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Filed pursuant to Rule 424(b)(4)
Registration Nos. 333-284147 and 333-284587

PROSPECTUS

12,000,000 Shares

Beta Bionics

Common Stock

This is the initial public offering of shares of common stock of Beta Bionics, Inc. We are selling 12,000,000 shares of our common stock, and the underwriters have an option for a period of 30 days to purchase up to an additional 1,800,000 shares, consisting of 475,000 shares from us and 1,325,000 shares from the selling stockholders identified in this prospectus, in each case at the initial public offering price less the underwriting discounts and commissions. We will not receive any proceeds from the sale of shares by the selling stockholders.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock is $17.00 per share. Our common stock has been approved for listing on the Nasdaq Global Market (Nasdaq) under the symbol "BBNX."

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 24 of this prospectus.

	Per Share	Total
Initial public offering price	$ 17.00	$204,000,000
Underwriting discounts and commissions(1)	$ 1.19	$ 14,280,000
Proceeds, before expenses, to Beta Bionics, Inc.	$ 15.81	$189,720,000

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

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.

We have entered into a Common Stock Purchase Agreement, dated January 21, 2025, with Wellington Hadley Harbor Aggregator IV, L.P. (Wellington), an existing stockholder (the Purchase Agreement). Pursuant to the Purchase Agreement, Wellington has agreed to purchase and we have agreed to sell 1,000,000 shares of our common stock (the Private Placement Shares) in a concurrent private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a per share price equal to the initial public offering price. The private placement would close concurrently with, and be contingent and conditioned upon consummation of, this offering. However, this offering is not contingent on the consummation of the concurrent private placement. The underwriters have agreed to act as placement agents in connection with the concurrent private placement and will receive a placement agent fee equal to 7.0% of the total purchase price of the Private Placement Shares.

The underwriters expect to deliver the shares of common stock to purchasers on or about January 31, 2025.

BofA Securities **Piper Sandler** **Leerink Partners**

Stifel

Lake Street

The date of this prospectus is January 29, 2025.

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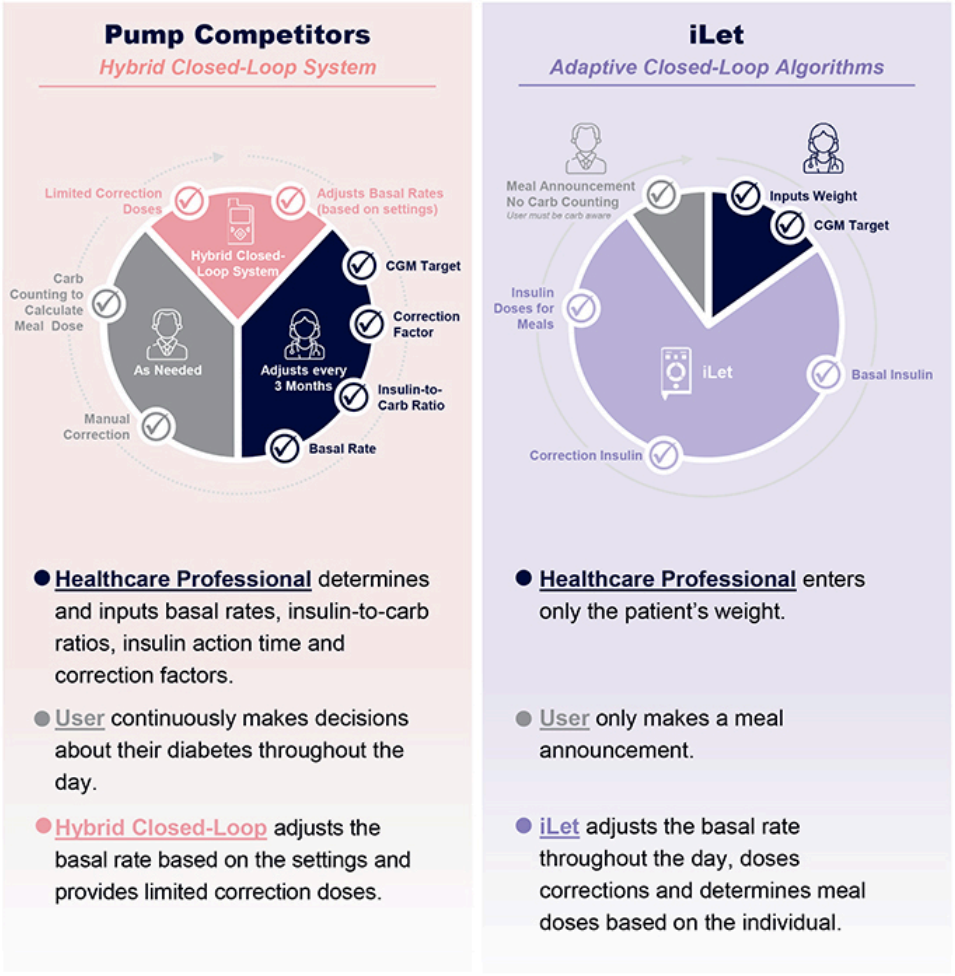
Unique Algorithms Require Minimal Human Intervention



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Neither we, the selling stockholders 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, the selling stockholders 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, the selling stockholders 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: neither we, the selling stockholders nor the underwriters have 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.

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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. The adaptive closed-loop algorithms are designed to remove the need to manually adjust insulin pump therapy settings and variables required by conventional pump therapy and hybrid closed-loop systems, which both require the user to determine the size and timing of both meal and correction insulin doses and to adjust basal insulin dosing. Therefore, we believe the adaptive closed-loop algorithms can make the iLet easier to initiate and use on a daily basis than other available AID systems. 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 in type 1 diabetes (T1D), an indication for which we received FDA clearance in patients six and older in May 2023 in the United States. 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. According to the Centers for Disease Control and Prevention (CDC), there are approximately 1.8 million people with T1D

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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, which is 7.0% or lower. 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). We believe that approximately one-third of people with T1D in the United States utilize insulin pumps or hybrid closed-loop systems to receive their daily insulin, while the majority receive their daily insulin via MDI therapy, which is less complex, but often less effective and has been shown to be associated with higher HbA1c levels. This is based on our internal estimates factoring epidemiologic data from government and leading industry organizations such as the CDC, as well as industry sales data from public filings and disclosures made by the leading device manufacturers (Medtronic plc (Medtronic), Tandem Diabetes Care, Inc. (Tandem) and Insulet Corporation (Insulet), who collectively hold approximately 96% market share) and aggregated by third-party data service providers. Our initial commercial results suggest that the iLet's value proposition is resonating strongly within the MDI population, as approximately 67% 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 5x—from $3.1 million for the quarter ended September 30, 2023 to $16.7 million for the quarter ended September 30, 2024—while our operating expenses have grown only 2x during the same time period—from $10.0 million to $19.9 million, respectively.

Our revenue for the nine months ended September 30, 2024 was $44.7 million, more than 3.5x 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 $36.6 million for the nine months ended September 30, 2024. Our historical net losses are mainly due to our limited commercial history. We recently launched the iLet in May 2023 and leading up to it we incurred substantial research and development expenses to obtain FDA clearance as well as increased sales and marketing expenses related to the iLet product launch. Our net losses have also been impacted by the issuance of Class B common stock warrants in August 2023, which contributed a change of $11.0 million in the fair value of warrant liabilities. This change, driven by adjustments in the fair value assumptions of the warrant liability, contributed to an increase in our net losses as of December 31, 2023. These strategic investments in the iLet are reflected in the accumulated deficit of $229.7 million and $278.6 million, as of December 31, 2023 and September 30, 2024, respectively.

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

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in a pivotal clinical trial of an AID system. The trial met its primary endpoint, finding that, collectively, the adults and children who randomized to iLet therapy experienced an average reduction in HbA1c of 0.6%, 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 including AID systems, saw no change from a baseline of 7.7% over the same period. The baseline-adjusted group difference was a reduction in HbA1c of 0.5% for those randomized to iLet therapy relative to those randomized to standard of care ($P<0.001$). Additionally, participant cohorts within important subgroups among the overall T1D population, including adults, children, those with starting HbA1c levels greater than 7.0%, and those on MDI, who used the iLet also demonstrated statistically significant and clinically relevant (as defined by a decrease in HbA1c of at least 0.5%) improvements in glycemic control versus the standard of care. For more information regarding the BPPT, please see the section titled "Business—iLet Development History—The iLet Bionic Pancreas Pivotal Trial testing the iLet in adults and children with T1D."

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 baseline HbA1c (provided to us by the medical providers in the statements of medical necessity) of 8.5% to an average glucose management indicator (GMI)—a population-based estimate of HbA1c based on mean CGM glucose that is widely accepted as an indicator in the diabetes industry —on the iLet of 7.3%. This demonstrated an improvement in HbA1c that was larger than that observed in the BPPT and is clinically meaningful (as defined by a decrease in HbA1c of at least 0.5%) in this patient population, which was much larger and had worse glucose control at baseline than those who participated in the BPPT. GMI is frequently used as a substitute for HbA1c in remote monitoring (iCGM) settings (which is what iLet users upload to the Beta Bionics cloud) given that HbA1c is typically measured in a laboratory setting. For more information regarding how GMI and HbA1c are comparable, please see the section titled "Business—Overview."

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, as well as sponsor-initiated retrospective analyses, 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). For more information regarding these results, please see the section titled "Business—iLet Development History—iLet device outcomes are independent of the frequency of user interaction."

Commercial Opportunity and Strategy

We believe the commercial opportunity for the iLet in T1D is substantial. We estimate the T1D total addressable market for insulin pumps in the United States is approximately $6 billion, which is comprised of the

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approximately $2 billion total addressable market of existing pump users and the approximately $4 billion total addressable market of potential new pump adopters, as further described below. In the coming decades, we believe this market will grow approximately in line with the expected overall U.S. population growth rate of about 2% per year. Our estimates of the T1D total addressable market for insulin pumps and related growth rate are based on independent industry publications and public industry data, as well as third-party forecasts derived from the same. Total addressable market is the total overall revenue opportunity that we believe is available for insulin pumps if 100% market share is achieved, and it is not a representation that we will achieve such market share. The market share we achieve is subject to a number of assumptions, risks and uncertainties, including new pump adoption and conversion rates, which will fluctuate from time to time. For example, and as described below, since their introduction, CGMs have been adopted by an estimated 70% of people with T1D in the United States. For more information, please see the section titled "Risk Factors—Risks Related to our Business, Strategy and Industry—The market opportunities for our iLet for the treatment of diabetes may be smaller than we anticipated, limiting our ability to successfully sell our current and future products."

There are two distinct subpopulations whose needs could be addressed by a product of the iLet's profile:

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

Based on publicly available industry data, including sales data publicly disclosed by the leading device manufacturers (Medtronic, Tandem and Insulet, who collectively hold approximately 96% market share), we estimate that the current dollar value of the insulin pump market for people with T1D in the United States is approximately $2 billion and that the percentage of people with T1D who utilize a pump is approximately one-third of the overall population.

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

We believe approximately two-thirds of people with T1D in the United States do not currently utilize a pump for insulin treatments and instead use MDI from either a syringe or an insulin pen, based on public and industry data, including data publicly disclosed by the leading device manufacturers (Medtronic, Tandem and Insulet). 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. We believe this U.S. patient population would be valued at approximately $4 billion, assuming current users of MDI fully converted to pumps instead, and at current pump pricing levels.

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. Currently, our iLet is cleared only for the treatment of T1D in adults and children six years of age or older. 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. Although DexCom is our partner, the DexCom G6 is not our product, and we cannot provide any assurance that a similar potential for the iLet will be reached.

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. While the iLet can be prescribed by any health care providers (HCP) (primary care physicians (PCP) or subspecialists), we are promoting sales of the iLet through an internal sales organization, where our initial direct sales efforts are focused on people with T1D who are treated within high-volume

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endocrinology practices in the United States. Over time, we plan to expand into the more diffuse population of people with T1D who are treated by PCP. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. 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 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 (such as adjustments at quarterly visits) those systems place on clinical practices in follow-on care.

Product Development Pipeline and Future Initiatives

Patch Pump

We are in the early stages of 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. We are initially focused on T1D but plan to expand to T2D.

We have currently designed a prototype of the patch pump and, following product development, we plan to seek FDA 510(k) clearance for the patch pump in T1D and T2D. We believe our patch pump will require 510(k) clearance as an alternate controller enabled pump (ACE pump) prior to commercialization and that clinical trials will not be required for an ACE pump 510(k) clearance. The iLet algorithm, which the patch pump will leverage, has already obtained a 510(k) clearance as an interoperable automated glycemic controller (iAGC). Subject to receiving 510(k) clearance for our patch pump, we expect to launch our patch pump commercially by the end of 2027.

Bihormonal iLet

We are also in the early stages of 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. Analysis of hospital admission code data has shown that hypoglycemic episodes are responsible for over half of all emergency room visits by PWD each year, despite their relatively low frequency. According to the ADA and the National Institutes of Health, approximately 25-40% 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.

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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. For more information regarding these trials, see the section titled "Business—iLet Development History—Pre-pivotal clinical trials testing the bionic pancreas algorithms and the iLet Bionic Pancreas System." Prior to conducting clinical trials with the new glucagon formulation, we plan to evaluate whether the glucagon is compatible for pumping, and its concentration in the body is consistent with our expectations. If these evaluations are successful, we plan to initiate at least one pre-pivotal clinical trial and a pivotal clinical trial before submitting the device and algorithm to the FDA for 510(k) clearance as well as submit a new drug application (NDA) seeking approval for the pump compatible glucagon for chronic use. Glucagon is currently only approved in an acute formulation for rescue from acute hypoglycemia, so approval of an NDA will be required for this chronic use glucagon, in addition to FDA clearance for the algorithm and bihormonal configuration of the iLet as a device, in order for the bihormonal system to be used as we intend.

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. We believe our planned expansion for the iLet's use in T2D will require an additional 510(k) clearance. We expect that we will need to conduct studies to determine the iLet's performance in patients in order to obtain the additional 510(k) clearance. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. 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. This is based on our internal estimates factoring epidemiologic data from government and leading industry organizations such as the CDC, as well as industry sales data from public filings and disclosures made by the leading device manufacturers (Medtronic, Tandem and Insulet) and aggregated by third-party data service providers. 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.

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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. According to the CDC, 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 according to the CDC, of whom an estimated 1.8 million require intensive insulin therapy, based on public and industry data.

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. The iLet is not compatible with third-party infusion sets or insulin cartridges.

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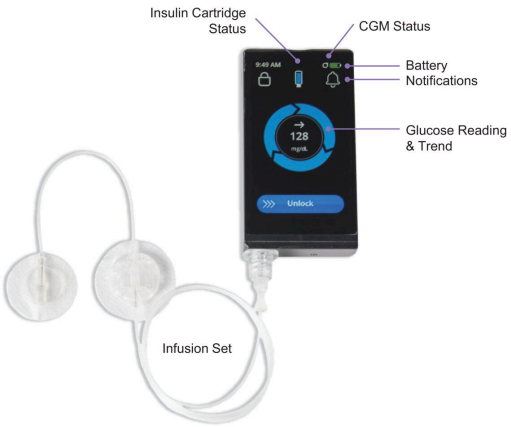
The iLet Bionic Pancreas



Use of the iLet requires the independent purchase of a compatible third-party integrated continuous glucose monitor (iCGM) to provide real-time data to the iLet user. Currently, the only models that are compatible with our iLet are DexCom's G6 and G7 devices and Abbott's FreeStyle Libre 3 Plus CGM sensor. A iCGM is a wearable device that works by inserting a small sensor under the skin into fatty tissue and tracks blood sugar levels in real time. The sensor measures glucose levels in the interstitial fluid and sends the information to a receiver, smartphone or insulin pump. The user can view their glucose levels, trends, and to what degree their levels are rising or falling.

We have submitted and the FDA has accepted our post-market surveillance plan for our iLet, which requires us to conduct a 1-year, prospective single-arm cohort study with a sample size that is statistically justified for T1D patients ages six years and older. For additional information, please see the section titled "Risk Factors—Risks Related to the Development, Regulatory Approval and Commercialization of our iLet Bionic Pancreas and Product Candidates—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."

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.*** Through clinical trials, the BPPT and our analysis of post-approval data, we have developed a significant body of clinical data from more

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than 3,000 patients, which we believe supports 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 in the early stages of 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 in the early stages of 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. We entered into a device license agreement and a control algorithm license agreement with BU, under which we received exclusive, royalty-bearing licenses to certain patent rights and proprietary technology. We also entered into an exclusive collaboration and license agreement with Xeris to facilitate the 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 the bihormonal configuration. For more information regarding these agreements, see the section titled "Business—License and Collaboration Agreements."

- ***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. While the iLet can be prescribed by any HCP (PCP or subspecialists), we are promoting sales of the iLet through an internal sales organization,

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where the initial direct sales efforts are focused on people with T1D who are treated within high-volume endocrinology practices in the United States. Over time, we plan to expand into the more diffuse population of people with T1D who are treated by PCP. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline.

- ***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. We believe that the T2D total addressable market for insulin pumps in the United States is estimated to be approximately $6 billion.

Recent Developments

Preliminary estimated selected financial results for the three months and year ended December 31, 2024

Included below are certain preliminary estimated selected unaudited financial results for the three months and year ended December 31, 2024 and the corresponding periods of the prior fiscal year derived from our audited financial statements. We have provided ranges, rather than specific amounts, for the three months and year ended December 31, 2024 because our closing procedures for the fiscal year ended December 31, 2024 are not yet complete, these results are preliminary and subject to change, and there is a possibility that our actual results may differ materially from these preliminary estimates. These ranges are based on the information available to us as of the date of this prospectus. Additionally, we expect to report that we had approximately $103.6 million of cash, cash equivalents and short-term investments as of December 31, 2024.

