent Beta acquires any trademark or trade dress rights on the basis of using the ADC Marks in commerce with the consequence that the marks have attained market recognition Beta is obliged to transfer such Trademark rights acquired by use to ADC or its Affiliate upon termination of this Agreement. Beta agrees that neither it nor its agents shall, during or after the Term of the Agreement, anywhere in the world, take any action that in ADC's sole, good faith discretion impairs or contests or tends to impair or contest the validity of ADC's or its Affiliates' right, title and interest in and to the ADC Marks, including using, or filing an application to register, any word, mark, domain name, user name, hashtag, symbol or device, or any combination thereof, that is confusingly similar to or dilutes the distinctiveness of any of the ADC Marks.

(b) Subject to compliance with Applicable Law and subject to, and in accordance with, the terms and conditions of this Agreement, Beta hereby grants to ADC and its Affiliates a [***] license to use the Beta Marks for the sole and exclusive purposes of developing the Libre-Beta System and marketing, the CGM System for use with the Libre-Beta System in the Launch Country in accordance with the Commercialization Plan. ADC may sublicense its right to use the Beta Marks with [***]. Beta shall provide ADC with copies of the Beta Marks in an appropriate form for the uses contemplated herein. Beta shall have the right to approve the appearance and placement of the Beta Marks in advance of their use. ADC agrees to use the Beta Marks solely in the form provided or approved in writing by Beta and to comply with any standards or guidelines regarding the usage or presentation of the Beta Marks which Beta may communicate from time to time, with any revisions to be effective upon written notice to ADC. ADC acknowledges that Beta is the sole and exclusive owner of all right, title and interest in and the Beta Marks. Beta shall retain all right, title, and interest in the Beta Marks, and all goodwill derived from the use of the Beta Marks shall inure solely to the benefit of Beta. To the extent ADC acquires any trademark or trade dress rights on the basis of using the Beta Marks in commerce with the consequence that the marks have attained

market recognition ADC is obliged to transfer such Trademark rights acquired by use to Beta upon termination of this Agreement. ADC agrees that neither it nor its agents shall, during or after the Term of the Agreement, anywhere in the world, take any action that in Beta's sole, good faith discretion impairs or contests or tends to impair or contest the validity of Beta's right, title and interest in and to the Beta Marks, including using, or filing an application to register, any word, mark, domain name, user name, hashtag, symbol or device, or any combination thereof, that is confusingly similar to or dilutes the distinctiveness of any of the Beta Marks.

(c) Except as expressly permitted pursuant to subsection (a) above and Sections 7.5 and 7.8, Beta shall refrain from any use of ADC's name, trade names, trademarks, trade dress, service marks, designs or logos, including the ADC Marks, in any publication, press release, marketing or promotional materials, domain name, user name, hashtag, web site or otherwise without the prior written approval of ADC, which may be granted or withheld at ADC's sole discretion. Beta shall refrain from any use of the ADC Marks in a manner that threatens to damage the goodwill associated with the ADC Marks or which threatens to tarnish the reputation or otherwise unfavorably reflect upon ADC. Beta shall advise ADC of any instances of possible infringement or other violation of ADC's rights in the ADC Marks in connection with the Libre-Beta System that come to its attention during the Term. Beta agrees to fully cooperate with ADC regarding any action ADC may take with respect to such infringement or violation. ADC shall have the exclusive right, exercisable in its sole and unlimited discretion, to institute in its own name and to control or settle all actions against Third Parties relating to ADC's rights, at ADC's expense. ADC shall be entitled to receive and retain all amounts awarded, if any, as damages, profits or otherwise in connection with such actions.

(d) Except as expressly permitted pursuant to subsection (b) above and Sections 7.5 and 7.8, ADC shall refrain from any use of Beta's name, trade names, trademarks, trade dress, service marks, designs or logos, including the Beta Marks, in any publication, press release, marketing or promotional materials, domain name, user name, hashtag, web site or otherwise without the prior written approval of Beta, which may be granted or withheld at Beta's sole discretion. ADC shall refrain from any use of the Beta Marks in a manner that threatens to damage the goodwill associated with the Beta Marks or which threatens to tarnish the reputation or otherwise unfavorably reflect upon Beta. ADC shall advise Beta of any instances of possible infringement or other violation of Beta's rights in the Beta Marks in connection with the Libre-Beta System that come to its attention during the Term. ADC agrees to fully cooperate with Beta regarding any action Beta may take with respect to such infringement or violation. Beta shall have the exclusive right, exercisable in its sole and unlimited discretion, to institute in its own name and to control or settle all actions against Third Parties relating to Beta's rights, at Beta's expense. Beta shall be entitled to receive and retain all amounts awarded, if any, as damages, profits or otherwise in connection with such actions.

(e) Except for the limited right to use the ADC Marks granted to Beta as set forth herein, no right, license or other interest with respect to any ADC Marks is granted to Beta under this Agreement.

(f) Except for the limited right to use the Beta Marks granted to ADC as set forth herein, no right, license or other interest with respect to any Beta Marks is granted to ADC under this Agreement.

6.3 Licenses on Intellectual Property Created with Beta System Data or CGM Data.

(a) ADC License to Beta. Subject to the terms and conditions of this Agreement, ADC hereby grants to Beta and its Affiliates, manufacturers, distributors, and customers a non-exclusive, royalty-free, fully paid-up, perpetual, irrevocable license under any of ADC's Sole IP that was invented, discovered, reduced to practice, or created using Beta System Data and that relates to automated insulin dosing for use in products sold, distributed, or manufactured by or on behalf of Beta or its Affiliates.

(b) Beta License to ADC. Subject to the terms and conditions of this Agreement, Beta hereby grants to ADC and its Affiliates, manufacturers, distributors, and customers a non-exclusive, royalty-free, fully paid-up, perpetual, irrevocable license under any of Beta's Sole IP that was invented, discovered, reduced to practice, or created using CGM Data and that relates to analyte sensing or monitoring for use in products sold, distributed, or manufactured by or on behalf of ADC or its Affiliates.

6.4 No Implied Licenses. No rights or licenses are granted, by implication or otherwise, by either Party to the other Party hereunder except as expressly set forth in this Agreement.

ARTICLE VII COMMERCIALIZATION, DISTRIBUTION AND MARKETING

7.1 Commercialization Plan.

(a) Within [***] after the Effective Date, the Parties shall prepare and present to the JSC for review a preliminary commercialization plan for the Libre-Beta System, [***] (the "**Commercialization Plan**"). The Parties will present an updated Commercialization Plan to the JSC for approval within [***] thereafter, which shall incorporate any initial feedback and changes based on the input of the JSC. If the Parties are unable to reach agreement on the Commercialization Plan within the foregoing time periods, then either Party may refer the matter to the JSC for resolution at its next meeting. If the JSC is unable to resolve the matter within [***] after its next meeting, either Party may refer the matter to the Senior Officers for resolution pursuant to Section 2.5. The Commercialization Plan shall be consistent with the terms of this Article VII and include a written plan to comply with Section 9.1. The Commercialization Plan may thereafter be amended by the JSC.