These preliminary estimated results are derived from our preliminary internal financial records and are subject to revisions based on our procedures and controls associated with the completion of our financial reporting, including all the customary reviews and approvals, and completion by our independent registered public accounting firm of its review of such financial statements for the year ended December 31, 2024. These preliminary estimated results should not be viewed as a substitute for financial statements prepared in accordance with U.S. GAAP. Our independent registered public accounting firm has not conducted a review of, and does not express an opinion or any other form of assurance with respect to, these preliminary estimated results. It is possible that we or our independent registered public accounting firm may identify items that would require us to

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make adjustments to the preliminary estimates set forth below as we complete our financial statements and that our actual results may differ materially from these preliminary estimates. Accordingly, undue reliance should not be placed on these preliminary estimates. These preliminary estimates are not necessarily indicative of any future period and should be read together with "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Three Months Ended December 31,			Year Ended December 31,		
	2024 (Low)	2024 (High)	2023	2024 (Low)	2024 (High)	2023
		(unaudited)	(in thousands, except percentages)		(unaudited)	
Selected Statement of Operations Data:						
Net sales	$ 20,240	$ 20,640	$ 8,350	$ 64,474	$ 65,774	$ 11,995
Gross profit	11,372	12,010	5,062	34,885	36,904	6,308
Gross margin (as a percentage of revenue)	56.2%	58.2%	60.6%	54.1%	56.1%	52.6%
Loss from operations	(12,777)	(13,297)	(8,367)	(44,801)	(45,701)	(35,850)
Net loss	(17,928)	(18,288)	(18,848)	(54,206)	(55,306)	(44,099)
Key Business Metrics and Non-GAAP Financial Measures:						
New patient starts(1)	3,936	4,096	1,818	12,846	13,006	2,304
New patient starts from MDI as a percentage of total new patient starts(1)	67%	70%	55%	66%	69%	51%
Installed customer base(1)	15,150	15,310	2,304	15,150	15,310	2,304
Adjusted gross profit(2)	$ 11,554	$ 12,202	$ 5,317	$ 35,836	$ 37,885	$ 6,937
Adjusted gross margin (as a percentage of revenue)(2)	57.1%	59.1%	63.7%	55.6%	57.6%	57.8%
Adjusted EBITDA(2)	$(11,205)	$(11,290)	$ (6,554)	$(37,326)	$(38,106)	(29,021)

(1) These key metrics are fully described in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Key Business Metrics."
(2) Adjusted gross profit, adjusted gross margin and adjusted earnings before interest, taxes, depreciation and amortization (EBITDA), as used herein, are non-GAAP financial measures that are presented as supplemental disclosure and are fully described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures." Additionally, see below for a reconciliation of (i) adjusted gross profit and adjusted gross margin from the most comparable GAAP measures, gross profit and gross margin, respectively, and (ii) adjusted EBITDA from the most comparable GAAP measures, net loss.

For the three months ended December 31, 2024, we expect net sales to be between $20.2 million and $20.6 million, compared to $8.4 million for the three months ended December 31, 2023. The expected increase in net sales is primarily due to an increase in volume of sales of the iLet and single-use products to customers as a result of the expansion of our commercial sales efforts. For the year ended December 31, 2024, we expect net sales to be between $64.5 million and $65.8 million, compared to $12.0 million for the year ended December 31, 2023. The expected increase in net sales is primarily due to an increase in volume of sales of the iLet and single-use products to customers predominantly driven by a shorter sales period following the FDA clearance and commercialization of the iLet in May 2023, as compared to the full twelve months of commercial sales in 2024, and expansion of our commercial sales efforts.

For the three months ended December 31, 2024, we expect gross profit to be between $11.4 million and $12.0 million, compared to $5.1 million for the three months ended December 31, 2023. The expected increase in gross profit is primarily due to an increase in volume of sales of the iLet and single-use products to customers as a result of the expansion of our commercial sales efforts. For the year ended December 31, 2024, we expect gross profit to be between $34.9 million and $36.9 million, compared to $6.3 million for the year ended December 31,

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2023. The expected increase in gross profit is primarily due to an increase in volume of sales of the iLet and single-use products to customers predominantly driven by a shorter sales period following the FDA clearance and commercialization of the iLet in May 2023, as compared to the full twelve months of commercial sales in 2024, and expansion of our commercial sales efforts.

For the three months ended December 31, 2024, we expect gross margin to be between 56.2% and 58.2%, compared to 60.6% for the three months ended December 31, 2023. The expected decrease in gross margin is primarily due to product mix. More specifically, a higher percentage of the new patients starts in the three months and year ended December 31, 2024 were reimbursed through the PBP channel. For the three months ended December 31, 2024, a low-double digit percentage of our new patient starts were reimbursed through the PBP channel, compared to a mid-single digit percentage for the three months ended December 31, 2023. For the year ended December 31, 2024, a high-single digit percentage of our new patient starts were reimbursed through the PBP channel, compared to a mid-single digit percentage for the year ended December 31, 2023. The PBP channel, by contrast to the DME channel, recognizes less revenue in the fiscal quarter when the iLet is sold. For the year ended December 31, 2024, we expect gross margin to be between 54.1% and 56.1%, compared to 52.6% for the year ended December 31, 2023. The expected increase in gross margin is primarily due to increased sales volume, resulting in a reduction in fixed costs on a per unit basis, which led to lower per unit costs.

For the three months ended December 31, 2024, we expect loss from operations to be between $12.8 million and $13.3 million, compared to $8.4 million for the three months ended December 31, 2023. The expected increase in loss from operations is primarily due to a one-time, nonrefundable milestone payment of $3.0 million made under the License and Collaboration Agreement with Xeris. For the year ended December 31, 2024, we expect loss from operations to be between $44.8 million and $45.7 million, compared to $35.9 million for the year ended December 31, 2023. The expected increase in loss from operations is primarily due to an increase in payroll-related expenses driven by an increase in headcount and one-time, nonrefundable payments made under the License and Collaboration Agreement with Xeris, totaling $3.5 million.

For the three months ended December 31, 2024, we expect net loss to be between $17.9 million and $18.3 million, compared to $18.8 million for the three months ended December 31, 2023. The expected decrease in net loss is primarily due to an increased loss from operations offset by a decrease in expense from the change in fair value of warrant liabilities. For the year ended December 31, 2024, we expect net loss to be between $54.2 million and $55.3 million, compared to $44.1 million for the year ended December 31, 2023. The expected increase in net loss is primarily due to an increased loss from operations and an increase in expense related to the change in fair value of warrant liabilities.

For the three months ended December 31, 2024, we expect adjusted gross profit to be between $11.6 million and $12.2 million, compared to $5.3 million for the three months ended December 31, 2023. The expected increase in adjusted gross profit is primarily due to an increase in volume of sales of the iLet and single-use products to customers as a result of the expansion of our commercial sales efforts. For the year ended December 31, 2024, we expect adjusted gross profit to be between $35.8 million and $37.9 million, compared to $6.9 million for the year ended December 31, 2023. The expected increase in adjusted gross profit is primarily due to an increase in volume of sales of the iLet and single-use products to customers as a result of the expansion of our commercial sales efforts, partially offset by an increase in stock-based compensation expense driven by an increase in headcount and depreciation and amortization expense driven by the addition of manufacturing equipment during 2024.

For the three months ended December 31, 2024, we expect adjusted gross margin to be between 57.1% and 59.1%, compared to 63.7% for the three months ended December 31, 2023. The expected decrease in adjusted gross margin is primarily due to product mix. More specifically, a higher percentage of the new patients starts in the three months and year ended December 31, 2024 were reimbursed through the PBP channel, as noted

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above. The PBP channel, by contrast to the DME channel, recognizes less revenue in the fiscal quarter when the iLet is sold. For the year ended December 31, 2024, we expect adjusted gross margin to be between 55.6% and 57.6%, compared to 57.8% for the year ended December 31, 2023. The expected decrease in adjusted gross margin is primarily due to higher per-unit costs related to stock-based compensation expense and depreciation and amortization expense for the year ended December 31, 2023.

The following table presents a reconciliation of adjusted gross profit and adjusted gross margin from the most comparable GAAP measure, gross profit and gross margin, respectively, for the three months and year ended December 31, 2024:

	Three Months Ended December 31,			Year Ended December 31,		
	2024 (Low)	2024 (High)	2023	2024 (Low)	2024 (High)	2023
		(unaudited)	(in thousands, except percentages)		(unaudited)	
Gross profit	$11,372	$12,010	$5,062	$34,885	$36,904	$6,308
Gross margin (as a percentage of revenue)	56.2%	58.2%	60.6%	54.1%	56.1%	52.6%
Add:						
Depreciation and amortization expense	110	115	165	676	696	390
Stock-based compensation expense	72	77	90	275	285	239
Adjusted gross profit	$11,554	$12,202	$5,317	$35,836	$37,885	$6,937
Adjusted gross margin (as a percentage of revenue)	57.1%	59.1%	63.7%	55.6%	57.6%	57.8%

For the three months ended December 31, 2024, we expect adjusted EBITDA to be between $(11.2) million and $(11.3) million, compared to $(6.6) million for the three months ended December 31, 2023. The expected decrease in adjusted EBITDA is primarily due to an increase in net loss driven by the expansion of our commercial sales efforts offset by a one-time refundable milestone payment of $3.0 million made under the License and Collaboration Agreement with Xeris and a decrease in expense from the change in fair value of warrant liabilities. For the year ended December 31, 2024, we expect adjusted EBITDA to be between $(37.3) million and $(38.1) million, compared to $(29.0) million for the year ended December 31, 2023. The expected decrease in adjusted EBITDA is primarily due to a shorter sales period following the FDA clearance and commercialization of the iLet in May 2023, as compared to the full twelve months of commercial sales in 2024, and expansion of our commercial sales efforts, offset by an increase in payroll-related expenses driven by an increase in headcount and one-time, nonrefundable payments made under the License and Collaboration Agreement with Xeris, totaling $3.5 million, as well as an increase in expense related to the 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 three months and year ended December 31, 2024:

	Three Months Ended December 31,			Year Ended December 31,		
	2024 (Low)	2024 (High)	2023	2024 (Low)	2024 (High)	2023
		(unaudited)	(in thousands)		(unaudited)	
Net loss	$(17,928)	$(18,288)	$(18,848)	$(54,206)	$(55,306)	$(44,099)
Add:						
Depreciation and amortization expense	230	235	292	1,141	1,161	1,226
Stock-based compensation expense	1,532	1,582	1,576	6,324	6,444	5,658
Interest income	(941)	(961)	(1,251)	(3,869)	(3,949)	(1,777)
Provision for state taxes	—	—	—	2	2	12
Change in fair value of warrant liabilities	5,902	6,142	11,677	13,282	13,542	9,958
Adjusted EBITDA	$(11,205)	$(11,290)	$ (6,554)	$(37,326)	$(38,106)	$(29,021)

Concurrent Private Placement

We have entered into the Purchase Agreement with Wellington, an existing stockholder. Pursuant to the Purchase Agreement, Wellington has agreed to purchase and we have agreed to sell the Private Placement Shares in a concurrent private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a per share price equal to the initial public offering price. The private placement would close concurrently with, and be contingent and conditioned upon consummation of, this offering. However, this offering is not contingent on the consummation of the concurrent private placement. The underwriters have agreed to act as placement agents in connection with the concurrent private placement and will receive a placement agent fee equal to 7.0% of the total purchase price of the Private Placement Shares.

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 and the concurrent private placement, 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.

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- 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.
- 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 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.

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- 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 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.
- 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;

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- 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.

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The Offering	
Common stock offered by us	12,000,000 shares.
Underwriters' option to purchase additional shares of common stock from us and the selling stockholders	The underwriters have an option for a period of 30 days to purchase an additional 1,800,000 shares of our common stock, consisting of 475,000 shares from us and 1,325,000 shares from the selling stockholders identified in this prospectus.
Concurrent private placement	We have entered into a Common Stock Purchase Agreement, dated January 21, 2025, with Wellington Hadley Harbor Aggregator IV, L.P. (Wellington), an existing stockholder (the Purchase Agreement). Pursuant to the Purchase Agreement, Wellington has agreed to purchase and we have agreed to sell 1,000,000 in shares of our common stock (the Private Placement Shares) in a concurrent private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a per share price equal to the initial public offering price. The private placement would close concurrently with, and be contingent and conditioned upon consummation of, this offering. However, this offering is not contingent on the consummation of the concurrent private placement. The underwriters have agreed to act as placement agents in connection with the concurrent private placement and will receive a placement agent fee equal to 7.0% of the total purchase price of the Private Placement Shares.
Common stock to be outstanding immediately after this offering and concurrent private placement	42,859,341 shares.
Use of proceeds	We estimate that the net proceeds to us from the sale of our common stock in this offering and concurrent private placement will be approximately $199.2 million (or approximately $206.7 million if the underwriters exercise in full their option to purchase up to 475,000 additional shares of common stock from us), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering and concurrent private placement, together with our existing cash, cash equivalents and short-term investments, to fund (i) the development of the bihormonal configuration of the iLet through regulatory submissions to the FDA for 510(k) clearance of the bihormonal configuration and for approval of the glucagon product; (ii) the development and manufacturing capability of the patch pump through regulatory submissions to the FDA for 510(k) clearance; and (iii) the expansion

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	of our sales and manufacturing infrastructure, working capital and general corporate purposes. We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders. See the section titled "Use of Proceeds" for additional information.
Selling stockholders; concentration of ownership	The underwriters have an option for a period of 30 days to purchase up to an additional 1,325,000 shares of our common stock from the selling stockholders in this offering. Following this offering, our executive officers, directors and stockholders holding more than 5% of our outstanding shares, together with their affiliates, will beneficially own in the aggregate, approximately 8.6% of our outstanding capital stock (or 6.3% of our outstanding capital stock if the underwriters exercise in full their option to purchase additional shares of our common stock from us and the selling stockholders). See the section titled "Principal and Selling Stockholders" 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.
Reserved share program	At our request, the underwriters have reserved up to 5.0% of the shares of our common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale, at the initial public offering price, to certain of our directors, officers, employees and certain other parties related to us. Shares purchased by our directors and officers will be subject to the 180-day lock-up restriction described in the section of this prospectus titled "Underwriting." The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.
Exchange	We have entered into an Exchange Agreement, dated January 21, 2025, with certain holders of our capital stock (Exchange Agreement), pursuant to which we agreed to issue to such holders, immediately prior to the closing of this offering, pre-funded warrants in exchange for outstanding shares of our common stock, in an amount such that shares held by such holders, including any shares purchased in this offering, will result in such holder beneficially owning not more than 9.99% of our common stock as of immediately following the closing of this offering (the Exchange). No pre-funded warrants will be issued in connection with the Exchange. See "Certain Relationships and Related Person Transactions—Exchange Agreement" for additional information.
Nasdaq symbol	"BBNX"

The number of shares of our common stock to be outstanding after this offering and concurrent private placement is based on 29,859,341 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

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common stock into an aggregate of 6,662,861 shares of a single class of our common stock, (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into 15,474,610 shares of common stock, (iii) the automatic net exercise of all outstanding Class B common stock warrants and the automatic net exercise and subsequent conversion of all outstanding Series C convertible preferred stock warrants into an aggregate of 3,369,477 shares of our common stock, as described below, (iv) the Exchange and (v) the issuance and subsequent conversion of all of our Series E convertible preferred stock issued and sold in November 2024 into an aggregate of 4,352,393 shares of our common stock, each immediately prior to the closing of this offering, and excludes:

- 5,658,801 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 $6.73 per share;
- 159,810 shares of our Class B common stock (all to employees, none of which were executive officers) issuable upon exercise of stock options granted under our 2016 Plan subsequent to September 30, 2024 and before January 28, 2025, with a weighted-average exercise price of $10.81 per share;
- 1,307,630 shares of our common stock (902,837 to executive officers and 404,793 to employees) issuable upon the exercise of stock options granted under the 2025 Equity Incentive Plan (2025 Plan), which became effective upon the execution and delivery of the underwriting agreement for this offering, with an exercise price that is equal to the initial public offering price in this offering;
- 12,016,744 shares of our common stock reserved for future issuance under our 2025 Plan, which became effective upon the execution and delivery of the underwriting agreement for this offering (which shares include 4,890,000 new shares plus the number of shares (not to exceed 7,126,744 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, withheld or settled in cash, 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
- 410,000 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 became 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 2,939,085 shares of our Class A common stock, 3,674,858 shares of our Class B common stock and 48,918 shares of our Class C common stock as of September 30, 2024 into an aggregate of 6,662,861 shares of our common stock immediately prior to the closing of this offering;
- the conversion, in accordance with our existing certificate of incorporation, of (i) all outstanding shares of our convertible preferred stock as of September 30, 2024 into an aggregate of 15,474,610 shares of our common stock and (ii) all of our shares of Series E convertible preferred stock issued and sold in November 2024 into an aggregate of 4,352,393 shares of our common stock, each immediately prior to the closing of this offering;

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- the issuance of shares of our common stock upon the automatic net exercise of warrants to purchase 2,672,422 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 $0.02 per share (based on the initial public offering price of $17.00 per share);
- the issuance of shares of our common stock upon the automatic net exercise of warrants to purchase 697,055 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 $0.02 per share (based on the initial public offering price of $17.00 per share);
- the issuance of 1,000,000 shares of our common stock in the concurrent private placement, which is to be completed concurrently with, and be contingent and conditioned upon consummation of, the closing of this offering;
- no issuance of pre-funded warrants in exchange for shares of common stock in the Exchange;
- no exercise of the outstanding options described above;
- no exercise of the underwriters' option to purchase additional shares of our common stock from us and the selling stockholders;
- 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-1.970 reverse stock split of our common stock and convertible preferred stock effected on January 21, 2025.

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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. We have derived the summary statements of operations and comprehensive loss data for the nine months ended September 30, 2023 and 2024 and the summary balance sheet data as of September 30, 2024, from our unaudited interim condensed financial statements included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information set forth in those statements. Our historical results presented below are not necessarily indicative of the results to be expected for any future period and the results for any interim period are not necessarily indicative of the results that may be expected for the full year. 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,		Nine Months Ended September 30,	
	2022	2023	2023	2024
	(in thousands, except share and per share data)		(unaudited)	
Statements of Operations and Comprehensive Loss Data:				
Revenue:				
Net sales	$ —	$ 11,995	$ 3,645	$ 44,684
Collaboration revenue	179	—	—	—
Total revenue	179	11,995	$ 3,645	$ 44,684
Cost of sales[1]	—	5,687	2,399	20,485
Gross profit	179	6,308	1,246	24,199
Operating expenses:				
Research and development[1]	31,428	17,943	13,483	16,970
Sales and marketing[1]	8,827	11,990	6,372	26,282
General and administrative[1]	25,768	12,225	8,874	13,161
Total operating expenses	66,023	42,158	28,729	56,413
Loss from operations	(65,844)	(35,850)	(27,483)	(32,214)
Other income (expense), net:				
Interest income	196	1,777	526	2,958
Interest and other expense	(14)	(68)	(13)	(2)
Change in fair value of warrant liabilities	911	(9,958)	1,719	(7,390)
Total other income (expense), net	1,093	(8,249)	2,232	(4,434)
Net loss	$ (64,751)	$ (44,099)	$ (25,251)	$ (36,648)
Other comprehensive income (loss):				
Unrealized gain on short-term investments	—	137	—	(79)
Comprehensive loss	$ (64,751)	$ (43,962)	$ (25,251)	$ (36,727)
Net loss per share attributable to common stockholders, basic and diluted[2]	$ (12.96)	$ (8.31)	$ (4.98)	$ (5.86)
Weighted-average common stock outstanding, basic and diluted[2]	4,997,244	5,303,684	5,062,429	6,264,162
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[3]		$ (1.14)		$ (0.96)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)[3]		29,853,889		30,495,423

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

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	Year Ended December 31,		Nine Months Ended September 30,	
	2022	2023	2023	2024
	(in thousands)			
Cost of sales	$ —	$ 239	$ 149	$ 201
Research and development	1,554	1,781	1,411	844
Sales and marketing	384	610	362	1,150
General and administrative	4,162	3,028	2,160	2,638
Total stock-based compensation expense	$ 6,100	$ 5,658	$ 4,082	$ 4,833

(2) See Note 16 to our audited financial statements and Note 15 to our unaudited interim condensed 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 and outstanding warrants. 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 and the concurrent private placement. 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 applicable period.

	As of September 30, 2024		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
		(in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and short-term investments	$ 60,897	$ 120,551	$ 319,781
Working capital(3)	64,676	124,330	$ 323,560
Total assets	96,938	156,592	$ 352,727
Convertible preferred stock	261,713	—	—
Total stockholders' (deficit) equity	$(228,847)	$ 131,396	$ 327,531

(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 6,662,861 shares of our common stock immediately prior to the closing of this offering, (ii) the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of 15,474,610 shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity immediately prior to the closing of this offering, (iii) the automatic net exercise of all outstanding Class B common stock warrants into an aggregate of 2,672,422 shares of our common stock immediately prior to the closing of this offering; (iv) the automatic net exercise and subsequent conversion of all outstanding Series C convertible preferred stock warrants into an aggregate of 697,055 shares of our common stock and the related reclassification of the carrying value of our Series C convertible preferred stock to permanent equity immediately prior to the closing of this offering; (v) the issuance and sale of our Series E convertible preferred stock in November 2024 for aggregate net proceeds of approximately $59.7 million and the subsequent conversion into 4,352,393 shares of our common stock and the related reclassification of the carrying value of our Series E convertible preferred stock to permanent equity immediately prior to the closing of this offering and (vi) 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 12,000,000 shares of common stock in this offering and 1,000,000 shares in the concurrent private placement, at the initial public offering price of $17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(3) 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.

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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 $36.6 million, respectively. As of September 30, 2024, we had an accumulated deficit of $278.6 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.

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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.

Additionally, we are subject to customer concentration risk as a result of our reliance on a relatively small number of DME distributors for a significant portion of our revenues. For the year ended December 31, 2023, our top four DME distributors represented approximately 70% of our total sales. In order to mitigate this concentration risk, we are actively pursuing our multi-channel DME and PBP coverage and reimbursement strategy. However, we cannot guarantee that we will be successful in executing this strategy and as such, we may need to continue to depend on the sales to a relatively small number of significant customers. Any reduction in the amount of revenues that we derive from these customers, without an offsetting increase in new sales to other customers, could have a material adverse effect on our results of operations and financial condition.

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 and the concurrent private placement, 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 $60.9 million. Based on our planned use of the net proceeds of this offering and the concurrent private placement 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 the first half of 2028. 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;

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- 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;
- 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 and the concurrent private placement, 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.

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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;

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- 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, limiting our ability to successfully sell our current and future products.

Our current and future target patient populations and total addressable markets for our current and future products are based on our beliefs and estimates regarding pump adoption rates and the incidence or prevalence of T1D and T2D, including the patient population using intensive insulin therapy for treatment, which are derived from a variety of sources including scientific literature and third-party estimates. Total addressable market is the total overall revenue opportunity that we believe is available for insulin pumps if 100% market share is achieved, and it is not a representation that we will achieve such market share. While we believe our assumptions and the data underlying our estimates are reasonable, our projections may prove to be incorrect and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these estimates. For example, the number of potential patients may turn out to be lower than expected. Even though we estimate we have obtained approximately 10% share of new patient starts during the fourth quarter of 2024 for our iLet (calculated by taking the number of new patient starts on the iLet and dividing that by the number of assumed new patient starts in the entire insulin pump market in the United States for the same quarter), 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, specifically in T2D, which we have not obtained. If the actual number of patients who would benefit from our products, the price at which we can sell products, or the total addressable market for our products is smaller than we anticipated, it may impair our sales growth and have an adverse impact on our business.

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 primarily compete with a number of companies that manufacture and sell insulin pumps, such as

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Medtronic, Tandem, and Insulet. The iLet has certain characteristics that other insulin pumps manufactured by such competitors, to our knowledge, do not currently have, such as the ability to be initialized with only the user's body weight, being enabled by algorithms that determine 100% of the user's insulin doses, no carb counting, an option for pay-as-you-go pharmacy reimbursement and prefilled cartridges. For more information regarding the current commercial landscape for the iLet, see the section titled "Business—The Commercial Opportunity for the iLet Bionic Pancreas to Address the Unmet Need." Outside of the insulin pump market, 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 prefilled insulin syringes, insulin pens and inhalable insulin products, as well as companies with approved therapeutics or in-development therapeutic candidates impacting diabetes.

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

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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 encountered significantly higher demand than initially expected by our forecast model. Such demand, driven by faster than expected adoption of the iLet in endocrinology centers in which we operate, as well as by the earlier than expected launch of our Dexcom G7 integration in December 2023, exceeded our existing supply of the iLet, which resulted in backorders. However, no resulting backorders materially impacted our results of operations. 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. In order to mitigate any demand issues, we have increased our inventory levels of the iLet to address any unpredictability. However, 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.

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,

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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

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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

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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 material 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 material 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,

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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 December 31, 2024, we had 291 full-time employees and three part-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

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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

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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.

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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 separately need to develop and obtain approval for our glucagon product candidate as a drug via an NDA submission in order to successfully commercialize our iLet in a bihormonal configuration. We expect that the bihormonal configuration will require completion of clinical trials and submission of a 510(k) for both the infusion pump and algorithm. In addition, we expect that the single hormone and bihormonal algorithms will require separate studies to be performed in T1D and T2D populations in order to seek clearance in these patient populations. In addition, we are in the early states of developing an insulin pump, also commonly referred to as a "patch pump," for which we have engaged with the FDA in pre-submission interactions and intend to seek FDA clearance via a 510(k) submission. 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;

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- 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.

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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. Specifically, the FDA has asked that we conduct a one-year, prospective single-arm cohort study and has accepted our plan for this study, which will assess the safety and effectiveness of the iLet in commercial users and is expected to enroll 1,875 users. The FDA also typically issues a 522 Order for any class II device like the iLet that (1) would be reasonably likely to have serious adverse health consequences if it were to fail and (2) is expected to have significant use in pediatric populations. Other class II software algorithms used with AID systems meet these two criteria and have therefore been issued similar 522 Orders. One purpose of the 522 Order is to determine incidence rates of rare adverse events associated with device use (e.g., severe hypoglycemia or DKA). In addition, the FDA expressed concern with the limited safety and effectiveness data for design features specific to the iLet (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). As part of FDA's request to conduct a post-market surveillance study, the FDA set forth several criteria to evaluate the iLet to address these specific concerns. We have submitted and the FDA has accepted our post-market surveillance plan.

Specifically, 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 have initiated a single-arm prospective observational study and expect to enroll a total of 1,875 users who will be followed for one year. We expect that the study will compare outcomes data during iLet use to safety and efficacy outcomes data derived from independent epidemiological studies, such as studies published by the T1D Exchange registry, and to the results of the iLet Bionic Pancreas Pivotal Trial, with an emphasis on serious adverse effects such as severe hypoglycemia and DKA. Further, we expect that an analysis will be conducted comparing glycemic outcomes during iLet use to baseline pre-iLet CGM and HbA1c data in participants who have provided this data. In addition, the study will evaluate the frequency and types of anticipated and unanticipated device issues experienced by users during real-world use. Following completion of the 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 we 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 522 Order, as well as the recall or withdrawal of the iLet, 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

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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

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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

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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.

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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.

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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. Rates of severe hypoglycemia (SH) are reported as the number of patients with ≥1 event per 100 patient years of exposure in the BPPT. With 83 patient-years of exposure on iLet therapy, and 13 participants having ≥ 1 SH event, the SH rate was 15.6 events per 100 patient years. In the post-market setting, with 434 patient-years of exposure on iLet therapy through January 31, 2024, and 39 participants having ≥ 1 SH

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event, the SH rate was 9.0 events per 100 patient years. In the BPPT with 83 patient-years of exposure on iLet therapy, the DKA rate was 2.4 patient events per 100 patient years. In the post-market setting with 434 patient-years of exposure, the DKA rate was 2.1 patients per 100 patient years.

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

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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 seek clearance of our iLet for use with select FDA-cleared iCGM models that are compatible with our iLet. Use of the iLet requires the independent purchase of a compatible third-party iCGM to provide real-time data to the iLet user. 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 (FDCA). Section 505(b)(2) permits the filing of an 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.

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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.

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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

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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, particularly in light of the change of administration.

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, particularly in light of the change of administration. 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

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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;
- 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;

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- 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

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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.

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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

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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;

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- 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 $1.1 million 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.

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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

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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,

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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

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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 522 Order, which is an order by the FDA to conduct a post-market study of an authorized or cleared medical device. For additional information, please see the section titled "Risk Factors—Risks Related to Development, Regulatory Approval and Commercialization of our iLet Bionic Pancreas and Product Candidates—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

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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

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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,

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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.

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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, protected health information, individually identifiable health information, 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, we are considered a "covered entity" under HIPAA, as amended by HITECH, and regulations implemented thereunder, or collectively HIPAA. HIPAA imposes specific requirements relating to the privacy, security, breach notification obligation on certain healthcare providers, health plans, healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities and business associates to develop and maintain policies with respect to the protection of, use and disclosure of PHI, including the adoption of

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administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI.

Additionally, under HIPAA, covered entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach by a covered entity or its agents. Notification also must be made to the U.S. Department of Health and Human Services Office for Civil Rights, or OCR, and, in certain circumstances involving large breaches, to the media. Business associates must report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents. A non-permitted use or disclosure of PHI is presumed to be a breach under HIPAA unless the covered entity or business associate establishes that there is a low probability the information has been compromised consistent with requirements enumerated in HIPAA.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the U.S. Department of Health and Human Services, or HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Further, 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 individuals. 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. Numerous U.S. states 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 information 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

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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 have adopted similar consumer health data privacy laws, such as Connecticut's SB-3 which amended the Connecticut Data Privacy Act to cover consumer health data and Nevada's Consumer Health Data Privacy Law and additional states are expected to pass similar laws governing consumer health data.

The FTC also has authority under Section 5 of the FTC Act to initiate enforcement actions against entities that engage in unfair or deceptive practices such as misleading customers, about HIPAA compliance, making unfair or deceptive statements about the use of personal data (including PHI) in privacy policies, failing to limit service providers use of PHI, or failing to implement policies to protect PHI or engaging in other unfair practices that harm customers. For information that is not subject to HIPAA and deemed to be a "personal health record," the FTC may also impose penalties for violations of the Health Breach Notification Rule (HBNR) to the extent we are considered a "personal health record-related entity" or "third party service provider." The FTC has taken several enforcement actions under the HBNR and indicated that the FTC will continue to protect consumer privacy through greater use of the agency's enforcement authorities. As a result, we expect even greater scrutiny by federal and state regulators, partners, and consumers of our collection, use and disclosure of health information.

We may in the future use artificial intelligence (AI), including generative AI, and machine learning (ML) technologies in our products and services (collectively, "AI/ML" technologies). The development and use of AI/ML present various privacy and security risks that may impact our business. AI/ML are subject to privacy and data security laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed, enacted, or are considering laws governing AI/ML, such as the EU AI Act. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML and restrict our rights to use certain personal data to train AI/ML models. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. AI/ML have the potential to benefit our business and operations, possibly significantly, including by potentially creating efficiencies and enabling powerful research and development that may otherwise not be possible, and we may be at a competitive disadvantage if we do not or are unable to use AI or only use it for limited purposes.

While we implement certain technical, physical and organizational processes (depending on the environment, systems, and data) designed to safeguard sensitive information, such as incident detection and response processes, penetrating testing, employee training and access controls, if we start using AI/ML in our products and services, use of such AI/ML in connection with our confidential, proprietary, or otherwise sensitive information, including personal data or software source code, may still result in leaks, disclosure, or otherwise unauthorized or unintended access to such information, including if such information is used to further refine and train the underlying AI/ML models. Any such access or any improper or inappropriate use of AI/ML could, for example, reveal trade secrets that may enable third parties to replicate or improve upon our technologies and programs, or otherwise negatively impact the value of, or our ability to obtain or maintain, intellectual property rights.

Moreover, AI/ML models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI/ML with bad inputs or logic), or if the logic of the AI/ML is flawed (a so-called "hallucination"). We may in the future use AI/ML outputs to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to unknowingly make decisions that could bias certain individuals (or classes of individuals).

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We may also face novel and urgent cybersecurity risks and emerging ethical risks relating to the use of AI/ML, which could adversely affect our operations, assets, including intellectual property and other sensitive information, and reputation, as well as those of any third parties involved in our operations. Therefore, if, in the future, we use AI/ML technologies in our business, such use could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI/ML, 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 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.

Outside the United States, we may become subject to an increasing number of laws, regulations, and industry standards that 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.

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 or have already adopted similarly stringent 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 will be able to 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

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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, whitepapers and other statements concerning data privacy, security and artificial intelligence. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading 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, including protected health information, 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

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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.

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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

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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.

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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

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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;

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- 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 "non-exclusive, 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 "non-exclusive, 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

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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

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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

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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 or 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

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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

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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;

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- 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. Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "BBNX." The initial public offering price for our common stock was determined through negotiations among us, the selling stockholders and the underwriters, and may vary from the market price of our common stock following the completion of this offering. 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 was 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;

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- 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, principal stockholders, selling 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;

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- 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 and concurrent private placement, 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 and concurrent private placement, 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 8.6% 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 and concurrent private placement 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 and concurrent private placement, we will have 42,859,341 shares of common stock outstanding. 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 29.9 million 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." In addition, at our request, the underwriters have reserved up to 5.0% of the shares of our common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale, at the initial public offering price, to certain of our directors, officers, employees and certain other parties related to us, under the reserved share program (RSP). Except for any shares acquired by our directors and officers, shares purchased pursuant to the RSP will not be subject to 180-day lock-up restriction with the underwriters. Future sales of such shares may cause the price of our common stock to be reduced or become more volatile.

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Moreover, after this offering and concurrent private placement, holders of an aggregate of approximately 27.0 million 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 and concurrent private placement, 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 and concurrent private placement. Based on the initial public offering price of $17.00 per share, you will experience immediate dilution of $10.75 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 concurrent private placement, and the initial public offering price. This dilution is due to our investors who purchased shares prior to this offering and concurrent private placement having paid a price for their shares that is substantially less than the price offered to the public in this offering and concurrent private placement, 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 and concurrent private placement 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 5% of the total number of shares of our capital 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) 1% 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) 1,230,000 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

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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 and concurrent private placement, 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 and concurrent private placement.