(b) The Libre-Beta System shall only be launched and commercialized in the United States (the "**Launch Country**"). The Parties may amend this Agreement to add additional country(ies) or region(s) for launching and commercializing the Libre-Beta System, subject to all Applicable Laws, including all Data Protection Laws.

7.2 Commercialization Activities.

(a) Each Party shall use Commercially Reasonable Efforts to perform its obligations as set forth in each approved Commercialization Plan (including, in the case of ADC, to make the CGM System and, in the case of Beta, to make the Libre-Beta System commercially available in the Launch Country) and shall provide the other Party with [***] written notice of any occurrence that may substantially affect the Party's ability to perform such obligations.

(b) In executing the Commercialization Plan:

(i) ADC shall [***]; and

(ii) Beta shall [***].

(c) Notwithstanding anything to the contrary herein, neither Party shall be obligated to conduct any commercialization activities in a Launch Country related to the Libre-Beta System until the Commercialization Plan for such Launch Country has been approved by the JSC.

7.3 [***].

7.4 Handling of Prescriptions.

(a) In a Launch Country that uses forms for prescriptions, referrals or statements of medical necessity that do not distinguish between types of continuous glucose monitors, at ADC's request, Beta shall use Commercially Reasonable Efforts compliant with Applicable Law to establish, and to cause its Affiliates, its distributors and its and their subcontractors to establish, new forms that separately identify the CGM System (in a manner that is no less favorable than other continuous glucose monitoring systems) so that health care providers are able to specifically select the CGM System for use with the Libre-Beta System.

(b) The Parties shall establish, as part of the Commercialization Plan, processes to enable the transfer of prescriptions, referrals, or statements of medical necessity for CGM Systems received by Beta directly from a patient or health care provider to ADC or ADC's designated distributors.

7.5 Marketing Materials.

(a) **Marketing Materials and Guidelines for Libre-Beta System.** The Parties shall jointly develop marketing and promotion materials and guidelines for the Libre-Beta System for use throughout the Launch Country in compliance with (i) Applicable Law, (ii) the regulatory approved label of the CGM System, the Beta System and the Libre-Beta System and (iii) each Party's internal promotional guidelines for the purpose of publicizing and encouraging interest in the Libre-Beta System (such materials and guidelines collectively, the "**Master Materials**"). Such Master Materials must be approved by each Party and, unless otherwise agreed by the Parties, in a timely manner in writing prior to use, whether directly or indirectly through Affiliates, distributors or subcontractors, by a Party. The Master Materials may be updated by the Parties from time to time upon the written agreement of the Parties and, unless otherwise agreed by the Parties, which such agreement shall be provided in a timely manner. Subject to the terms and conditions of this Agreement, each Party shall have sole discretion over its use of the Master Materials.

(b) License. Subject to the terms and conditions of this Agreement including the obligations in Section 6.2, each Party hereby grants to the other Party a [***] license to use, distribute, transmit and reproduce the marketing and promotional materials created pursuant to Section 7.5(a) for the sole and exclusive purpose of marketing and having marketed the Libre-Beta System for use as the Libre-Beta System in the Launch Country.

(c) Use of Name. Except as provided in Section 7.5(a), neither Party nor its Affiliates directly, or through a Third Party, shall publish or distribute any written or electronic marketing, promotional, customer services, or other similar materials that mention the other Party's name or products or use the other Party's trademark without other Party's prior review and written approval, which approval may be provided by e-mail. The foregoing provision applies to, without limitation, websites, advertising, sales aids, brochures, marketing collateral, emails, social media, and letters or other communications to customers, distributors, healthcare providers, and other Third Parties.

7.6 Joint Promotion Activities. The Parties will address any joint sales, marketing or promotional efforts for the Libre-Beta System in the Commercialization Plan.

7.7 Limit on Other Device Communication. With respect to each Launch Country, following the launch of the Libre-Beta System in such Launch Country:

(a) During the Term, neither Beta nor its Affiliates, may, directly or through a Third Party, issue in such Launch Country an outbound communication of any kind or in any medium specifically targeted to users of the CGM System (as opposed to a broader base of insulin delivery system users or insulin users, including users of a Beta System) and that is intended to (or could reasonably be interpreted as intending to) encourage, convince, or otherwise solicit a CGM System user to switch to or request any continuous glucose monitor made by any entity other than ADC.

(b) During the Term, neither ADC nor its Affiliates, may, directly or through a Third Party, issue in such Launch Country an outbound communication of any kind or in any medium specifically targeted to users of the Beta System (as opposed to a broader base of insulin delivery system users or insulin users, including users of CGM System) and that is intended to (or could reasonably be interpreted as intending to) encourage, convince, or otherwise solicit a Beta System user to switch to or request any CSII System made by any entity other than Beta.

7.8 Publicity [*].**

(a) Neither Party shall issue any public announcement, press release or other public disclosure, written or oral, relating to the other Party, the other Party's products, this Agreement, or the existence of an arrangement between the Parties, without the other Party's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

(b) [***].

(c) Notwithstanding anything to the contrary herein, either Party may make any public statement, written or oral, relating to the Libre-Beta System (i) to the extent such public statement is specifically included in product manuals, registrations with a regulatory agency or notified body or (ii) specifically requested by a regulatory agency or notified body in connection with a product registration or in response to a product safety or quality issue. In addition the [***] from each Party shall have the right without the other's Party's approval to make public statements regarding the Libre-Beta System to the extent such public statements are reflected in all material respects published (in any industry recognized scientific publication) peer-reviewed studies; provided, however, that any such peer-reviewed studies shall be registered on www.clinicaltrials.gov or other World Health Organization Registry Network or International Committee of Medical Journal Editors approved registry network or that are independent studies (i.e., studies that are not directly or indirectly funded, endorsed or otherwise sponsored by such Party [***] or primarily done for marketing purposes).

7.9 Costs. Unless otherwise expressly provided for in this Agreement or the Commercialization Plan, each Party shall be responsible for all costs and expenses it incurs in connection with its commercialization, sales and marketing activities conducted hereunder.

ARTICLE VIII QUALITY AGREEMENT

8.1 Negotiation of Quality Agreement. Within [***] after the Effective Date, the Parties shall commence negotiations in good faith for a quality agreement to address customer training, service and support, complaint handling, adverse event reporting and other regulatory, operational, and quality responsibilities for the Libre-Beta System (the "**Quality Agreement**"). If the Parties are unable to reach agreement on the terms of the Quality Agreement at least [***] before the first Target Launch Date, the matter will be addressed at the next JSC meeting and, if the JSC is unable to resolve the matter, either Party may refer the matter to the Senior Officers for resolution pursuant Section 2.5. In addition, at least [***] before the Target Launch Date determined by the JSC for the Launch Country, the Parties shall evaluate and, if needed, amend the Quality Agreement to align with the Commercialization Plan for such Launch Country.