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.

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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 the concurrent private placement and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and the concurrent private placement 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 and the concurrent private placement 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 and the concurrent private placement 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;

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- 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. Such ability to issue preferred stock with voting or conversion rights 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.

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 the 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:

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(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

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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

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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 Nasdaq. 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.

We and our directors and executive officers may be subject to litigation for a variety of claims, which could harm our reputation and adversely affect our business, results of operations and financial condition.

In the ordinary course of business, we have in the past and may in the future be involved in and subject to litigation for a variety of claims or disputes and receive regulatory inquiries. These claims, lawsuits and proceedings could include labor and employment, wage and hour, commercial, alleged securities law violations or other investor claims, claims that our employees have wrongfully disclosed or we have wrongfully used proprietary information of our employees' former employers and other matters. The number and significance of these potential claims and disputes may increase as our business expands. Further, our general liability insurance may not cover all potential claims made against us or be sufficient to indemnify us for all liability that may be imposed. Any claim against us, regardless of its merit, could be costly, divert management's attention and operational resources, and harm our reputation.

Our directors and executive officers may also be subject to litigation. Our amended and restated certificate of incorporation and our amended and restated bylaws 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. The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and our 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. We also maintain customary directors' and officers' liability insurance. See the section titled "Executive and Director Compensation—Limitation of Liability and Indemnification of Matters."

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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.

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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

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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.

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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;

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- 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 and the concurrent private placement and our existing cash, cash equivalents and short-term investments.

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.

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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.

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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.

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USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $183.5 million (or approximately $191.0 million if the underwriters' option to purchase up to 475,000 additional shares from us is exercised in full) based on the initial public offering price of $17.00 per share of common stock, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any of the proceeds from the sale of common stock in this offering by the selling stockholders identified in this prospectus. We also expect to receive net proceeds of approximately $15.7 million from the sale of 1,000,000 shares of our common stock to Wellington in the concurrent private placement, at the initial public offering price of $17.00 per share, after deducting placement agent fees and estimated expenses payable by us.

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 and the concurrent private placement, together with our existing cash, cash equivalents and short-term investments, as follows:

- approximately $50.0 million to fund the development of the bihormonal configuration of the iLet through regulatory submissions to the FDA for 510(k) clearance of the bihormonal configuration and for approval of the glucagon product;
- approximately $50.0 million to fund the development and manufacturing capability of the patch pump through regulatory submissions to the FDA for 510(k) clearance; and
- the remaining amounts for the expansion of our sales and manufacturing infrastructure, 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 and the concurrent private placement, 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 the first half of 2028. 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 and the concurrent private placement 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 the concurrent private placement, 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.

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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 an aggregate of 6,662,861 shares of our common stock immediately prior to the closing of this offering, (ii) the conversion of shares of our convertible preferred stock outstanding as of September 30, 2024 into an aggregate of 15,474,610 shares of our common stock immediately prior to the closing of this offering and the related reclassification of the carrying value of our convertible preferred stock to permanent equity immediately prior to the closing of this offering, (iii) the automatic net exercise of all Class B common stock warrants outstanding as of September 30, 2024 into an aggregate of 2,672,422 shares of our common stock immediately prior to the closing of this offering, (iv) the automatic net exercise and subsequent conversion of all Series C convertible preferred stock warrants outstanding as of September 30, 2024 into an aggregate of 697,055 shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity immediately prior to the closing of this offering, (v) the issuance and sale of our Series E convertible preferred stock in November 2024 for aggregate net proceeds of approximately $59.7 million and the subsequent conversion into 4,352,393 shares of our common stock and the related reclassification of the carrying value of our Series E convertible preferred stock to permanent equity immediately prior to the closing of this offering and (vi) 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 12,000,000 shares of common stock in this offering and 1,000,000 shares of common stock in the concurrent private placement, each at the initial public offering price of $17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and the placement agent fees and estimated expenses payable by us, respectively.

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 and the concurrent private placement will be adjusted based on the actual initial public offering price and other terms of this offering and the concurrent private placement 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.

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	As of September 30, 2024		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash, cash equivalents and short-term investments	$ 60,897	$ 120,551	$ 319,781
Warrant liabilities	$ 38,876	$ —	$ —
Convertible preferred stock (Series A, A-2, B, B-2, C, D and E), $0.0001 par value; 39,059,408 shares authorized, 19,827,003 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	261,713	—	—
Stockholders' deficit:			
Common stock, $0.0001 par value; no shares authorized issued or outstanding, actual; 700,000,000 shares authorized, pro forma and pro forma as adjusted; 29,859,341 shares issued and outstanding, pro forma; 42,859,341 shares issued and outstanding, pro forma as adjusted	—	3	4
Class A common stock, $0.0001 par value; 5,790,000 shares authorized, 2,939,085 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	1	—	—
Class B common stock, $0.0001 par value; 70,000,000 shares authorized, 3,674,858 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Class C common stock, $0.0001 par value; 96,910 shares authorized, 48,918 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Additional paid-in capital	49,723	402,574	598,708
Accumulated other comprehensive income	58	58	58
Accumulated deficit	(278,629)	(271,239)	(271,239)
Total stockholders' deficit	(228,847)	131,396	327,531
Total capitalization	$ 71,742	$ 131,396	$ 327,531

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The information in the table above excludes:

- 5,658,801 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 $6.73 per share;
- 159,810 shares of our Class B common stock (all to employees, none of which were executive officers) issuable upon exercise of stock options granted under our 2016 Plan subsequent to September 30, 2024 and before January 28, 2025, with a weighted-average exercise price of $10.81 per share;
- 1,307,630 shares of our common stock (902,837 to executive officers and 404,793 to employees) issuable upon the exercise of stock options granted under the 2025 Plan, which became effective upon the execution and delivery of the underwriting agreement for this offering, with an exercise price that is equal to the initial public offering price in this offering;
- 12,016,744 shares of our common stock reserved for future issuance under our 2025 Plan, which became effective upon the execution and delivery of the underwriting agreement for this offering (which shares include 4,890,000 new shares plus the number of shares (not to exceed 7,126,744 shares) (i) that remain available for the issuance of awards under the 2016 Plan at the time the 2025 Plan became effective, and (ii) any shares underlying outstanding stock awards granted under the 2016 Plan that, on or after the 2025 Plan became effective, terminate or expire or are repurchased, forfeited, withheld or settled in cash, 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
- 410,000 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 became effective upon the execution and delivery of the underwriting agreement for this offering.

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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 and the concurrent private placement.

As of September 30, 2024, we had a historical net tangible book value (deficit) of approximately $(231.9) million, or $(34.81) per share of common stock based on 6,662,861 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 shares of our Class A common stock, Class B common stock and Class C common stock outstanding as of September 30, 2024 into an aggregate of 6,662,861 shares of our common stock, immediately prior to the closing of this offering, (ii) the automatic conversion of all shares of our convertible preferred stock outstanding as of September 30, 2024 into an aggregate of 15,474,610 shares of our common stock, (iii) the automatic net exercise of all Class B common stock warrants outstanding as of September 30, 2024 into an aggregate of 2,672,422 shares of our common stock immediately prior to the closing of this offering, (iv) the automatic net exercise and subsequent conversion of all Series C convertible preferred stock warrants outstanding as of September 30, 2024 into an aggregate of 697,055 shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity immediately prior to the closing of this offering (v) the issuance and sale of our Series E convertible preferred stock in November 2024 for aggregate net proceeds of approximately $59.7 million and the subsequent conversion into 4,352,393 shares of our common stock, and the related reclassification of the carrying value of our convertible preferred stock to permanent equity immediately prior to the closing of this offering, our pro forma net tangible book value as of September 30, 2024, would have been approximately $68.6 million, or approximately $2.30 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 concurrent private placement and the pro forma as adjusted net tangible book value per share of common stock immediately after closing of this offering and the concurrent private placement. After giving further effect to the sale of 12,000,000 shares of our common stock in this offering and 1,000,000 shares of common stock in the concurrent private placement that we are offering at the initial public offering price of $17.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses and the placement agent fees and estimated expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2024 would have been $267.9 million, or approximately $6.25 per share. This amount represents an immediate increase in pro forma net tangible book value of $37.11 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $10.75 per share to new investors participating in this offering and the concurrent private placement.

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

Initial public offering price per share		$17.00
Historical net tangible book deficit per share as of September 30, 2024	$(34.81)	
Pro forma increase in historical net tangible book value per share as of September 30, 2024	37.11	
Pro forma net tangible book value per share as of September 30, 2024, before this offering and concurrent private placement	2.30	
Increase in pro forma net tangible book value per share attributed to investors purchasing shares in this offering and in the concurrent private placement	3.95	
Pro forma as adjusted net tangible book value per share after this offering and concurrent private placement		6.25
Dilution per share to investors in this offering and in the concurrent private placement		$10.75

If the underwriters exercise their option to purchase up to 475,000 additional shares from us in full, our pro forma as adjusted net tangible book value per share after this offering and concurrent private placement would be $6.35 per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of $0.10 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of $10.65 to investors purchasing common stock in this offering and concurrent private placement, based on the initial public offering price of $17.00 per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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.

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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 and in the concurrent private placement, 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 and in the concurrent private placement. The calculation below is based on the initial public offering price of $17.00 per share, before deducting the estimated underwriting discounts and commissions and estimated offering expenses and the placement agent fees and estimated expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	29,859,341	70.0%	$356,553,910	62.0%	$ 11.94
New investors	13,000,000	30.0%	$221,000,000	38.0%	$ 17.00
Total	42,859,341	100.0%	$577,553,910	100.0%	

The table above assumes no exercise by the underwriters of their option to purchase additional shares of our common stock from us and the selling stockholders in this offering.

If the underwriters' option to purchase additional shares from us and the selling stockholders is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 28,534,341, or approximately 66% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by investors participating in the offering would be increased to 14,800,000, or approximately 34% of the total number of shares of our common stock outstanding after this offering.

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:

- 5,658,801 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 $6.73 per share;
- 159,810 shares of our Class B common stock (all to employees, none of which were executive officers) issuable upon exercise of stock options granted under our 2016 Plan subsequent to September 30, 2024 and before January 28, 2025, with a weighted-average exercise price of $10.81 per share;
- 1,307,630 shares of our common stock (902,837 to executive officers and 404,793 to employees) issuable upon the exercise of stock options granted under the 2025 Plan, which became effective upon the execution and delivery of the underwriting agreement for this offering, with an exercise price that is equal to the initial public offering price in this offering;
- 12,016,744 shares of our common stock reserved for future issuance under our 2025 Plan, which became effective upon the execution and delivery of the underwriting agreement for this offering (which shares include 4,890,000 new shares plus the number of shares (not to exceed 7,126,744 shares) (i) that remain available for the issuance of awards under the 2016 Plan at the time the 2025 Plan became effective and (ii) any shares underlying outstanding stock awards granted under the 2016 Plan that, on or after the 2025 Plan became effective, terminate or expire or

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are repurchased, forfeited, withheld, or settled in cash, 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

- 410,000 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 became 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.

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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, 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 everchanging 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. The adaptive closed-loop algorithms are designed to remove the need to manually adjust insulin pump therapy settings and variables required by conventional pump therapy and hybrid closed-loop systems, which both require the user to determine the size and timing of both meal and correction insulin doses and to adjust basal insulin dosing. Therefore, we believe the adaptive closed-loop algorithms can make the iLet easier to initiate and use on a daily basis than other available AID systems.

Our initial commercialization efforts for the iLet are in T1D, an indication for which we received FDA clearance in patients six and older in May 2023, in the United States. 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. According to the CDC, 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

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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. We believe that approximately one-third of people with T1D in the United States utilize insulin pumps or hybrid closed-loop systems to receive their daily insulin, while the majority receive their daily insulin via MDI, which is less complex, but often less effective, and has been shown to be associated with higher HbA1c levels. This is based on our internal estimates factoring epidemiologic data from government and leading industry organizations such as the CDC (to establish the overall size of the T1D population) and industry sales data from public filings and disclosures made by the leading device manufacturers (Medtronic, Tandem and Insulet, who collectively hold approximately 96% market share) and aggregated by third-party data service providers (to provide independent estimates of both overall device penetration of various diabetes populations). Our initial commercial results suggest that the iLet's value proposition is resonating strongly within the MDI population as approximately 51% and 67% of the iLet's adoption through December 31, 2023 and September 30, 2024, respectively, came from PWD who were previously utilizing MDI.

We have also partnered with Dexcom and Abbott—global leaders in popular and easy to use iCGM technology—to integrate the iLet with the Dexcom G6 and G7 iCGMs and with Abbott's FreeStyle Libre 3 Plus CGM sensor. A iCGM is a wearable device that works by inserting a small sensor under the skin into fatty tissue and tracks blood sugar levels in real time. The sensor measures glucose levels in the interstitial fluid and sends the information to a receiver, smartphone or insulin pump. The user can view their glucose levels, trends and to what degree their levels are rising or falling. The iCGM is a crucial component of AID systems, and by partnering with these leading global iCGM platforms, we believe we leverage all of the benefits that these CGMs offer in an elegant solution for PWD. Use of the iLet requires the independent purchase of a compatible third-party iCGM to provide real-time data to the iLet user.

The iLet requires the use of single-use products, which we sell separately to our customers. These single -use products include cartridges for storing and delivering insulin, as well as infusion sets that connect the insulin pump to a user's body. The user fills the cartridge with insulin and inserts it into the iLet. The iLet then administers the insulin from the cartridge to the user's body through a single-use infusion set. These single-use products are generally recommended to be disposed of entirely every 2-3 days, or as directed by a healthcare provider. 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. While the iLet can be prescribed by any HCP (PCP or subspecialists), 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 in the United States. Over time, we plan to expand into the more diffuse population of patients with T1D who are treated by PCP. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. 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 (such as adjustments at quarterly visits) those systems place on clinical practices in follow-on care.

A key element of our commercialization strategy is educating users and potential users on the use of the iLet. We provide this education primarily through healthcare providers, online resources, and our customer care

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team. We offer all users with an initial training to provide an overview of the functionalities of our product either through our own clinical diabetes specialists or by contracting with healthcare providers that provide this training directly to the user. These users also receive a reference guide with their initial shipment in addition to access to our customer care team for immediate assistance. Our website also offers numerous resource guides, including frequently asked questions (FAQs), to help all users understand the functionalities and operation of the iLet, available to both current and potential users.

As part of these efforts to educate this community within the United States, we are optimizing our direct sales efforts by growing a community support team called 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. The Bionic Universe aims to create a people-focused community dedicated to making diabetes management easier for everyone. This community is designed to facilitate the sharing of experiences and to help members learn more about the iLet. We employ both direct media and social media communication strategies to build the Bionic Universe and leverage feedback from this community to continuously improve both current and future device generations.

Our primary customers are 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.

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 represented 6% of net sales. For the nine months ended September 30, 2023 and 2024, PBP channel sales represented 9% of net sales in each period.

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 over time 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 over time 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.

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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 in the early stages of 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 in the early stages of 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, February 2022 and November 2024 (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 regulatory milestones relating to our marketing applications to the FDA 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 1,160 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

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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.

In consideration for the licensed patent rights and other rights granted to us under the Control Algorithm Agreement, we issued 1,140 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, (ii) 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

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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 a one-time milestone payment of $3.0 million for the achievement of certain development milestones, both of which are recognized as research and development expense when incurred. 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 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 non-exclusive, 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 non-exclusive, limited license to use the specifications and communication protocol integrating our system with DexCom’s G6 and G7 iCGM devices and (b) a non-exclusive, 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.

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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 non-exclusive, 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 non-exclusive, limited license to use Abbott's trademarks for the sole purposes of developing and marketing the Libre-Beta System.

We granted Abbott a non-exclusive, 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 non-exclusive, limited license to use our trademarks for the sole purposes of developing the Libre-Beta System and marketing the continuous glucose monitoring system for use with the Libre-Beta System.

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 the more diffuse population of people with T1D who are treated by PCP 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.

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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 over time 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 over time 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 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 represented 7% of net sales. For the nine months ended September 30, 2023 and 2024, PBP channel sales represented 9% of net sales in each period. 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,

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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 Challenges 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 (components of the iLet), 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.

We currently rely on a number of suppliers who manufacture the components of the iLet and obtain them on a purchase order basis. We have a supply agreement with Unomedical for the production of infusion sets for our iLet, a contract manufacturing agreement with PMC for the manufacture of our cartridge connectors and a supplier quality agreement with 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. For additional information regarding the risks of our reliance on these suppliers, please see the section titled “Risk Factors—Risks Related to Manufacturing and Our Reliance on Third Parties”.

To date, we have been able to successfully mitigate the challenges described above and ensure uninterrupted supply to our customers. However, there may be times at 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.

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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, all of which differ by product and sales mix. 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, 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 products 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. 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. We do not track research and development expenses by individual product candidate.

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

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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.

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 anticipate a significant increase in sales and marketing expenses for the foreseeable future to support the continued commercialization of the iLet.

Our sales and marketing expenses primarily consist of personnel-related costs, including salaries, sales incentive compensation, stock-based compensation expense and benefits for our sales representatives, field clinical specialists, and other sales and marketing personnel. We additionally incur expenses related to 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. Other expenses include 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 primarily consist of personnel-related costs, including 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 roles. We additionally incur expenses related to patent filings, legal fees for patent and corporate matters, as well as other professional fees for accounting, auditing, consulting and tax services. Other expenses include insurance, travel, facilities, depreciation and other expenses not otherwise included in research and development or sales and marketing expenses. We anticipate a significant increase in general and administrative expenses for the foreseeable future due to additional costs associated with operating as a public company. These include increased expenses for professional services, director and officer insurance, investor and public relations and compliance with SEC rules and regulations and exchange listing standards.

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.

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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. 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(1)	—	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	$ (64,751)	$ (44,099)	$ 20,652	*

* Not meaningful
(1) Includes stock-based compensation expense as follows:

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	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

Net Sales

The increase in net sales is attributable to the commercialization of the iLet, which received FDA clearance 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 sales of the iLet and single-use products, which represented 89% and 11% of net sales, respectively. For the year ended December 31, 2023, a majority of our sales to customers were derived through the DME reimbursement channel, which represented approximately 94% of net sales.

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 clearance 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 cleared 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 $12.3 million reduction in research and development expenses was primarily due to the significant costs incurred in 2022, the year before FDA clearance and commercialization, such as pre-clinical and clinical trial costs, licensing fees, and manufacturing expenses. After FDA clearance in May 2023, capitalizable manufacturing costs are now included as part of the cost of inventory. The remaining $1.2 million decrease was attributable to a decrease in payroll and payroll-related expenses

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associated with a reduction in headcount. This was part of management's strategic initiatives to consolidate roles and optimize operations in transitioning from a research-focused company to a product-focused company, with a focus on commercializing the iLet.

The table below summarizes the nature of research and development expense by major expense category:

	Year Ended December 31,		Change	
	2022	2023	$	%
	(in thousands, except percentages)			
External research and development[1]	$ 5,392	$ 2,401	$ (2,991)	(55)%
Internal research and development[2]	24,332	13,699	(10,633)	(44)%
Stock-based compensation	1,554	1,781	227	15%
Other[3]	150	62	(88)	(59)%
Total research and development expense	$ 31,428	$ 17,943	$(13,485)	(43)%

(1) External research and development costs primarily includes expenses incurred with third-parties such as clinical research organizations conducting the clinical trials and engineering and product development consulting services associated with our development of the iLet.

(2) Internal research and development costs primarily includes personnel-related expenses for research and development functions, excluding stock-based compensation, internal costs to manufacture product candidates before FDA marketing authorization, such as raw materials and internal facilities-related expenses.

(3) Other primarily includes licensing fees.

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. This 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. This decrease of $13.6 million was attributable 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. This decrease of $9.3 million was primarily attributable to a $11.0 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.

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Comparison of the Nine Months Ended September 30, 2023, and 2024

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

	Nine Months Ended September 30,		Change	
	2023	2024	$	%
		(unaudited) (in thousands, except percentages)		
Net sales	$ 3,645	$ 44,684	$ 41,039	100%
Cost of sales[1]	2,399	20,485	18,086	100%
Gross profit	1,246	24,199	22,953	100%
Operating expenses:				
Research and development[1]	13,483	16,970	3,487	26%
Sales and marketing[1]	6,372	26,282	19,910	100%
General and administrative[1]	8,874	13,161	4,287	48%
Total operating expenses	28,729	56,413	27,684	*
Loss from operations	(27,483)	(32,214)	(4,731)	*
Other income (expense), net:				
Interest income	526	2,958	2,432	*
Interest and other expense	(13)	(2)	11	*
Change in fair value of warrant liabilities	1,719	(7,390)	(9,109)	*
Total other income (expense), net	2,232	(4,434)	(6,666)	*
Net loss	$ (25,251)	$ (36,648)	$(11,397)	*

* Not meaningful

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

	Nine Months Ended September 30,	
	2023	2024
	(unaudited) (in thousands)	
Cost of sales	$ 149	$ 201
Research and development	1,411	844
Sales and marketing	362	1,150
General and administrative	2,160	2,638
Total stock-based compensation expense	$ 4,082	$ 4,833

Net Sales

Net sales for the nine months ended September 30, 2023 was $3.6 million, compared to $44.7 million for the nine months ended September 30, 2024. This $41.1 million increase in net sales was predominantly due to a shorter sales period following the FDA clearance and commercialization of the iLet in May 2023, as compared to the full nine months of commercial sales in 2024.

Approximately 77% of the $41.1 million increase can be attributed to the increase in adoption of the iLet by patients who previously used other commercial products, compared to the same period in the previous year. For the nine months ended September 30, 2024, single-use products sales accounted for 23% of net sales, up from 9% of net sales as of September 30, 2023.

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Our net sales for the nine months ended September 30, 2023, and 2024 were generated from customers within our DME and PBP channels, which represented 91% and 9% of net sales, respectively, in both periods.

Cost of Sales

Cost of sales was $2.4 million for the nine months ended September 30, 2023, compared to $20.5 million for the nine months ended September 30, 2024. This $18.1 million increase in cost of sales was due to the shorter sales period following the FDA clearance and commercialization of the iLet in May 2023, as compared to the full nine months of commercial sales in 2024. This increase in the cost of sales also includes a $0.9 million increase in our product warranty liability due to a higher installed customer base in 2024 as compared to 2023, in addition to a $1.5 million increase in royalties expenses from the Control Algorithm License Agreement with BU, which requires quarterly royalty payments to BU based on a percentage of net sales.

Gross Profit and Margin

Gross profit was $1.2 million for the nine months ended September 30, 2023, compared to $24.2 million for the nine months ended September 30, 2024. Gross margin was 34% for the nine months ended September 30, 2023, compared to 54% in the nine months ended September 30, 2024. The increases in both gross profit and gross margin percentage were driven by the influx of sales following the market launch of the iLet in May 2023 and adoption of the iLet by patients previously using other commercial products and new patients beginning intensive insulin therapy for treatment. Gross profit and gross margin for the nine months ended September 30, 2024 also benefited from controlled spending on fixed overhead and product mix, which included more supplies at a lower cost.

Research and Development Expenses

Research and development expenses were $13.5 million for the nine months ended September 30, 2023, compared to $17.0 million during the nine months ended September 30, 2024. This increase of $3.5 million was primarily attributable to an increase of $1.6 million in engineering and third-party consulting costs incurred from the development of our patch pump, bihormonal configuration of the iLet and incremental software and product updates. The remaining increase is attributable to a net increase of $1.3 million in payroll-related expenses driven by an increase in R&D personnel headcount and an increase of $0.6 million in facilities-related overhead.

The table below summarizes the nature of research and development expense by major expense category:

	Nine Months Ended September 30,		Change	
	2023	2024	$	%
	(unaudited) (in thousands, except percentages)			
External research and development[1]	$ 1,538	$ 3,077	$ 1,539	100%
Internal research and development[2]	10,371	12,549	2,178	21%
Stock-based compensation	1,411	844	(567)	(40)%
Other[3]	163	500	337	100%
Total research and development expense	$13,483	$16,970	$ 3,487	26%

(1) External research and development costs primarily include expenses incurred with third-parties, such as clinical research organizations conducting the clinical trials and engineering and product development consulting services associated with our development of the iLet.
(2) Internal research and development costs primarily include personnel-related expenses for research and development functions, excluding stock-based compensation and internal costs to manufacture product candidates before FDA marketing authorization, such as raw materials and internal facilities-related expenses.
(3) Other primarily includes licensing fees.

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Sales and Marketing Expenses

Sales and marketing expenses were $6.4 million for the nine months ended September 30, 2023, compared to $26.3 million for the nine months ended September 30, 2024. This increase of $19.9 million was primarily attributable to an increase of $15.7 million in payroll-related costs, including salaries and wages, sales incentive bonuses, and stock-based compensation, due to an increase in headcount of our sales force and customer care team in connection with the post-commercial launch of the iLet in the United States. The remaining increase includes $4.3 million in HCP-related marketing, training and entertainment costs and facilities-related expenses.

General and Administrative Expenses

General and administrative expenses were $8.9 million for the nine months ended September 30, 2023, compared to $13.2 million for the nine months ended September 30, 2024. This increase of $4.3 million was primarily attributable to an increase of $2.3 million in payroll-related expenses due to an increase in headcount of our quality assurance team to accommodate the growing demand for the iLet. The remaining increase is attributable to professional fees, including legal fees relating to patent and corporate matters and accounting services, of $0.7 million, software license fees of $0.8 million and other operating expenses of $0.5 million.

Other Income (Expense), Net

Total other income, net was $2.2 million for the nine months ended September 30, 2023, compared to total other expense, net of $4.4 million for the nine months ended September 30, 2024. This decrease of $6.6 million was attributable to a $9.1 million increase in expense from the change in fair value of our warrant liabilities due to changes in inputs associated with the Black-Scholes calculations used to determine the fair value of our warrant liabilities as of September 30, 2024. This was partially offset by a $2.4 million increase in interest income from our short-term investments.

Selected Quarterly Financial Information

The following table sets forth our selected unaudited quarterly consolidated statements of operations data for each of the seven quarters in the period ended September 30, 2024. The information for each of these quarters has been prepared in accordance with GAAP, on a basis consistent with our audited consolidated financial statements included elsewhere in this prospectus and include, in our opinion, all normal recurring adjustments necessary for the fair presentation of the results of operations for the periods presented. Our historical quarterly results are not necessarily indicative of the results that may be expected in the future and these quarterly results are not necessarily indicative of our operating results for a full year. The following quarterly financial information should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

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	Three Months Ended						
	Mar. 31, 2023	June 30, 2023	Sept. 30, 2023	Dec. 31, 2023	Mar. 31, 2024	June 30, 2024	Sept. 30, 2024
	(unaudited) (in thousands, except percentages)						
Net sales	$ —	$ 552	$ 3,093	$ 8,350	$ 12,933	$ 15,046	$ 16,705
Cost of sales[1]	—	531	1,868	3,288	5,732	6,962	7,791
Gross profit	—	21	1,225	5,062	7,201	8,084	8,914
Gross margin	—	3.8%	39.6%	60.6%	55.7%	53.7%	53.4%
Operating expenses:							
Research and development[1]	5,867	3,762	3,854	4,460	5,479	6,350	5,141
Sales and marketing[1]	942	2,103	3,327	5,618	7,663	8,974	9,645
General and administrative[1]	2,877	3,171	2,826	3,351	3,512	4,544	5,105
Total operating expenses	9,686	9,036	10,007	13,429	16,654	19,868	19,891
Loss from operations	(9,686)	(9,015)	(8,782)	(8,367)	(9,453)	(11,784)	(10,977)
Other income (expense), net:							
Interest income	65	68	393	1,251	1,139	993	826
Interest and other expense	—	(13)	—	(55)	4	(2)	(4)
Change in fair value of warrant liabilities	—	2,010	(291)	(11,677)	(4,139)	(3,670)	419
Total other income (expense), net	65	2,065	102	(10,481)	(2,996)	(2,679)	1,241
Net loss	$(9,621)	$(6,950)	$ (8,680)	$(18,848)	$(12,449)	$(14,463)	$ (9,736)

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

	Three Months Ended						
	Mar. 31, 2023	June 30, 2023	Sept. 30, 2023	Dec. 31, 2023	Mar. 31, 2024	June 30, 2024	Sept. 30, 2024
	(unaudited) (in thousands)						
Cost of sales	$ —	$ 73	$ 76	$ 90	$ 71	$ 61	$ 69
Research and development	557	554	300	370	263	287	294
Sales and marketing	70	117	175	248	288	390	472
General and administrative	588	857	715	868	735	762	1,141
Total stock-based compensation expense	$1,215	$1,601	$ 1,266	$1,576	$1,357	$1,500	$ 1,976

Selected Quarterly Trends

Net sales

Our quarterly net sales increased for all periods presented, primarily due to an increase in the number of patients adopting the iLet, resulting in an increase in installed customer base. The increase in installed customer base also contributes to an influx in net sales of single-use products that are disposed of and replaced every 2-3 days.

Cost of sales

Our quarterly cost of sales increased for all periods presented, primarily due to an increase in the number of patients adopting the iLet, resulting in a higher installed customer base and additional product

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warranty liability. The increase in net sales from the iLet also contributed to an increase in cost of sales from royalties expense, which are based on a percentage of net sales.

Operating expenses

Our quarterly research and development expenses increased in all periods presented, except the second quarter of 2023 and third quarter of 2024, primarily due to increases in engineering, third-party consulting costs and payroll-related expenses incurred to support our continued research and development efforts to enhance our existing product and develop new products.

Our sales and marketing expenses increased in all periods presented, primarily due to increases in payroll-related expenses driven by headcount increases in our sales force and customer care team, as well as other expenses incurred to market, educate and enhance the visibility of our product to HCPs.

Our general and administrative expenses increased in all periods presented, except the third quarter of 2023, primarily due to increases in payroll-related expenses driven by headcount increases in our quality assurance team, as well as expenses incurred for operational overhead expenses to meet the growing demand for the iLet.

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, 2023	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2024
New patient starts	2,304	486	8,910
New patient starts from MDI as a percentage of total new patient starts	51%	37%	67%
Installed customer base	2,304	486	11,214

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.

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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 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 facilitate 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 and gross margin, respectively, for the year ended December 31, 2023 and the nine months ended September 30, 2023 and 2024:

	Year Ended December 31, 2023	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2024
		(unaudited)	
	(in thousands, except percentages)		
Gross profit	$ 6,308	$ 1,246	$ 24,199
Gross margin (as a percentage of revenue)	52.6%	34.2%	54.2%
Add:			
Depreciation and amortization expense	390	225	574
Stock-based compensation expense	239	149	201
Adjusted gross profit	$ 6,937	$ 1,620	$ 24,974
Adjusted gross margin (as a percentage of revenue)	57.8%	44.4%	55.9%

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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.

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 and the nine months ended September 30, 2023 and 2024:

	Year Ended December 31,		Nine Months Ended September 30,	
	2022	2023	2023	2024
			(unaudited)	
	(in thousands)			
Net loss	$ (64,751)	$ (44,099)	$(25,251)	$(36,648)
Add:				
Depreciation and amortization expense	1,345	1,226	934	919
Stock-based compensation expense	6,100	5,658	4,082	4,833
Interest income	(196)	(1,777)	(526)	(2,958)
Provision for state taxes	14	13	13	2
Change in fair value of warrant liabilities	(911)	9,958	(1,719)	7,390
Adjusted EBITDA	$ (58,399)	$ (29,021)	$(22,467)	$(26,462)

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

	For the Three Months Ended			
	March 31, 2023	June 30, 2023	September 30, 2023	December 31, 2023
			(unaudited)	
			(in thousands)	
Net loss	$ (9,621)	$(6,950)	$ (8,680)	$ (18,848)
Add:				
Depreciation and amortization expense	325	311	298	292
Stock-based compensation expense	1,215	1,601	1,266	1,576
Interest income	(65)	(68)	(393)	(1,251)
Provision for state taxes	—	13	—	—
Change in fair value of warrant liabilities	—	(2,010)	291	11,677
Adjusted EBITDA	$ (8,146)	$(7,103)	$ (7,218)	$ (6,554)

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The following table presents a reconciliation of adjusted EBITDA from the most comparable GAAP measure, net loss, for each quarter of the nine months ended September 30, 2024:

	For the Three Months Ended		
	March 31, 2024	June 30, 2024	September 30, 2024
		(unaudited) (in thousands)	
Net loss	$(12,449)	$(14,463)	$ (9,736)
Add:			
Depreciation and amortization expense	287	299	333
Stock-based compensation expense	1,356	1,500	1,977
Interest income	(1,139)	(993)	(826)
Provision for state taxes	—	2	—
Change in fair value of warrant liabilities	4,139	3,670	(419)
Adjusted EBITDA	$ (7,806)	$ (9,985)	$ (8,671)

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.

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 $356.6 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 and approximately $59.7 million from the issuance and sale of our Series E convertible preferred stock in November 2024. 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 September 30, 2024, we had cash and cash equivalents and short-term investments of $60.9 million.

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Cash Flows

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

	Year Ended December 31,		Nine Months Ended September 30,	
	2022	2023	2023	2024
			(unaudited)	
		(in thousands)		
Net cash used in operating activities	$ (60,208)	$ (32,445)	$ (26,098)	$ (33,994)
Net cash (used in) provided by investing activities	(769)	(69,693)	(85)	26,186
Net cash provided by (used in) financing activities	56,782	101,029	101,020	(1,277)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (4,195)	$ (1,109)	$ 74,837	$ (9,085)

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 following the FDA clearance 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.

During the nine months ended September 30, 2023, net cash used in operations was $26.1 million, primarily resulting from our net loss of $25.3 million and net cash used by changes in our operating assets and liabilities of $4.7 million. This was partially offset by non-cash charges of $3.9 million, including $1.7 million from the change in fair value of our warrant liabilities, $4.1 million in stock-based compensation expense and $0.9 million in depreciation and amortization. Changes in our operating assets and liabilities for the nine months September 30, 2023 primarily relate to a $2.0 million increase in accounts receivable from the launch of commercial sales of the iLet in May 2023, a $1.1 million decrease attributable to the extinguishment of the funded research and development liability following the FDA clearance of the iLet in May 2023, a $0.7 million decrease in accruals and other current liabilities on payments to vendors, and a $0.7 million decrease in operating lease liabilities.