8.2 Content of Quality Agreement. Among other things, the Quality Agreement will provide that:

(a) the Parties will adopt a mutually agreed framework to report to one another and cooperate with respect to customer service inquiries and all complaints, failure analysis, recalls, or potential recalls, and related regulatory issues, relating to the Libre-Beta System during the Term and thereafter;

(b) ADC shall be responsible for all customer service inquiries and all complaints, failure analysis, recalls, or potential recalls, and related regulatory matters, solely related to the CGM System and shall manage the foregoing in a commercially reasonable manner. Such undertakings shall be at ADC's expense;

(c) Beta shall be responsible for all customer service inquiries and all complaints, failure analysis, recalls, or potential recalls, and related regulatory matters, solely related to the Beta System and shall manage the foregoing in a commercially reasonable manner. Such undertakings shall be at Beta's expense;

(d) the Parties shall work together in good faith to resolve customer service inquiries and all complaints, failure analysis, recalls, or potential recalls, and related regulatory matters, that involve both (i) the CGM System and (ii) the Beta System; and

(e) the Parties will adopt a mutually agreed framework to address customer service inquiries and all complaints, failure analysis, recalls, or potential recalls, and related regulatory matters, where it is not clear if the cause is (i) the CGM System, on the one hand or (ii) any portion of the remainder of the Libre-Beta System, on the other hand, or a combination of both (i) and (ii).

ARTICLE IX DATA PROTECTION, SHARING AND USE

9.1 Data Protection.

(a) Each Party is individually responsible for compliance, and shall comply with all Data Protection Laws applicable to its respective Processing and Disclosure of Personal Information.

(b) Each Party shall have no influence on the purpose of Processing of Shared Personal Information of the other Party and as such, there is no common purpose jointly determined by both Parties with regard to any such Processing under this Agreement, the Development Plan or any Commercialization Plan. The Parties are not joint controllers and as such, any provisions relating to joint controllers (or analogous provisions) under applicable Data Protection Laws do not apply.

(c) The Parties shall cooperate and work in good faith to draft, and incorporate into the Libre-Beta System any Consents in a form agreed in writing between the Parties, authorizations, privacy notices, and terms and conditions required by applicable Data Protection Laws to permit the Processing and Disclosure of Shared Personal Information and release, transfer, provision of, providing access to, or divulging in any other manner of Shared Personal Information in accordance with this Agreement, the Development Plan or Commercialization Plan.

(d) Each Party shall [***] notify, and in any event within [***], the other Party in the event it receives (i) a request, query, or complaint from a user of the Libre-Beta System in relation to Shared Personal Information or (ii) a request for information or documentation of compliance with applicable Data Protection Laws by any Authority, in connection with any investigations, audits, or inquiries made by an Authority in relation to Shared Personal Information of users of the Libre-Beta System.

(e) Each Party shall provide, [***], all necessary and reasonable cooperation and assistance to the other Party (i) to enable it to comply and respond to a request, query, or complaint from a user of the Libre-Beta System in relation to Shared Personal Information; and (ii) to enable it to comply with and respond to a request for information or documentation of compliance with applicable Data Protection Laws by any Authority, in connection with any investigations, audits, or inquiries made by an Authority in relation to Shared Personal Information of users of the Libre-Beta System.

(f) Each Party shall remain fully responsible and liable for the acts and omissions of any Third Party to whom it has Disclosed or who is Processing Shared Data, in each case as if they were the acts or omissions of such Party directly.

(g) Except with the prior written consent of ADC and Beta shall (i) restrict the CGM Data to which a Third Party has access to only such data as that Third Party needs in the course of their duties in connection with this Agreement, (ii) be responsible for confirming that each Third Party, in advance of obtaining access to or receiving the CGM Data, shall have implemented appropriate measures to ensure the protection of such data and compliance with the terms of this Agreement and is obligated to protect such data in accordance with terms no less restrictive than those in this Agreement, (iii) enter into a written agreement with each Third Party Processing or Disclosing Shared Personal Information on its behalf where required by and in accordance with applicable Data Protection Laws, and (iv) except only as required otherwise by Applicable Law, prohibit each Third Party from Processing or Disclosing the CGM Data or any derivative thereof for other purposes than as agreed between ADC and that Third Party.

(h) Except with the prior written consent of Beta, ADC shall (i) restrict the Beta System Data to which a Third Party has access to only such data as that Third Party needs in the course of its duties in connection with this Agreement, (ii) be responsible for confirming that each Third Party, in advance of obtaining access to or receiving the Beta System Data, shall have implemented appropriate measures to ensure the protection of such data and compliance with the terms of this Agreement and is obligated to protect such data in accordance with terms no less restrictive than those in this Agreement, and is obligated to protect such data in accordance with terms no less restrictive than those in this Agreement, (iii) enter into a written agreement with each Third Party that is Processing or Disclosing Shared Personal Information on its behalf where required by and in accordance with applicable Data Protection Laws, and (iv) except only as required otherwise by Applicable Law, prohibit each Third Party from Processing or Disclosing Beta System Data or any derivative thereof for other purposes than agreed between Beta and that Third Party.

9.2 [***].

9.3 Data Disclosure.

(a) ADC and Beta each have the independent right to Disclose Libre-Beta User Data for any purpose that is in compliance with the terms of this Article IX.

(b) This Agreement has no effect on ADC's rights to Disclose CGM Data and no effect on Beta's rights to Disclose Beta System Data.

(c) ADC may Disclose Beta System Data only to the following Persons; provided it does so consistent with the terms of this Article IX:

(i) the patient who generated that particular Beta System Data;

(ii) upon request of a patient who generated that particular Beta System Data, such patient's health care professionals, caregivers, or other Persons identified and authorized by such patient;

(iii) Service Providers that provide hosting, transfer, storage, and data analysis services to ADC for such Beta System Data, except for (A) [***] and (B) Third Parties engaged in development, manufacture, distribution, marketing or commercialization of any CSII System (which may not receive any Beta System Data); and

(iv) an Authority upon request by such Authority (subject to notice to Beta where allowed by Applicable Law).

(d) ADC may Disclose Insulin Metrics to payors to support reimbursement of the CGM System provided that the Insulin Metrics are not identified as Beta System Data, and are disclosed together with the same data elements from other insulin delivery systems (i.e., there shall be no such Disclosure of Beta System Data alone) and such Disclosure by ADC is in a form that does not allow further analysis of the Beta System Data by such payors.

(e) Beta may Disclose CGM Data only to the following Persons; provided it does so in compliance with the terms of this Article IX:

(i) the patient who generated that particular CGM Data;

(ii) upon request of a patient who generated that particular CGM Data, such patient's health care providers, caregivers, or other Persons identified and authorized by such patient;

(iii) Service Providers that provide hosting, transfer, storage, and data analysis services to Beta for such CGM Data, except for (A) [***] and (B) Third Parties engaged in development, manufacture, distribution, marketing or commercialization of any glucose monitoring system (which may not receive any CGM Data); and

(iv) an Authority upon request by such Authority (subject to notice to ADC where allowed by Applicable Law).