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During the nine months ended September 30, 2024, net cash used in operating activities was $34.0 million, primarily resulting from our net loss of $36.6 million and net cash used by changes in our operating assets and liabilities of $8.9 million. This was partially offset by non-cash charges of $11.6 million, including $7.4 million attributable to the change in fair value of our warrant liabilities, $4.8 million in stock-based compensation expense and $0.9 million in depreciation and amortization. Changes in our operating assets and liabilities for the nine months September 30, 2024 are primarily attributable to a $3.1 million increase in accounts receivable and a $9.9 million increase in inventories from the growth in commercial sales. Additionally, there was a $1.7 million increase of prepaid expenses and other current asset attributable to additional raw materials and clinical supply purchases and a $0.8 million decrease in operating lease liabilities. These were partially offset by a $1.6 million increase in accounts payable, a $1.7 million increase in deferred revenue and a $3.3 million increase in accrued expenses and other current liabilities from additional raw materials purchases, changes in our bonus accrual and the establishment of sales related accruals such as warranty, returns, chargebacks, and rebates, as a result of the growth in net sales since the commercialization of the iLet in May 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.

During the nine months ended September 30, 2023, net cash used in investing activities was $0.1 million, consisting of purchases of property and equipment.

During the nine months ended September 30, 2024, net cash provided by investing activities was $26.2 million, as a result of $56.0 million in proceeds from maturities and redemptions of short-term investments, partially offset by $27.0 million in purchases of short-term investments as well as $2.8 million in additional investment in property and equipment for 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.

During the nine months ended September 30, 2023, net cash provided by financing activities was $101.0 million, consisting primarily of net proceeds from the issuance of Series D convertible preferred stock.

During the nine months ended September 30, 2024, net cash used in financing activities was $1.3 million, consisting primarily of payments of deferred offering costs associated with the IPO.

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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 and the concurrent private placement, 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 the first half of 2028. 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.

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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 a one-time, non-refundable milestone payment of $3.0 million for the achievement of certain developmental milestones. In connection with the arrangement with Xeris, during the nine months ended September 30, 2024, we ordered $0.9 million in clinical material, covering both material and labor costs, to be used in phase 2 clinical trials and have paid a deposit equal to 30% of the estimated clinical material costs, which is recognized in prepaid expenses and other current assets in the condensed balance sheets. 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.” We may continue to incur costs as we progress into Phase 2 and Phase 3 clinical trials.

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 September 30, 2024, we had cash, cash equivalents and short-term investments of $60.9 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.

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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

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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

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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.

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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

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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.

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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 nearly 5x, from 2,304 iLets as of December 31, 2023 to 11,214 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. According to the Centers for Disease Control and Prevention (CDC), 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 according to the CDC, of whom an estimated 1.8 million require daily intensive insulin therapy, based on public and industry data.

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

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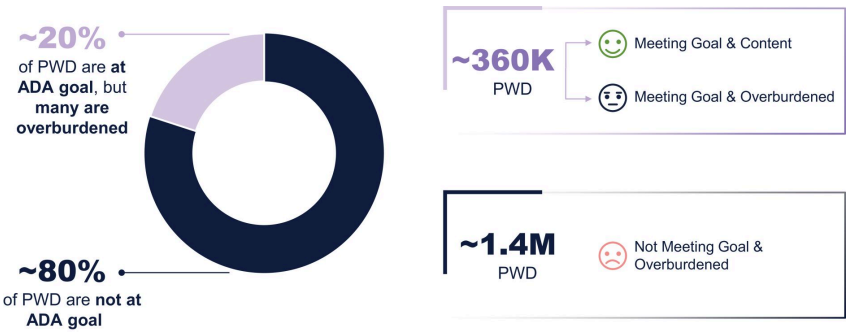
and unachievable by many. We believe that the iLet marks a significant breakthrough in the achievement of our ultimate goal, as it has been shown to enable clinically relevant improvements in glycemic control across broad populations of PWD, while dramatically reducing necessary user engagement.

Our initial commercialization efforts for the iLet are in T1D in the United States. 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, which is 7.0% or lower. 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). We believe that approximately one-third of people with T1D in the United States utilize insulin pumps or hybrid closed-loop systems to receive their daily insulin, 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 has been shown to be associated with higher HbA1c levels. This is based on our internal estimates factoring epidemiologic data from government and leading industry organizations such as the CDC (to establish the overall size of the T1D population) and industry sales data from public filings and disclosures made by the leading device manufacturers (Medtronic plc (Medtronic), Tandem Diabetes Care, Inc. (Tandem) and Insulet Corporation (Insulet), who collectively hold approximately 96% market share) and aggregated by third-party data service providers (to provide independent estimates of both overall device penetration of various diabetes populations). Despite many advances in pump therapy over the past several decades, pump penetration in people with T1D in the United States has remained stable for years.

Figure 1.~80% of Type 1 PWD in the United States Are 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

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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 adaptive closed-loop algorithms are designed to remove the need to manually adjust insulin pump therapy settings and variables required by conventional pump therapy and hybrid closed-loop systems, which both require the user to determine the size and timing of both meal and correction insulin doses and to adjust basal insulin dosing. Therefore, we believe the adaptive closed-loop algorithms can make the iLet easier to initiate and use on a daily basis than other available AID systems. 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.

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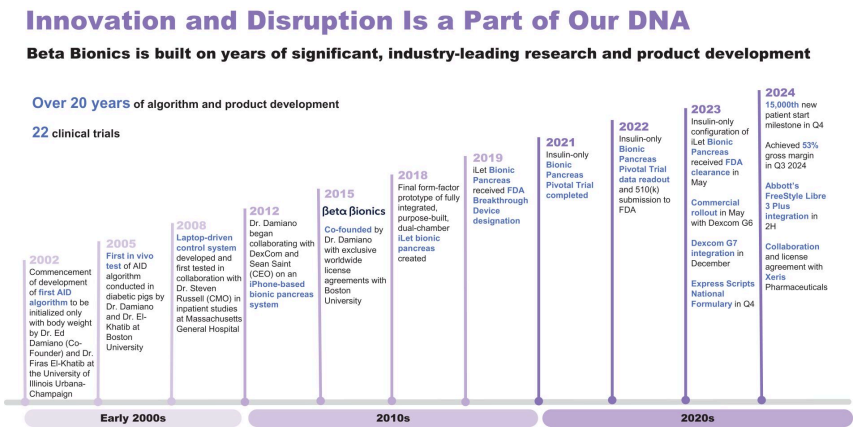
Figure 3. Select Historical Achievements



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 of 0.6%, 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 (as defined by a decrease in HbA1c of at least 0.5%) 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 7.0%, those on MDI, and those on insulin pump therapy without automation. For more information regarding the BPPT, please see subsection titled "—The iLet Bionic Pancreas Pivotal Trial testing the iLet in adults and children with T1D" below.

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 baseline HbA1c (as provided to us by the medical providers in the statements of medical necessity) of 8.5% to an average glucose management indicator (GMI)—a population-based estimate of HbA1c based on mean CGM glucose that is widely accepted as an indicator in the diabetes industry (and further explained below)—on the iLet of 7.3%. This demonstrated an improvement in HbA1c that was larger than that observed in the BPPT and is clinically meaningful (as defined by a decrease in HbA1c of at least 0.5%) in this patient population, which was much larger and had worse glucose control at baseline than those who participated in the BPPT. GMI is frequently used

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as a substitute for HbA1c in remote monitoring (iCGM) settings (which is what iLet users upload to the Beta Bionics cloud) given that HbA1c is typically measured in a laboratory setting.

The GMI and HbA1c are directly comparable measures of BG levels. The GMI was specifically designed by leaders in the field to be a CGM-derived measure of average BG levels that could be compared to the HbA1c, which requires a blood test. A means to enable this translatability has become increasingly necessary given the recent rise in CGM utilization as the principal means of measuring BG levels. The HbA1c correlates with a person's average historical BG level over a period of several months, whereas the GMI is derived from a mathematical formula that converts a person's average CGM value over at least two weeks into the HbA1c that would be expected based on that average. The HbA1c for any particular individual may be impacted by exogenous factors unrelated to the average BG, such as individual variability in both the red-blood-cell lifespan and/or the glycosylation propensity of the hemoglobin molecule within red blood cells. The GMI, on the other hand, may be impacted by how consistently a person uses the CGM. In practice, therefore, the correlation between the GMI and HbA1c values can differ from person to person, but the values are typically well-correlated in population studies as these inter-subject variations tend to cancel each other out in large populations.

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 iCGMs and with Abbott's FreeStyle Libre 3 Plus CGM sensor. A iCGM is a wearable device that works by inserting a small sensor under the skin into fatty tissue and tracks blood sugar levels in real time. The sensor measures glucose levels in the interstitial fluid and sends the information to a receiver, smartphone or insulin pump. The user can view their glucose levels, trends, and to what degree their levels are rising or falling. The iCGM is a crucial component of AID systems, and by partnering with these global leading iCGM platforms, we believe we leverage all of the benefits that these iCGMs offer in an elegant solution for PWD. Use of the iLet requires the independent purchase of a compatible third-party iCGM to provide realtime data to the iLet user.

While the iLet can be prescribed by any HCP (PCP or subspecialists), we are promoting sales of the iLet through an internal sales organization, where our initial direct sales efforts are focused on people with T1D who are treated within high-volume endocrinology practices in the United States. Over time, we plan to expand into the more diffuse population of people with T1D who are treated by primary care physicians (PCP). Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. These 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 (such as adjustments at quarterly visits) those systems place on clinical practices in follow-on care.

We are also optimizing our direct sales efforts by growing, in parallel, a community support team, a recent strategic marketing initiative and a targeted campaign we call the "Bionic Universe," which is built around a community of the iLet users, caregivers, and key opinion leaders (KOLs) who share their stories to inspire others. The Bionic Universe aims to create a people-focused community dedicated to making diabetes management easier for everyone. This community is designed to facilitate the sharing of experiences and to help members learn more about

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the iLet. We employ both direct media and social media communication strategies to build the Bionic Universe and leverage feedback from this community to continuously improve both current and future device generations.

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 in the early stages of 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 in the early stages of 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. We believe our planned expansion for the iLet's use in T2D will require an additional 510(k) clearance. We expect that we will need to conduct studies to determine the iLet's applicability for T2D in order to obtain the additional 510(k) clearance. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. 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. This is based on our internal estimates factoring epidemiologic data from government and leading industry organizations such as the CDC, as well as industry sales data from public filings and disclosures made by the

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leading device manufacturers (Medtronic, Tandem and Insulet) and aggregated by third-party data service providers. 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 5x—from $3.1 million for the quarter ended September 30, 2023 to $16.7 million for the quarter ended September 30, 2024—while our operating expenses have grown only 2x during the same time period—from $10.0 million to $19.9 million, respectively. Approximately 67% 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 $44.7 million, more than 3.5x 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 $36.6 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

Through our clinical trials, the BPPT and our analysis of post-approval data, we have developed a significant body of clinical data from more than 3,000 patients, which we believe supports 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 (as defined by the FDA as a decrease of at least 0.5%) 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 7.0%, 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.

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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). For more information regarding the BPPT, please see subsection titled "—The iLet Bionic Pancreas Pivotal Trial testing the iLet in adults and children with T1D" below.

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 in the early stages of 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 in the early stages of 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 December 13, 2024, we own or have rights in 61 issued U.S. patents, 21 pending U.S. nonprovisional patent applications, 6 pending U.S. provisional patent applications, 100 issued foreign patents (including 9 issued European patents and their national validations), and 48 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. This includes 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 54% 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, 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.

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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. While the iLet can be prescribed by any HCP (PCP or subspecialists), we are promoting sales of the iLet through an internal sales organization, where the initial direct sales efforts are focused on people with T1D who are treated within high-volume endocrinology practices in the United States. Over time, we plan to expand into the more diffuse population of people with T1D who are treated by PCP. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. 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 (such as adjustments at quarterly visits) 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 the iLet users, caregivers, and KOLs who share their stories to inspire others. The Bionic Universe aims to create a people-focused community dedicated to making diabetes management easier for everyone. This community is designed to facilitate the sharing of experiences and to help members learn more about the iLet. 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

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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. We believe our planned expansion for the iLet's use in T2D will require an additional 510(k) clearance. We expect that we will need to conduct studies to determine the iLet's applicability for T2D and in order to obtain the additional 510(k) clearance. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. 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. This is based on our internal estimates factoring epidemiologic data from government and leading industry organizations such as the CDC, as well as industry sales data from public filings and disclosures made by the leading device manufacturers (Medtronic, Tandem and Insulet, who collectively hold approximately 96% market share) and aggregated by third-party data service providers. We designed the iLet to serve both the T1D and T2D populations, and we believe that the T2D total addressable market for insulin pumps in the United States is estimated to be approximately $6 billion.

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

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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. Based on data from long-term population studies, including an analysis of epidemiological data from the Scottish Care Information–Diabetes Collaboration (SCI-DC) public database published in the Journal of the American Medical Association (JAMA), 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 ADA.

According to the 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, based on public and industry data.

- 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 5% of the overall T2D population require intensive insulin therapy, based on public and industry data.

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 approximately in line with the expected overall U.S. population growth rate of about 2% per year, 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 7.0% 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 (based on our internal estimates and publicly available industry data, including sales data publicly disclosed by the leading device manufacturers). 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.

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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 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

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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, we believe approximately two-thirds of the population utilize MDI, based on public and industry data. 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 the introduction of CGMs, based on public and industry data, we believe that 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.

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- ***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.

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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. The iLet is not compatible with third-party infusion sets or insulin cartridges.

- 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.

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- A wirelessly rechargeable battery, which must be recharged every 5-7 days, similar to the battery life of other competitive pump products, 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, using the user's glucose levels from the CGM and the user's qualitative meal announcements, 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 based on CGM data and autonomously adapts to the user's changing insulin needs. The Basal Algorithm is initialized only with the user's body weight. From this value, it then computes a nominal basal insulin infusion rate that is a fixed proportion of the body weight. The actual basal insulin dose that is to be infused at each five-minute interval — referred to as the instantaneous basal dose — is computed using a PD control strategy that utilizes the current and past CGM values and the value of the nominal basal infusion rate at that instant. Over time, the nominal basal infusion rate will adapt upward or downward over those parts of the day and night where the instantaneous basal rate runs higher or lower, respectively, than the current nominal basal infusion rate. This adaptation of the nominal basal infusion rate will lead to a variable nominal basal infusion rate throughout the day and night. The instantaneous basal doses will then be anchored around the current nominal basal infusion rate at every five-minute time step (288 segments each day) and not on the initial fixed nominal basal rate that was determined based only on the user's body weight. This adaptive capability of our Basal Algorithm obviates the need for the user to ever have to set, or even know, their basal-rate profile.

Corrections Algorithm

Running in parallel with the Basal Algorithm, the model-predictive control (MPC) Corrections Algorithm uses CGM data to automatically modulate 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 formulation of the Corrections Algorithm by augmenting it with a mathematical formulation for estimating the current concentration of insulin in the blood and predicting future concentrations. Insulin pharmacokinetics is based on a two-compartment model of insulin absorption through the subcutaneous tissue and into blood. It assumes a bi-exponential time course of insulin absorption and clearance for each dose of insulin delivered every five minutes. The Corrections Algorithm uses the superposition of the time course of all past doses to determine the total amount of insulin pending in the subcutaneous tissue and blood as it makes its dose determination at each five-minute step. Our Corrections Algorithm, therefore, 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 Corrections 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 throughout the day and over the course of weeks, months and years. Our adaptive Corrections Algorithm, therefore, obviates the need for the user to ever have to set, or even know, their insulin correction factor (also known as insulin sensitivity factor).

Meal Announcement Algorithm

The Meal Announcement Algorithm automatically adapts insulin doses at mealtime without requiring the user to determine the specific quantity of carbohydrates eaten. Instead, the user makes a simple declaration that an upcoming meal will be within historical norms, "the usual for me," or "more" or "less" than usual. Our

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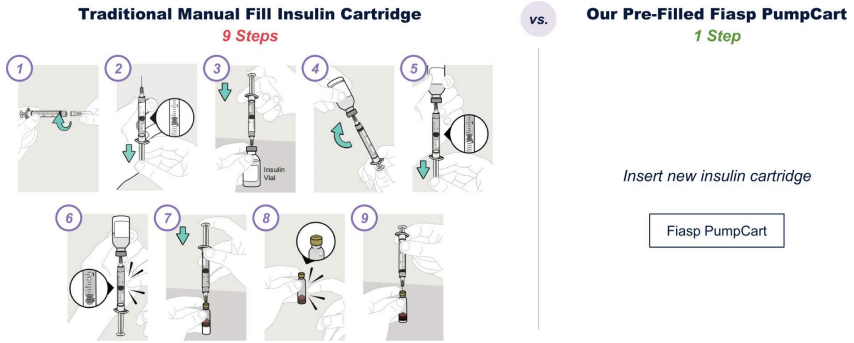
adaptive Meal Announcement Algorithm predicts the amount of insulin that is needed for the announced meal type and relative size based on the amount of insulin that was required in previously announced meals of that type and relative size. Any additional insulin needed is provided by the Corrections Algorithm based on CGM data and pending insulin previously dosed. If the user declares a meal as more than usual or less than usual at the time they announce the meal, the Meal Announcement Algorithm will then deliver a dose that is, respectively, 1.5 or 0.5 times the size of the dose that would be delivered for the "usual for me" meal announcement. If the meal has less than about a quarter of the amount of carbohydrates in a "usual for me" meal, the user should not announce the meal but rather let the Corrections Algorithm automatically provide all of the insulin needed to treat that meal in real time. If the meal has more than about 1.5 times the amount of carbohydrates in a "usual for me" meal, the user should announce multiple meals for that meal (e.g. a "usual for me" meal announcement plus a "less" than usual meal announcement, or two "usual for me" meal announcements, etc.). As the user makes meal announcements, the Meal Announcement Algorithm continually adapts the size of the insulin doses it delivers for meal announcements based on data from the most recent past meal announcements. This adaptive nature of the Meal Announcement Algorithm obviates the need for the user to ever have to set, or even know, their carbohydrate-to-insulin ratios.

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



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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

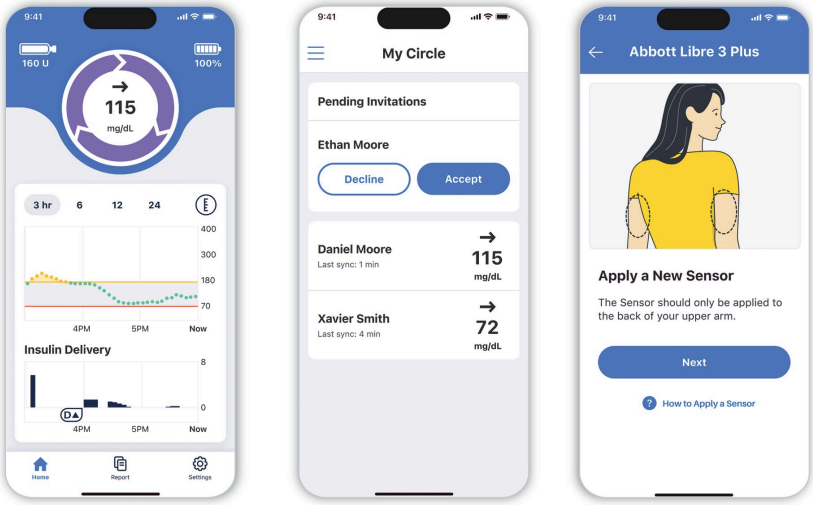
The iLet mobile application's features include:

- 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



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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% and 67% of the iLet's adoption through December 31, 2023 and September 30, 2024, respectively, 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	✓	×	×	×

We believe the commercial opportunity for the iLet in T1D is substantial. We estimate the T1D total addressable market for insulin pumps in the United States is approximately $6 billion, which is comprised of the approximately $2 billion total addressable market of existing pump users and the approximately $4 billion total addressable market of potential new pump adopters, as further described below. Total addressable market is the total overall revenue opportunity that we believe is available for insulin pumps if 100% market share is achieved, and it is not a representation that we will achieve such market share. The market share we achieve is subject to a number of assumptions, risks and uncertainties, including new pump adoption and conversion rates, which will fluctuate from time to time. For example, and as described below, since their introduction, CGMs have been adopted by an estimated 70% of people with T1D in the United States. For more information, please see the section titled "Risk Factors—Risks Related to our Business, Strategy and Industry—The market opportunities for our iLet for the treatment of diabetes may be smaller than we anticipated, limiting our ability to successfully sell our current and future products." In the coming decades, we believe this market will grow approximately in line with the expected overall population growth rate of about 2% per year. Our estimates of the T1D total addressable market for insulin pumps and related growth rate are based on independent industry publications and public industry data, as well as third-party forecasts derived from the same. There are two distinct subpopulations whose needs could be addressed by a product of the iLet's profile:

Existing Pump Users: Approximately one-third of the total T1D population, $2 billion total addressable market

Based on publicly available industry data, including sales data publicly disclosed by the leading device manufacturers (Medtronic, Tandem and Insulet, who collectively hold approximately 96% market share), we estimate that the current dollar value of the insulin pump market for people with T1D in the United States is approximately $2 billion and that the percentage of people with T1D who utilize a pump is approximately one-third of the overall population.

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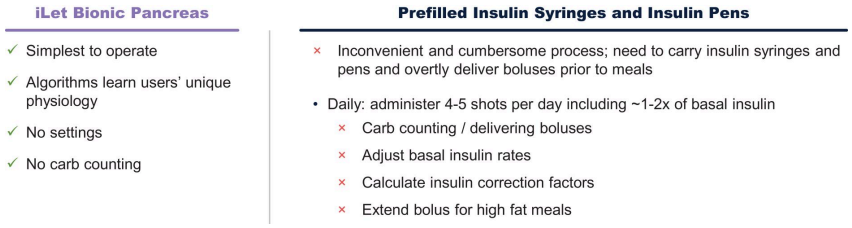
Potential New Pump Adopters: Approximately two-thirds of the total T1D population, $4 billion total addressable market

We believe approximately two-thirds of people with T1D in the United States do not currently utilize a pump for insulin treatments and instead use MDI from either a syringe or an insulin pen, based on public and industry data, including data publicly disclosed by the leading device manufacturers (Medtronic, Tandem and Insulet). 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. We believe this U.S. patient population would be valued at approximately $4 billion, assuming current users of MDI fully converted to pumps instead, and at current pump pricing levels.

Figure 8. A Comparison Between the iLet and MDI Therapy



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. Currently, our iLet is cleared only for the treatment of T1D in adults and children six years of age or older. 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. Although DexCom is our partner, DexCom G6 is not our product, and we cannot provide any assurance that a similar potential for the iLet will be reached.

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

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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 and in all 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) Science Translational Medicine, 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) Diabetes Care, 35:2148-2155*

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Year	Name of Study	System	Setting	Design			Evolution of Bionic Pancreas and Algorithm Innovations
				Cohort	Method	Duration / Participant	
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) Journal of Clinical Endocrinology & Metabolism, 99:1701-1711*
2013	*The Beacon Hill Study*	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 *Reference: Russell et al. (2014) New England Journal of Medicine, 371:313-325*
2013	*The 2013 Summer Camp Study*	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 *Reference: Russell et al. (2014) New England Journal of Medicine, 371:313-325*
2014	*The 2014 Summer Camp Study*	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 *Reference: Russell et al. (2016) The Lancet Diabetes and Endocrinology, 4:233-243*
2014-2015	*The Multi-Center Study*	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 *Reference: El-Khatib et al. 2017 The Lancet, 389:369-380*

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Year	Name of Study	System	Setting	Design			Evolution of Bionic Pancreas and Algorithm Innovations
				Cohort	Method	Duration / Participant	
2015-2016	*The Stanford Insulin-Only Study*	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 *Reference: Ekhlaspour et al. (2019) Journal Diabetes Science & Technology, 13:1001-1007*
2015-2016	*The MGH Set-Point Study*	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 *Reference: Balliro et al. (2017) 77th Scientific Sessions of the American Diabetes Association, 1062-P*
2017	*The MGH Monitoring Study*	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 *Reference: Sherwood et al. (2018) 78th Scientific Sessions of the American Diabetes Association, 299-OR*
2018	*The Insulin-Only Bridging Study*	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 *Reference: Jafri et al. (2019) 79th Scientific Sessions of the American Diabetes Association, 77-OR*
2018	*The Day-Camp Transitional Study*	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

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Year	Name of Study	System	Setting	Design			Evolution of Bionic Pancreas and Algorithm Innovations
				Cohort	Method	Duration / Participant	
							Reference: Ekhlaspour et al. (2019) 79th Scientific Sessions of the American Diabetes Association, 1063-P
2018	*The Fiasp Tmax Study*	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 *Russell et al. (2021) Diabetes Therapy, 12:2019-2033*

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.

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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 baseline adjusted group difference in glycated hemoglobin level at 13 weeks for iLet versus SC was –0.5 percentage points favoring the iLet, with a p-value of <0.001 (significance was defined as a p-value of <0.05). The baseline-adjusted difference in HbA1c between the iLet and standard of care were also least -0.5% favoring the iLet for important subgroups, including adults (-0.5%, P<0.001), children (-0.5%, P<0.001), those with starting HbA1c level >7% (-0.7%, P<0.001), and those using MDI at baseline (-0.8%, P<0.05), with all differences having p-values <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).

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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 Group (N=219)	SC Group (N=107)	iLet Group (N=219)	SC Group (N=107)	iLet minus SC [a] (95% CI)	P-value
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 <7.0%, 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.

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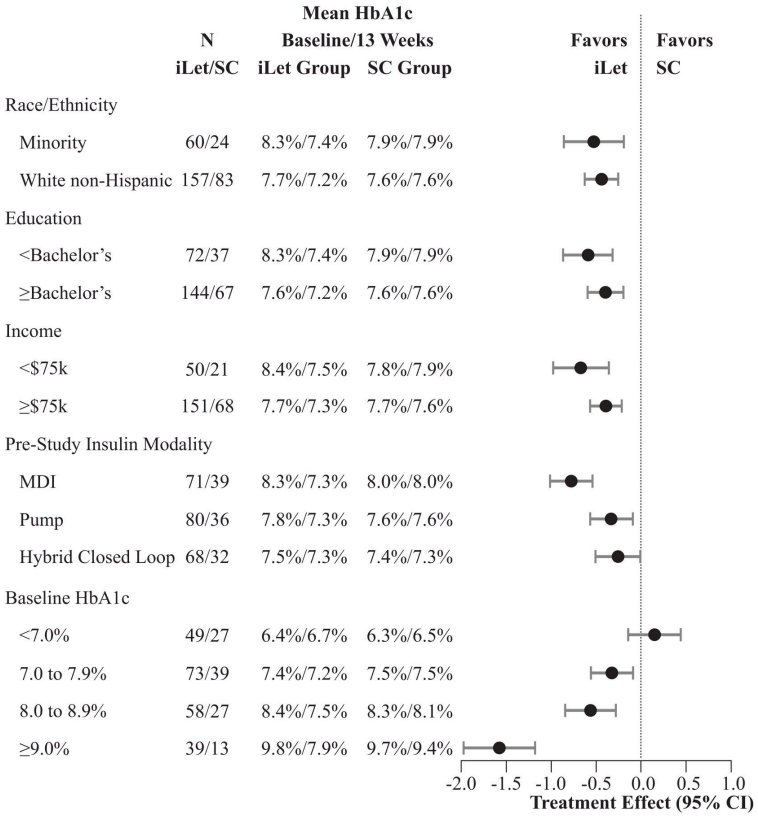
Figure 11. Glycated Hemoglobin Levels, in the Primary Analysis (All Ages, iLet-A/L vs. SC), According to Subgroups at Baseline



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.

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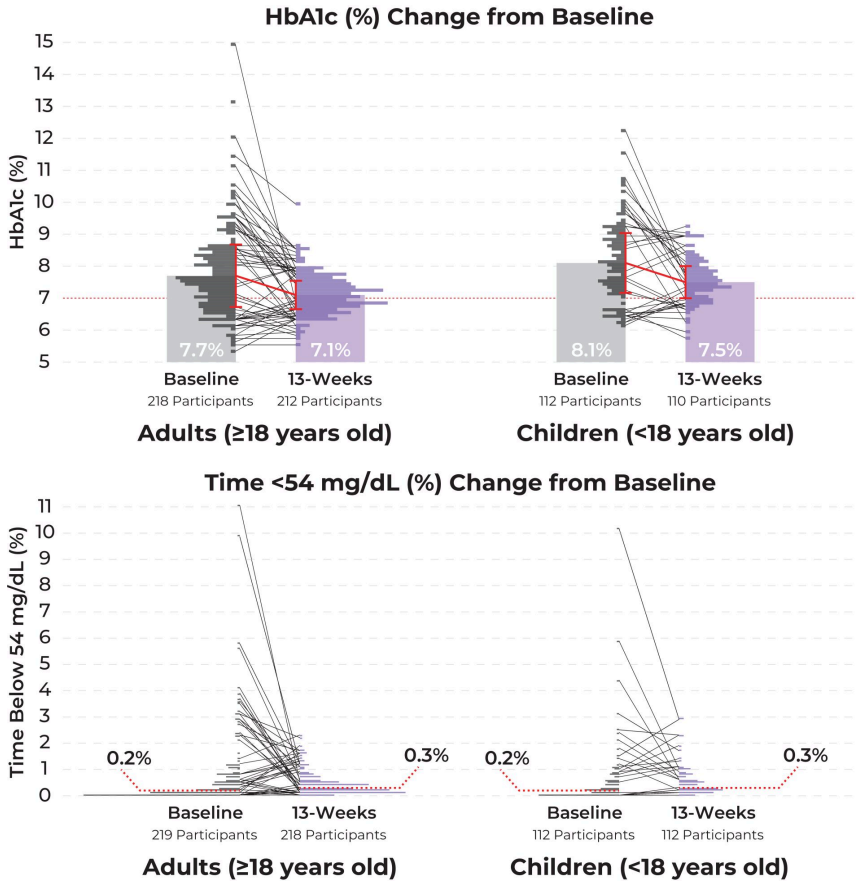
Secondary analyses were performed separately in adults randomized to the iLet with faster insulin aspart (Fiasp, iLet-F group). The mean adjusted group difference in glycated hemoglobin level at 13 weeks between the iLet-F and SC groups was –0.5 percentage points (P<0.001). There was no significant difference 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



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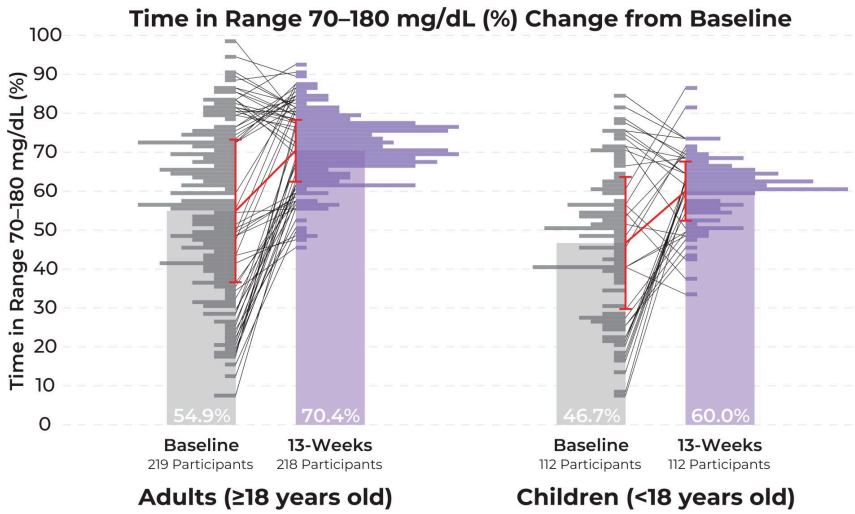

Glycated hemoglobin levels and time with glucose <54 mg/dL in the iLet groups for all participants (iLet-A/L, iLet-F, and SC) by age group at baseline. Baseline and 13-week values are connected by lines for the top and bottom 10% of values at either baseline or over 13 weeks.

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, 160 of which were related to a trial device (which included both the iLet and the infusion set). Of the 160 events in the iLet-A/L group that were related to the trial device, 130 were adjudicated by the medical monitor as due to infusion set failure. It is common for infusion sets to be accidentally pulled out or for the

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cannula, the thin plastic tube that delivers the insulin under the skin, to pull out or become kinked and prevent insulin delivery. The other 30 device-related problems with insulin delivery included that the subject failed to connect the cartridge or tubing properly, failed to replace the insulin cartridge in a timely fashion or did not fill it completely and ran out of insulin or failed to recharge the battery and the iLet lost power, among other similar issues. 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, socioeconomics, 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 BPPT[1–4] 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

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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 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).

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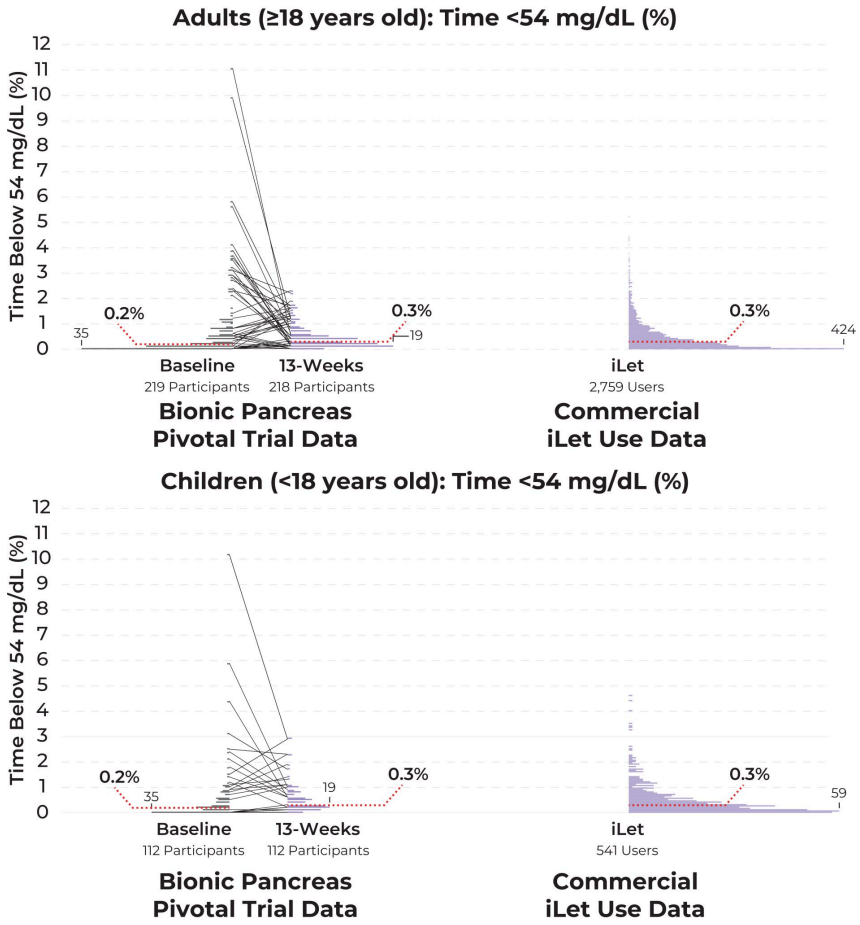
Figure 14. Percentage of Time Spent with CGM Glucose <54 mg/dL at Baseline and Over 13 Weeks on the iLet



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.