(f) Beta may Disclose Glucose Metrics to payors to support reimbursement of the Libre-Beta System provided that the Glucose Metrics are not identified as CGM Data, and are Disclosed together with the same data elements from other continuous glucose monitoring devices (i.e., there shall be no Disclosure of CGM Data alone) and such Disclosure by Beta is in a form that does not allow further analysis of the CGM Data by such payors.

(g) The Parties acknowledge that the Libre-Beta System may allow users to select an alternative continuous glucose monitoring product or a non-continuous blood glucose meter not manufactured by ADC ("*Alternate Devices*") for diabetes therapy. If a user selects an Alternate Device, Beta is prohibited from providing access to any CGM Data or other ADC data to such Alternate Devices manufacturers.

(h) Except as set forth in this Section 9.3, neither Party shall [***]. Without limiting the generality of the foregoing, and notwithstanding anything else set forth in this Agreement, (i) Beta may not Disclose any CGM Data to [***] and (ii) ADC may not Disclose any Beta System Data to [***].

(i) Notwithstanding the foregoing, none of the restrictions set forth in this Section 9.3 shall be construed as to restrict or limit disclosure or sharing of Beta Systems Data, CGM Data, Libre-User Data, or Caregiver Data with patients, healthcare professionals, caregivers, payors or other authorized entities for healthcare treatment, payment or operations as may be permitted by HIPAA or other Applicable Laws.

ARTICLE X
DATA AND CYBER SECURITY

10.1 Data Security.

(a) Each Party shall implement reasonable and appropriate administrative, technical, physical and organizational data security measures and controls for protecting Shared Personal Information with at least the same degree of care as protecting its own user data and to protect Shared Personal Information against accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to Shared Personal Information transmitted, stored or otherwise Processed and as required by Data Protection Laws and in a manner that also protects the ongoing confidentiality, integrity, availability of Shared Personal Information. Such administrative, technical, physical and organizational security measures must ensure a level of security appropriate to the risk represented by the Processing and the nature of the Shared Personal Information and the nature of the Shared Personal Information and shall be in accordance with industry standards.

(b) Notwithstanding any other clause in this Agreement, each Party agrees to indemnify and keep indemnified and defend at its own expense the other Party and its Affiliates against all costs, claims, damages, expenses, losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, regulatory penalty or fine, penalties and legal costs (calculated on a full indemnity basis) and all other professional costs and expenses) suffered or incurred by the other Party arising out of or in connection with any Claim made against it by a Third Party [***].

(c) During the Term, upon reasonable written request of a Party and limited to [***], the other Party shall [***] and accurately complete a written information security questionnaire provided by the requesting Party to confirm compliance with the terms of this Agreement. The audited Party shall fully cooperate with such inquiries. Any responses or other information provided in such questionnaire shall remain the Confidential Information of the Disclosing Party.

10.2 Data Security Breach.

(a) The Development Plan will assign breach notification responsibilities to the Parties, as applicable, for Data Security Breaches affecting the Libre-Beta System as a whole and for Data Security Breaches affecting the components of the Libre-Beta System not expressly described in this Section 10.2(a). As between the Parties, ADC is responsible for the CGM System and all Data Security Breaches solely affecting the CGM System independent from the Libre-Beta System (and any associated notifications and other public statements) and is not required to notify Beta of any such Data Security Breaches. Beta is responsible for the Beta System related to Data Security Breaches solely affecting the Beta System independent from the Libre-Beta System (and any notifications and other public statements) and is not required to notify ADC of any such Data Security Breaches. Except where required by Applicable Law, each Party agrees not to make any public announcements relating to a Data Security Breach that solely impacts the other Party's system (e.g., ADC may not make any public announcements related to Data Security Breaches solely involving the Beta System and Beta may not make any public announcements related to Data Security Breaches solely involving the CGM System).

(b) It will not be a breach of this Agreement if a Party provides an Authority or user with any Personal Information or Shared Data the Authority requires such Party to provide to the Authority or which the Party is required to provide to a user in accordance with Applicable Law after the occurrence of a Data Security Breach.

10.3 Penetration Testing and Monitoring Procedures.

(a) As part of the development process, Beta shall cause a Third Party on Beta's behalf to conduct annual penetration and vulnerability testing of the Libre-Beta System ("**System Pen Testing**"). Such Third Party shall be an appropriately qualified supplier nominated by Beta and approved by ADC to conduct the System Pen Testing. If ADC does not provide such approval [***], then ADC shall only bear any additional cost of an alternative ADC approved System Pen Testing arrangement. From time to time but not more than [***], ADC may request additional System Pen Testing if there is a suspected breach or other event outside of the normal development cycle. The costs of the additional System Pen Testing will be the responsibility of ADC.

(b) Beta will provide an executive summary of the relevant System Pen Testing report to ADC identifying Critical Issues. If the System Pen Testing report identifies any critical, high level or medium level security issues that may impact the CGM System or ADC Highly Confidential Information ("**Critical Issues**"), the Parties shall work together and cooperate to implement a remediation plan to fully resolve all Critical Issues. Each Party shall bear its own costs with respect to implementation of such remediation plan.

(c) Upon confirmation that all Critical Issues have been resolved or if the System Pen Testing report does not reveal any Critical Issues, ADC shall provide written confirmation to Beta that the System Pen Testing process has been completed successfully. In all cases where Beta receives a System Pen Testing request by ADC, Beta shall thereafter refrain from initiating the commercial launch of the Libre-Beta System in a Launch Country without fully complying with the provisions of this Section 10.3 and receiving such confirmation from ADC.

10.4 Cyber Security Monitoring.

(a) During the Term, each Party shall establish and maintain commercially reasonable cybersecurity risk management processes and controls for the purposes of ensuring the security of the other Party's Highly Confidential Information, including monitoring, assessing, classifying, mitigating, documenting and reporting to the other Party potential and actual internal and external cybersecurity threats and vulnerabilities which may impact the other Party's Highly Confidential Information. Such processes shall include (i) regular [***] evaluations of risks to the security, privacy, and confidentiality of the Highly Confidential Information and the effectiveness of safeguards implemented to protect such information (ii) recovery plans in the event of a cybersecurity threat; (iii) maintenance plans that describe security patching processes and frequency; and (iv) operational processes and procedures to enable the Party to detect and log adequate details of all access, use, disclosure, or removal of Highly Confidential Information.

(b) Each Party agrees that upon request, it shall certify in writing whether it is in compliance with the provisions of this Section 10.4. [***] but no later than [***] after a Party becomes aware of its possible or actual noncompliance with this Section 10.4, such Party shall notify the other Party in writing. Such written notice shall include the nature and period of existence of the possible or actual noncompliance and what action such Party is taking or proposes to take to identify and cure such possible or actual noncompliance.

After delivery of such written notice, such Party shall work in good faith with the other Party to address and remediate such possible or actual noncompliance.

ARTICLE XI CONFIDENTIAL INFORMATION

11.1 Treatment of Confidential Information. The Receiving Party shall maintain the Confidential Information in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to any Third Party except as expressly permitted under this Agreement. The Receiving Party may not use any Confidential Information for any purpose other than as reasonably necessary to fulfill its obligations and exercise its rights under this Agreement. The Receiving Party hereby agrees to exercise the same standard of care it employs to protect its own Confidential Information (and in no event less than a reasonable standard of care) to prevent and restrain the unauthorized disclosure of Confidential Information by any of its Affiliates or its or their directors, officers, employees, consultants, subcontractors, sublicensees or agents. Without limiting the foregoing, the Receiving Party agrees not to make any disclosure of Confidential Information that will impair the Disclosing Party's ability to obtain U.S. or foreign patents on any patentable invention or discovery described in such Confidential Information. For clarity, Highly Confidential Information is subject to additional restrictions as set forth in this Agreement, including Sections 3.6 and 3.7.

11.2 Disclosures Required by Law.

(a) The Receiving Party shall not be in violation of this Article XI if Confidential Information of the Disclosing Party is required to be disclosed by the Receiving Party in response to a valid order by a court or other governmental body, provided that the Receiving Party provides the Disclosing Party with [***] in order to permit the Disclosing Party to seek confidential treatment of such information and cooperates reasonably with Disclosing Party in connection therewith.

(b) The Receiving Party may disclose the Disclosing Party's Confidential Information if the Receiving Party determines, based on advice from its legal counsel, that it is required to make such disclosure to comply with Applicable Law or the rules of a securities exchange on which the Receiving Party is listed (each such disclosure, a "**Mandatory Disclosure**"). With respect to each Mandatory Disclosure, [***], the Receiving Party shall (i) notify the Disclosing Party of the proposed content of the Mandatory Disclosure, (ii) give the Disclosing Party reasonable opportunity to review and comment on the proposed content of the Mandatory Disclosure, and (iii) in good faith, consider revising the content of the Mandatory Disclosure based on comments received from the Disclosing Party. The Receiving Party shall include in each Mandatory Disclosure only the information required to be disclosed by Applicable Law, including applicable securities rules, as determined by the Receiving Party's legal counsel, and, to the extent reasonably possible, shall seek confidential treatment of each Mandatory Disclosure.

11.3 [*].**

11.4 Confidential Information Proprietary to Disclosing Party; Return of Confidential Information. The Receiving Party understands and agrees that (a) the Disclosing Party's Confidential Information is and shall remain at all times the sole property of the Disclosing Party; (b) the Receiving Party shall not obtain any proprietary interest in any of the Disclosing Party's Confidential Information; and (c) subject to Section 12.7, all copies of the Disclosing Party's Confidential Information in the Receiving Party's possession shall, at the Receiving Party's election, be [***] destroyed or returned to the Disclosing Party in their entirety following Disclosing Party's request therefor after expiration or termination of this Agreement. Notwithstanding the foregoing, the Receiving Party (i) may retain this Agreement and one copy of the Disclosing Party's Confidential Information in the legal files of the Receiving Party for the sole purpose of determining the scope of obligations incurred under this Agreement or as otherwise required by Applicable Law; (ii) may retain any electronic copies of the Disclosing Party's Confidential Information held securely in the Receiving Party's electronic backup storage in accordance with its established document retention policies and (iii) may retain Confidential Information to the extent included in the Receiving Party's board of director or board committee materials or minutes or actions, quality systems, or regulatory history; subject in each case to the Receiving Party's continuing confidentiality and non-use obligations under this Agreement with respect to such Confidential Information.

11.5 Breaches of Confidentiality; Assistance in Respect of Same. The Receiving Party shall [***] notify the Disclosing Party if the Receiving Party becomes aware of any breach of this Article XI by any Person who has received the Disclosing Party's Confidential Information on the Receiving Party's behalf. The Receiving Party shall provide the Disclosing Party all reasonable assistance requested in connection with any action, demand, claim or proceeding that the Disclosing Party may institute against any such Person in respect of such disclosure.

11.6 Continuing Obligation. This Article XI shall survive for a period of [***] after any termination or expiration of this Agreement, provided, however, that the Parties' obligations under this Article XI with regard to any Confidential Information of the Disclosing Party that is identified in writing to the Receiving Party as a trade secret (including the ADC Highly Confidential Information, which are acknowledged to be ADC's trade secrets, and Beta Highly Confidential Information, which are acknowledged to be Beta's trade secrets) shall survive for as long as the relevant Confidential Information retains its status as a trade secret under Applicable Law.

ARTICLE XII

TERM, TERMINATION AND CERTAIN BREACHES

12.1 Term. This Agreement shall commence on the Effective Date and continue for an initial term of five (5) years thereafter, unless earlier terminated in accordance with this Agreement (the "**Initial Term**"). Upon expiration of the Initial Term, and unless a Party has given written notice at least [***] prior to expiration of non-renewal, this Agreement shall automatically renew for successive terms of two (2) years, unless earlier terminated in accordance with this Agreement (each a "**Renewal Term**" and together with the Initial Term, the "**Term**").

12.2 Termination for Material Breach. Either Party may terminate this Agreement in the event of a material breach; provided, however, that such termination shall not become effective unless and until (a) [***] have elapsed from the date on which the non-breaching Party gave written notice of such breach to the breaching Party and (b) the breaching Party has not cured such breach within that [***] period. If the breaching Party fails to cure such breach, termination of this Agreement shall automatically occur [***] after the non-breaching Party provided notice of the breach as set forth herein. Notwithstanding the foregoing, if the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a written notice provided by the other Party in accordance with this Section, and provides the other Party notice of such dispute within the [***] period following the date of the non-breaching Party's notice of breach, then, except for an alleged breach under Section 3.6, 3.7, Article IX, or Article X, the non-breaching Party may not terminate this Agreement under this Section unless and until the earlier of (a) the dispute being finally resolved in accordance with 15.11 with a decision that the alleged breaching Party has materially breached this Agreement, or, (b) [***] have passed from the date the alleged breaching party provided notice disputing the existence or materiality of the alleged breach (provided that (i) the Parties shall act in mutual good faith to reach a final ruling from any ADR proceeding pursuant to Exhibit 15.11 within such time period, (ii) the terminating Party shall not unreasonably delay any ADR proceeding as contemplated by Exhibit 15.11, and (iii) nothing in this Section 12.2 shall relieve the terminating Party from any liability with respect to a wrongful termination of this Agreement). During the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

12.3 Termination for Insolvency. Either Party may terminate this Agreement [***] upon written notice to the other Party, if the other Party (a) files in any court or agency a petition for the opening of bankruptcy or insolvency proceedings or for reorganization or for arrangement or for the appointment of a receiver or trustee of it or its assets under Applicable Law; (b) proposes a written agreement of composition or extension of all or substantially all of its debts; (c) is served with an involuntary petition against it, filed in any bankruptcy or insolvency proceeding, and such petition has not been dismissed within [***] after the filing thereof; (d) becomes subject to any dissolution or liquidation or resolution thereof; (e) makes a general assignment for the benefit of its creditors; or (f) is generally not paying its debts as they fall due unless those debts are subject to a bona fide dispute as to liability or amount.

12.4 Termination for Failure to Launch a Libre-Beta System. If the First Commercial Sale of a Libre-Beta System in the United States has not occurred before [***] then either Party may elect to terminate this Agreement upon [***] written notice to the other Party; provided, however, that, if the First Commercial Sale of a Libre-Beta System occurs within the [***] notice period, then this Agreement shall no longer terminate at the expiration of the notice period.

12.5 Termination for Convenience. At any time after the [***] anniversary of the First Commercial Sale in the United States, either Party may terminate this Agreement for any reason, with or without cause, by giving [***] written notice to the other Party of the terminating Party's invocation of this Section 12.5. This Agreement shall automatically terminate on the [***] anniversary of such notice.

12.6 [*].**

12.7 Effect of Expiration or Termination.

(a) Upon expiration or termination of this Agreement prior to the First Commercial Sale, subject to Applicable Law and the requirements of any ongoing, non-terminable clinical trials set forth in the Development Plan, the licenses set forth in Sections 6.1 and 6.2 shall [***] terminate.

(b) Upon expiration or termination of this Agreement after the First Commercial Sale:

(i) solely for the purpose of providing continued access and support to Existing Users, the licenses set forth in Sections 6.1 and 6.2 shall continue and the Parties may continue using each other's Confidential Information in each case, for a period of [***] following such expiration or termination; provided that, if termination is due to Section 12.6(a), Beta shall ensure that (x) all employees or subcontractors who work with glucose monitoring systems and components thereof, other than the CGM System (not including any such personnel of Beta whose work with such monitoring systems and components thereof includes only the integration or interoperability of such monitoring systems with the Beta System), do not have access to any of ADC's Confidential Information and (y) appropriate firewalls and other protections are established so the requirement in foregoing clause (x) can be met;

(ii) to the extent permitted by Applicable Law, and subject to Article IX and Article X, each Party may retain and Process or Disclose all Shared Data received prior to expiration or termination of this Agreement and received while providing continued access and support to Existing Users in accordance with Section 12.7(b)(i); provided that for termination pursuant to Section 12.6(a), Beta shall be prohibited from (A) Processing or Disclosing Shared Data received in accordance with Section 12.7(b)(i) for any purpose other than providing continued access and support to Existing Users, and (B) retaining such Shared Data for a period longer than [***] following such termination.

12.8 Survival of Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Notwithstanding anything to the contrary in this Agreement, the following provisions (and the corresponding licenses, covenants and other agreements therein contained) shall survive the expiration of the Term or termination of this Agreement and shall remain in full force and effect thereafter: Article I (to the extent the definitions are used in the other surviving provisions), Article V, Sections 6.1 (for the period described in Section 12.7), Section 6.2 (provided that the licenses granted therein shall only survive for the period described in Section 12.7(b)), Section 6.2(f), Section 6.4, Section 7.8(a), Article IX, Article X, Article XI (for the time period set forth in Section 11.6), Section 12.7, this Section 12.8, Article XIV and Article XV. The Quality Agreement shall survive in accordance with its terms.

ARTICLE XIII REPRESENTATIONS, WARRANTIES AND COVENANTS

13.1 Representations and Warranties by Each Party. Each Party represents and warrants as of the Effective Date, and where applicable, covenants that:

(a) such Party is a corporation duly organized, validly existing, and in good standing under the Applicable Law of the State of Delaware;

(b) such Party has the full corporate power and authority to execute, deliver, and perform under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against such Party in accordance with its terms;

(d) the execution and delivery of this Agreement and the consummation hereof, do not and shall not (i) conflict with or result in a breach of any provision of such Party's organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder, or (iii) violate any Applicable Law;

(e) there is no pending or threatened action, suit, claim, investigation or proceeding against such Party with respect to its right to enter into this Agreement or that challenges or seeks to prevent or enjoin its entry into this Agreement;

(f) such Party it is not subject to any agreement or order of any Authority that restricts it from granting the rights and licenses to the other Party set forth in this Agreement;

(g) such Party is in full compliance at all times and will continue to be in compliance at all times with all Applicable Law (including those related to anti-corruption) and shall not cause the other Party to be in violation of any Applicable Law; and

(h) on behalf of itself and each of its Affiliates, agents, subcontractors and employees performing activities under this Agreement, that they are not currently, nor have they been within the past [***] from the Effective Date, debarred, disqualified, or excluded under any Applicable Law from: (i) providing goods or services to a regulated health care company, (ii) participating in clinical research, (iii) participating in a government procurement or non-procurement program, or (iv) participating in a reimbursed government-funded or financed healthcare program (each, a “**Restriction**”).

13.2 Covenants.

(a) If any Restriction is proposed, pending or occurs with respect to a Party during the Term, then such Party shall [***] notify the other Party. Upon receipt of notice of a pending or actual Restriction, such other Party may elect, in its sole discretion, to [***] terminate this Agreement.

(b) No component of the Libre-Beta System shall be provided to any customer unless and until all necessary regulatory approvals have been received and thereafter shall only be made available in accordance with such regulatory approvals and Applicable Law.

13.3 [*].**

13.4 Disclaimer. THE PARTIES HEREBY ACKNOWLEDGE THAT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, (A) NEITHER PARTY MAKES ANY REPRESENTATION, WARRANTY, OR GUARANTEE OF ANY KIND, EXPRESS OR IMPLIED, AT LAW OR IN EQUITY AND (B) THE PARTIES EXPRESSLY DISCLAIM ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE XIV INDEMNIFICATION

14.1 ADC Indemnification of Beta. Subject to Section 14.3 and except for claims subject to indemnification under Sections 10.1(b) and 14.4, if any Claim is brought against the Beta Indemnitees that [***] then ADC will indemnify, defend and hold harmless the Beta Indemnitees at ADC's expense against all any and all damages, losses, liabilities, judgments, fines, amounts paid in settlement, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively, "**Losses**") arising in connection with such Claim. Notwithstanding the foregoing, with respect to those Claims for which Beta, in whole or in part, has an obligation to indemnify ADC pursuant to Section 14.2, each Party shall indemnify, defend and hold harmless the other to the extent of their respective liability for such Claims.

14.2 Beta Indemnification of ADC. Subject to Section 14.3 and except for claims subject to indemnification under Sections 10.1(b) and 14.4, if any Claim is brought against the ADC Indemnitees that [***] then Beta will indemnify, defend and hold harmless the ADC Indemnitees at Beta's expense against any and all Losses arising in connection with such Claim. Notwithstanding the foregoing, with respect to those Claims for which ADC, in whole or in part, has an obligation to indemnify Beta pursuant to Section 14.1, each Party shall indemnify, defend and hold harmless the other to the extent of their respective liability for such Claims.

14.3 Obligations of Party Seeking Indemnification. With respect to any Claim for which either Party seeks indemnification from the other Party under this Article XIV, Section 10.1(b), the Party seeking indemnification shall (i) provide [***] notice to the other Party of the Claim for which indemnification is sought, (ii) allow the other Party to assume the defense of such Claim, (iii) provide reasonable cooperation and assistance to the other Party in the defense of such Claim, and (iv) not settle or otherwise compromise such Claim, or make an admission of liability in relation to such Claim, without the other Party's prior written consent.

14.4 Beta agrees to indemnify and keep indemnified and defend at its own expense ADC and its Affiliates against all costs, claims, damages, expenses, losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, regulatory penalty or fine, penalties and legal costs (calculated on a full indemnity basis) and all other professional costs and expenses) suffered or incurred by ADC or its Affiliates arising out of or in connection with any Claim made against it by a Third Party [***]. If within [***] of written notice to Beta of ADC's IP Determination, [***] then Abbott may terminate the Agreement with [***] written notice of termination to Beta.

14.5 ADC may participate in the defense of any Claim under Section 14.4 at its option and in its sole discretion. Beta shall not agree to any settlement or compromise that would be binding on ADC or its Affiliates or involves making an admission of guilt or wrongdoing, without ADC's prior written consent.

14.6 Limitation of Liability.

(a) [***] in no event shall a Party's aggregate liability to the other Party for damages of any nature arising out of or in connection with this Agreement, regardless of the form of action, whether for breach of warranty or contract, in tort (including negligence) or otherwise, exceed [***].

(b) Neither Party shall be liable to the other Party or to any Third Party for any special, incidental, indirect, or consequential damages of any kind or for the loss of revenue or profits (even if such Party shall have been advised of or known of or should have known of the possibility of such potential damages or loss), [***].

(c) It is agreed that the limitation and exclusions of liability set forth in this Section 14.6 are intended by the Parties to be a reflection of the agreed allocation of the commercial risks that may arise out of or occur in connection with this Agreement. Further, the Parties hereto agree that the provisions of Sections 14.6(a) and 14.6(b) [***] shall in no event be invalidated or deemed unenforceable should any limited warranty or remedy set forth in this Agreement fail of its essential purpose (i.e., provide an insufficient remedy).

14.7 Insurance Requirements. During the Term and for [***] after the expiration or termination of this Agreement, each Party shall keep in full force and effect and maintain, at its sole cost and expense, insurance coverage in types and amounts commensurate in its industry for the performance of services substantially similar to the services to be performed hereunder by similarly sized companies, and as otherwise prudent or required by Applicable Law. During the Term, each Party agrees to provide the other Party with certificates of insurance if requested and on an annual basis. At minimum, the Parties shall maintain the insurance scheme in Exhibit 14.7.

ARTICLE XV MISCELLANEOUS

15.1 Assignment. Except as set forth in Section 15.16, neither Party may assign, delegate, or, except as permitted pursuant to Section 15.16, subcontract this Agreement or any of its rights or duties hereunder, in whole or in part, without the prior written consent of the other Party. Notwithstanding the foregoing, a Party may, without such consent, assign this Agreement in its entirety (i) to one of its Affiliates or (ii) in connection with the transfer or sale of substantially all of its business to which this Agreement pertains, a reorganization, or a merger or consolidation with another Person [***]. Upon assignment of this Agreement, the assignee must provide to the non-assigning Party a written confirmation that

assignee has assumed the assigning Party's obligations under this Agreement, including the provision to the non-assigning Party a written representation, warranty, and covenant that the assignee has and will commit to the conduct of the Development Plan, Regulatory Plan and Commercialization Plan at least the same amount of resources, labor, capital, and money as the assigning Party had committed to the conduct of the Development Plan, Regulatory Plan, and Commercialization Plan as of the assignment date, as reflected in the relevant plans and budgets. This Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of each Party. Any purported assignment or delegation in violation of the provisions of this Section 15.1 shall be null and void.

15.2 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of Delaware, without giving effect to the principles of conflicts of law thereof.

15.3 Force Majeure. If a Party is prevented from performing or is unable to perform any of its obligations under this Agreement (except for payment obligations) due to any cause beyond its reasonable control, such Party shall give [***] written notice to the other Party, and thereupon the affected Party's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to remedy its inability to perform. Such events shall include: acts of god; acts of the public enemy; terrorist acts; insurrections; riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; earthquakes; shortages of material or energy; delays in the delivery of raw materials; epidemics; pandemics; or other unforeseeable causes beyond the reasonable control of the Party so affected. The Party so affected shall give [***] notice to the other Party of such cause and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible.

15.4 No Waiver. No waiver will be implied from the Parties' course of conduct or any delay or failure to enforce any rights. No provision of this Agreement shall be deemed waived unless such waiver is in writing and signed by an authorized representative of the Party against whom it is sought to be enforced, which waiver shall be effective solely with respect to the incidences set forth therein. Waiver by either Party of any default by the other Party of any provision of this Agreement shall not be deemed a waiver by the waiving Party of any subsequent or other default.

15.5 Notices. Any notice or other communication in connection with this Agreement must be in writing and by certified mail, return receipt requested, or by delivery service that provides a written delivery confirmation. Notice shall be effective and deemed to be given when delivered to the addressee at the address listed below or such other address as the addressee shall have specified in a notice actually received by the addressor.

If to ADC:

Abbott Diabetes Care Inc.
1420 Harbor Bay Parkway
Alameda, CA 94502

[***]

with a copy (which shall not constitute notice) to:

Abbott Laboratories

[***]

[***]

[***]

If to Beta:

Beta Bionics Inc.
11 Hughes
Irvine, CA 92618

[***]

with a copy (which shall not constitute notice) to:

[***]

15.6 Relationship Between the Parties.

(a) Independent Contractor. The relationship of the Parties under this Agreement is that of independent contractors. The Parties will not be deemed partners or joint ventures, nor will one Party be deemed an agent or employee of the other Party. Neither Party has any express or implied right under this Agreement to assume or create any obligation on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement, or undertaking with any Third Party, and no conduct of a Party shall be deemed to imply such right.

(b) No Exclusivity. For clarity, the relationship between the Parties under this Agreement is non-exclusive and does not preclude (a) ADC from entering into agreements relating to Third Party insulin delivery devices or systems or (b) Beta from entering into agreements relating to Third Party glucose monitoring products or systems, except as set forth in Section 12.6.

15.7 Entire Agreement. Each Party acknowledges that in entering into this Agreement it does not rely on any statement, representation, or warranty other than those expressly set forth in this Agreement. This Agreement, the Exhibits hereto (which Exhibits are deemed to be a part of this Agreement for all purposes), the Development Plan, the Regulatory Plan, the Commercialization Plan and the Quality Agreement contain the entire agreement between the Parties with respect to their respective subject matter, and supersede all previous agreements (including the Exploratory Agreement), negotiations, discussions, writings, understandings, commitments and conversations with respect to such subject matter. In the event of a conflict between this Agreement and the Development Plan, Regulatory Plan, or Commercialization Plan, this Agreement shall control. In the event of a conflict between this Agreement and the Quality Agreement, the Quality Agreement shall control solely with regard to adverse event reporting and other quality matters, and this Agreement shall control in all other circumstances. For the avoidance of doubt, the Parties may continue ongoing activities under the Exploration Agreement as needed thereunder without conflict to this Agreement.

15.8 Amendments. No provisions of this Agreement shall be deemed amended, supplemented, or otherwise modified unless such amendment, supplement, or other modification is in writing and signed by an authorized representative of each Party. The express terms of this Agreement control and supersede any course of performance or dealing inconsistent with any of the terms hereof.

15.9 Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction or the ADR neutral to be unenforceable because it is invalid or in conflict with any law of any relevant jurisdiction, the validity of the remaining provisions shall not be affected, and the rights and obligations of the Parties shall be construed and enforced as if this Agreement did not contain the particular provisions held to be unenforceable. The Parties will in such an instance use their reasonable efforts to replace the invalid or unenforceable provision with a valid and enforceable provision that accomplishes, as nearly as possible, the original intention of the Parties with respect thereto.

15.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each Party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.

15.11 Dispute Resolution. Subject to Section 2.5, any dispute arising under or related to this Agreement shall be settled by the alternative dispute resolution provisions set forth in Exhibit 15.11 hereto. Notwithstanding the foregoing sentence, the Parties agree that any request for provisional remedies and any request for injunctive relief, whether preliminary or permanent, shall be decided by a court of competent jurisdiction and not through the alternative dispute resolution provisions set forth in Exhibit 15.11.

15.12 Interpretation. The headings of the Articles and Sections of, and any Exhibits to, this Agreement have been added for the convenience of the Parties and shall not be deemed a part hereof. Words in the singular shall be deemed to include the plural and vice versa, and words of one gender shall be deemed to include the other gender, as the context requires. The terms “hereof,” “herein,” and “herewith” and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole (including any and all of the Exhibits hereto) and not to any particular provision of this Agreement. Article, Section, and Exhibit references are to the Articles, Sections, and Exhibits to this Agreement, unless otherwise specified. Unless otherwise stated, all references to any agreement shall be deemed to include any and all Exhibits to such agreement. The word “including” and words of similar import when used in this Agreement shall mean “including, without limitation,” unless the context otherwise requires or unless otherwise specified. The word “or” shall not be exclusive unless the context clearly requires otherwise. Unless otherwise specified in a particular case, the word “days” refers to calendar days. References herein to this Agreement shall be deemed to refer to this Agreement as of the Effective Date and as it may be amended thereafter, unless otherwise specified. References to the performance, discharge, or fulfillment of any liability or obligation in accordance with its terms shall have meaning only to the extent such liability or obligation has terms; if the liability or obligation does not have terms, the reference shall mean performance, discharge, or fulfillment of such liability or obligation.

15.13 Joint Negotiation. This Agreement is the joint product of ADC and Beta, and each provision hereof has been subject to the mutual consultation, negotiation, and agreement of the Parties and their respective legal counsel and advisers, and any rule of construction that a document shall be interpreted or construed against the drafting Party shall not be applicable.

15.14 No Other Compensation. Beta and ADC hereby agree that the terms of this Agreement together with the Development Plan, Regulatory Plan, Commercialization Plan and the Quality Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by Beta to ADC and by ADC to Beta in connection with the transactions contemplated herein. Neither ADC nor Beta previously has paid or entered into any other commitment to pay, whether orally or in writing, any ADC or Beta employee, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transactions contemplated herein.

15.15 Records. Each Party shall, and shall ensure that its Affiliates and its and their employees, agents and subcontractors, maintain, in compliance with Applicable Law, complete and accurate records with respect to its performance of the development and commercialization activities under this Agreement. Such records shall be retained by each Party for at least [***] after the termination of this Agreement, or for such longer period as may be required by Applicable Law.

15.16 Performance by ADC Affiliates. Notwithstanding anything else set forth herein, any obligation or right of ADC may be fulfilled or exercised, in whole or in part, at ADC's sole option, either by ADC directly or by any of its Affiliates or (sub)contractors. In such case, ADC shall remain liable for any such obligation or right as if performed directly by ADC itself.

15.17 No Third Party Beneficiaries. Nothing in this Agreement, express or implied, is intended to, or shall, confer upon any Third Party any right, benefit, or remedy of any nature whatsoever under, or by reason of, this Agreement.

{Signature Page Follows}

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in their names by their properly and duly authorized officers or representatives as of the dates set forth below.

ABBOTT DIABETES CARE INC.

By: /s/ Jared L. Watkin
Name: Jared L. Watkin
Title: President
Date: April 2, 2024

BETA BIONICS, INC.

By: /s/ Sean Saint
Name: Sean Saint
Title: Chief Executive Officer
Date: April 2, 2024

EXHIBIT 1.2

[***]

EXHIBIT 1.6
ADC MARKS

EXHIBIT 1.11
BETA APPROVED PERSON

EXHIBIT 1.19

[***]

EXHIBIT 1.25

BETA MARKS

EXHIBIT 9.2(A)

MINIMUM DATA TO BE SHARED BETWEEN THE PARTIES

EXHIBIT 14.7
INSURANCE REQUIREMENTS

1. Each Party will obtain and maintain for at least the duration of the Agreement, at its own cost and expense, the following kinds and amounts of insurance providing coverage for their operations:
 - 1.1. [***]
 - 1.2. [***]
 - 1.3. [***]
2. [***]
 - 2.1. [***]
 - 2.2. [***]
 - 2.3. [***]
3. Each Party shall furnish to the other Party on an annual basis a certificate of insurance signed by an authorized representative of the other Party's insurance, giving evidence of such insurance in an acceptable form. In the event of any notice or action to cancel, non-renew, or materially change the above required insurance, each Party shall provide the other advance notice of such change.

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4. The acceptance by each Party of certificates of insurance providing for other or different coverage than herein required to be furnished, shall in no event be deemed to be a waiver of any provisions of this Agreement. Furthermore, the minimum limits of liability or conditions required in this Exhibit do not in any way limit any indemnity obligation or other liability of the Parties under this Agreement.

EXHIBIT 15.11

ALTERNATIVE DISPUTE RESOLUTION

The Parties recognize that from time to time a Dispute may arise. The Parties agree that, except set forth in Section 15.11 of this Agreement, any such Dispute shall be resolved by the Alternative Dispute Resolution (“***ADR***”) provisions set forth in this Exhibit, the result of which shall be binding upon the Parties.

[***]