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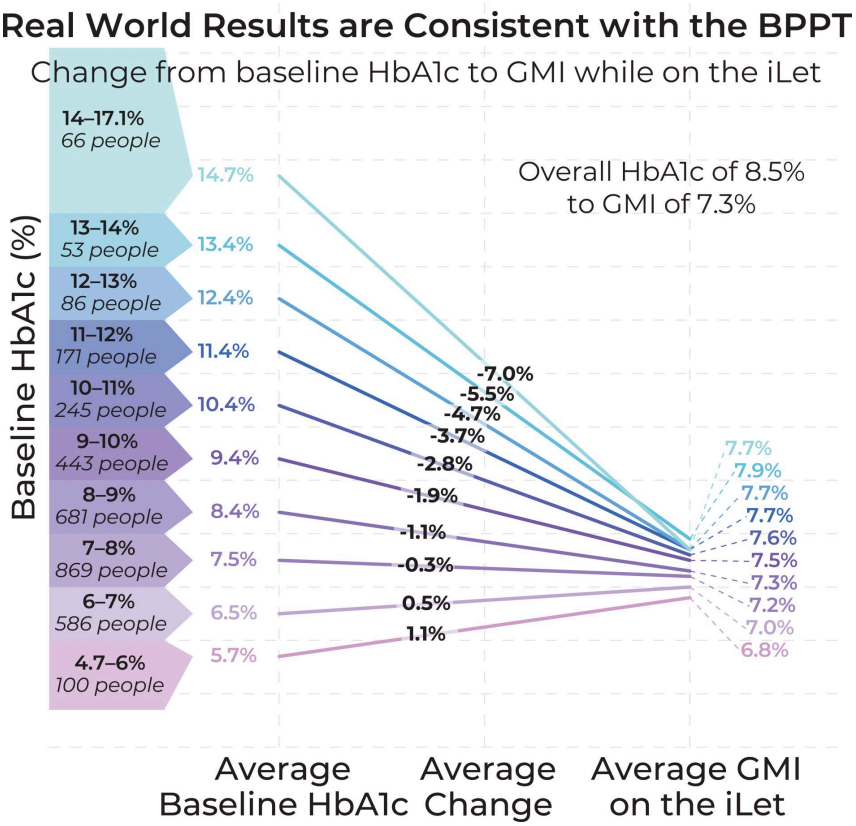
Figure 15. Real-World Results Are Consistent with the BPPT



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

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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 multiple other large population trials, each with thousands or tens-of-thousands of participants, as well as sponsor-initiated retrospective analyses, 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). These trials and analyses included: Miller et al. Diabetes Care 1 July 2013; 36 (7): 2009–2014; Dunn et al. Diabetes Research and Clinical Practice, Volume 137, 37 - 46; MacLeod et al. Diabetes Technology & Therapeutics 2024 26:1, 33-39; and Messer and Breton. Diabetes Technology & Therapeutics 2023 25:12, 877-882.

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 (%) *mean±SD*	R^2 < 0.01 *(7.0±0.3%)*	R^2 < 0.01 *(7.4±0.3%)*	R^2 < 0.01 *(7.2±0.4%)*	R^2 < 0.01 *(7.7±0.6%)*
Time <54 mg/dL (%) *median (IQR)*	R^2 < 0.01 *0.3% (0.1, 0.5)*	R^2 < 0.01 *0.3% (0.2, 0.6)*	R^2 < 0.01 *0.3% (0.1, 0.6)*	R^2 < 0.01 *0.3% (0.1, 0.6)*

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.

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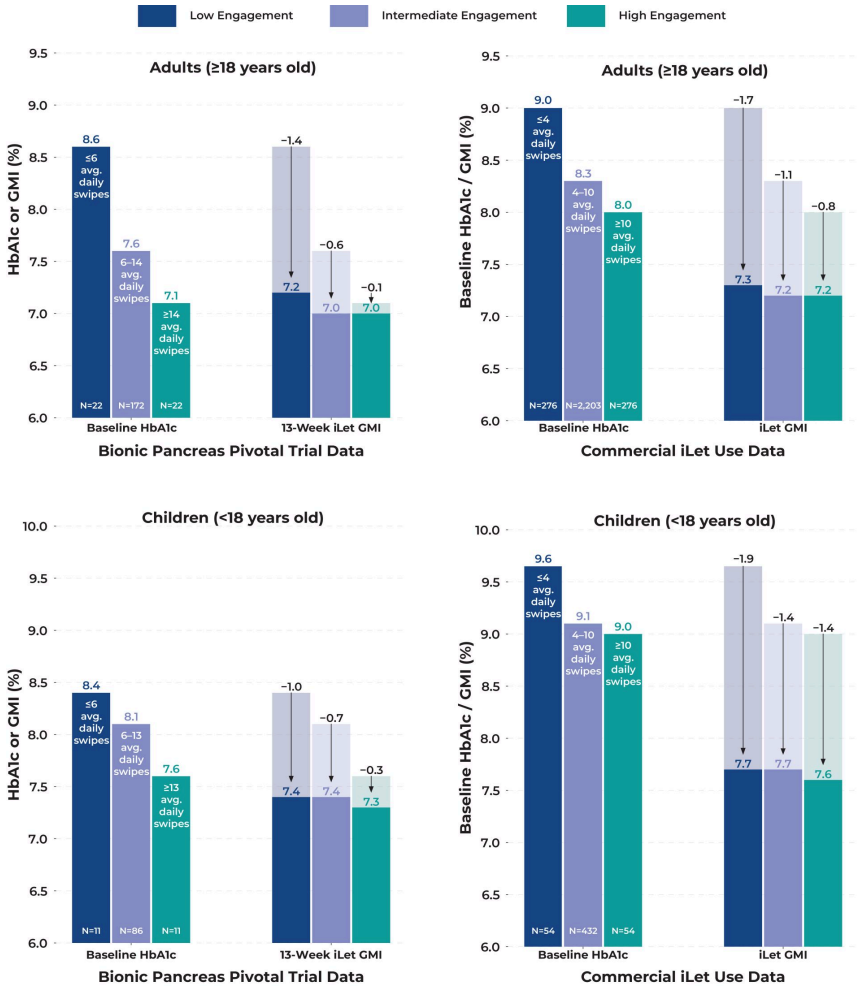
The bar chart in Figure 17 below also shows that, regardless of engagement level, adults and children in both the commercial and BPPT setting achieved similar GMI levels relative to disparate levels of baseline HbA1c.

Figure 17. Change from Baseline HbA1c to Mean GMI on the iLet



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.

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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 (such as adjustments at quarterly visits) 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.

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- **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.

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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

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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 in the early stages of 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. We are initially focused on T1D but plan to expand to T2D.

We have currently designed a prototype of the patch pump and, following product development, we plan to seek FDA 510(k) clearance for the patch pump in T1D and T2D. We believe patch pump will require 510(k) clearance as an alternate controller enabled pump (ACE pump) prior to commercialization and that clinical trials will not be required for an ACE pump 510(k) clearance. The iLet algorithm, which the patch pump will leverage, has already obtained a 510(k) clearance as an interoperable automated glycemic controller (iAGC). Subject to receiving 510(k) clearance for our patch pump, we expect to launch our patch pump commercially using our existing iLet iAGC algorithm by the end of 2027.

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. Analysis of hospital admission code data has shown that hypoglycemic episodes are responsible for over half of all emergency room visits by PWD each year, despite their relatively low frequency. According to the ADA and the National Institutes of Health, approximately 25-40% 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. Prior to conducting clinical trials with the new glucagon formulation, we plan to evaluate the compatability of glucagon for pumping, and whether its concentration in the body is consistent with our expectations. If these evaluations are successful, we plan to initiate at least one pre-pivotal clinical trial and a pivotal clinical trial before submitting the device and algorithm to the FDA for 510(k) clearance as well as submit an NDA seeking approval for the pump compatible glucagon for chronic use. Glucagon is currently only approved in an acute formulation for rescue from acute

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hypoglycemia, so approval of a new drug application will be required for this chronic use glucagon, in addition to FDA clearance for the algorithm and bihormonal configuration of the iLet device, in order for the bihoromonal system to be used as we intend.

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. We believe our planned expansion for the iLet's use in T2D will require an additional 510(k) clearance. We expect we will need to conduct studies to determine the iLet's applicability for T2D and in order to obtain the additional 510(k) clearance. Although we continue to analyze the timing related to this expansion, we do not currently have a specific timeline. 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. This is based on our internal estimates factoring epidemiologic data from government and leading industry organizations such as the CDC as well as industry sales data from public filings and disclosures made by the leading device manufacturers (Medtronic, Tandem and Insulet) and aggregated by third-party data service providers. 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 primarily compete with a number of companies that manufacture and sell insulin pumps, such as Medtronic, Tandem, and Insulet. The iLet has certain characteristics that other insulin pumps manufactured by such competitors, as far as we are aware, do not currently have, such as the ability to be initialized with only the user's body weight, being enabled by algorithms that determine 100% of the user's insulin doses, no carb counting, an option for pay-as-you-go pharmacy reimbursement and prefilled cartridges. For more information regarding the current commercial landscape for the iLet, see the section titled "Business—The Commercial Opportunity for the iLet Bionic Pancreas to Address the Unmet Need." Outside of the insulin pump market, 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 prefilled insulin syringes, insulin pens and 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.

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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 interfacing including disposables and wearables for connecting pumps to infusion sets. As of December 13, 2024, our owned and licensed patent estate contains approximately 61 issued U.S. patents, 21 pending U.S. nonprovisional patent applications, 100 issued foreign patents (including 9 issued European patents and their national validations), and 48 pending foreign patent applications. The 100 issued foreign patents include one or more issued patents in jurisdictions such as Australia, Canada, China, France, Germany, Great Britain, Hong Kong, Italy, Japan, Mexico and Spain. The 48 pending foreign patent applications include one or more pending applications in jurisdictions such as Australia, Canada, China, Europe, Israel, Japan, Mexico, 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 2042.

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As set forth in tabular form below, of the 61 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.	D1,032,624	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.

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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 December 13, 2024, our trademark portfolio consists of thirteen (13) registered trademarks and eight (8) pending trademark applications. For example, our trademark portfolio includes: 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, February 2022 and November 2024 (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

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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 regulatory milestones relating to our marketing applications to the FDA 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 1,160 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

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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.

In consideration for the licensed patent rights and other rights granted to us under the Control Algorithm Agreement, we issued 1,140 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, (ii) 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.

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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 non-exclusive, 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 non-exclusive, limited license to use the specifications and communication protocol integrating our system

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with DexCom's G6 and G7 iCGM devices and (b) a non-exclusive, 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 for three years from the date of First Commercial Launch of the Combined Platform, after which it renews for successive one-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 non-exclusive, 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 non-exclusive, limited license to use Abbott's trademarks for the sole purposes of developing and marketing the Libre-Beta System.

We granted Abbott a non-exclusive, 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 non-exclusive, limited license to use our trademarks for the sole purposes 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

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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

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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 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 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

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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.

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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;

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- 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.

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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.

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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

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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

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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

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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.

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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

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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

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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,

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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

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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, particularly in light of the change of administration. 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.

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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

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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, Washington's MHMD, the EU GDPR and the UK GDPR. 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 applies to personal information of consumers, business representatives, and employees who are California residents and 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 correct the individual's personal data, to delete the individual's personal data, to opt out of certain personal data disclosures, and to limit use of the individual's sensitive personal data in certain cases). Also, the CCPA provides for civil penalties and a private right of action for certain data breaches which may include an award of statutory damages.

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,

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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 June 2032, 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 December 31, 2024, we had 291 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.

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MANAGEMENT

The following table sets forth certain information for our executive officers and directors as of the date of this prospectus:

Name	Age	Position(s)
Executive Officers		
Sean Saint	49	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
Mark Hopman	47	Chief Commercial Officer
Edward Damiano, Ph.D.(4)	60	Executive Chairman
Non-Employee Directors		
Adam Lezack(2)(3)(5)	45	Chairperson
Sean Carney	55	Director
Dan Dearen(1)(3)	62	Director
Gilad Glick(4)	52	Director
Christy Jones(2)(3)	55	Director
Lennox Ketner(4)	47	Director
Maria Palasis, Ph.D.(1)(2)	60	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.
(4) Dr. Damiano, Mr. Glick and Ms. Ketner resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part (the Effective Date). In addition, Dr. Damiano retired as Executive Chairman and terminated his employment with us on the Effective Date (the Chairman Retirement).
(5) Effective immediately after the effectiveness of the Chairman Retirement, Mr. Lezack became the Chairperson of our board of directors.

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 from January 2021 to January 2025. 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.

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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 December 2017 and previously served as Assistant Professor of Medicine from April 2012 to November 2017. 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.

Mark Hopman has served as our Chief Commercial Officer since September 2024. Previously, Mr. Hopman served as our Senior Vice President, Market Access, from March 2023 to September 2024. Prior to that, Mr. Hopman served as Vice President, Market Access, at Pear Therapeutics, a prescription digital therapeutics company, from July 2021 to March 2023. Prior to Pear Therapeutics, Mr. Hopman worked at Dexcom, holding various roles of increasing responsibility, including Director, Retail Distribution from June 2014 to July 2016, Director, Trade from August 2016 to July 2017 and Senior Director, Trade from August 2017 to June 2021. Mr. Hopman received his B.S. in Pharmacy from The Ohio State University College of Pharmacy and M.B.A. from Xavier University Williams College of Business.

Edward Damiano, Ph.D. is our Co-Founder and served as our Executive Chairman from February 2022 to January 2025. Dr. Damiano was the President and CEO of Beta Bionics from its inception in October 2015 to February 2022. He has been a Research Professor of Biomedical Engineering at Boston University since July 2023 and previously 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

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Biomedical Engineering Department at the University of Virginia from 1994 to 1997. Dr. Damiano's experience working in the medical technology industry contributed to our board of directors' conclusion that he should serve as a director of our company. Dr. Damiano resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Non-Employee 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.

Dan Dearen has served as a member of our board of directors since October 2024. Mr. Dearen previously worked at Axonics, Inc., a medical device company, serving as Chief Operating Officer and Chief Financial Officer from October 2013 to August 2018 and as President and Chief Financial Officer from August 2018 to October 2023. Previously, he served as Chief Operating Officer and Chief Financial Officer of Vessix Vascular Inc. from July 2009 to November 2012, Chief Financial Officer of Miraval Holding from December 2004 to November 2008, and Chief Financial Officer of Q3DM, Fairbanks Systems Group, ESI Software, and Medication Delivery Devices from January 1995 to November 2004. Mr. Dearen also serves on the boards of several privately held companies, including JenaValve Technology, Inc., a developer and manufacturer of transcatheter aortic valve replacement systems, since January 2023. He previously served on the board of directors of Endotronix, Inc., a developer and manufacturer of digital health management solutions for patients suffering from heart failure, from March 2021 until its acquisition by Edwards Lifesciences in August 2024. Mr. Dearen received his B.B.A. in Accounting and Business from Southern Methodist University and his M.B.A. from Boston College. We believe that Mr. Dearen's extensive experience working in the medical device and pharmaceutical industries qualifies him to serve on our board of directors.

Gilad Glick served as a member of our board of directors from May 2022 to January 2025. Mr. Glick has served as the Vice President of Venture Investments (MedTech, JJDC) at Johnson & Johnson since July 2022. From 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. Mr. Glick's experience working in the medical technology industry contributed to our board of directors' conclusion that he should serve as a director of our company. Mr. Glick resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Christy Jones has served as a member of our board of directors since January 2025. Ms. Jones previously served on our board of directors from April 2021 to August 2023. Ms. Jones has served as Managing Director of Richmond Capital Partners, a private investment company focused on real estate, technology and growth company assets, since March 2017. Ms. Jones previously served on the board of directors of Optiva, Inc., a publicly held cloud-native revenue management software company, from March 2017 to July 2020. She has served on the board of directors of Extend Fertility LLC, a privately held company focused on the

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cryopreservation of women's eggs since April 2015. Ms. Jones received her B.A. in Economics from Stanford University and her M.B.A. from Harvard Business School. We believe that Ms. Jones's extensive entrepreneurial experience bringing new technologies to market qualifies her to serve on our board of directors.

Lennox Ketner served as a member of our board of directors from August 2023 to January 2025. 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. Ms. Ketner's extensive experience in life sciences investing contributed to our board of directors' conclusion that she should serve as a director of our company. Ms. Ketner resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Adam Lezack has served as a member of our board of directors since December 2023 and serves as Chairperson of our board of directors. 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.

Maria Palasis, Ph.D. has served as a member of our board of directors since January 2025. Dr. Palasis previously served on our board of directors from September 2022 to September 2023 and has served on our Advisory Board since September 2023. Dr. Palasis has served as the President and Chief Executive Officer of Lyra Therapeutics Inc., a publicly held biotechnology company focused on developing therapies for chronic rhinosinusitis, since December 2014, and as Executive Vice President and Chief Technology Officer from March 2011 to December 2014. Previously, she served as Executive Vice President from September 2008 to March 2011 of Arsenal Medical, Inc., a medical device company, and as President and Chief Executive Officer from December 2014 to June 2018 of both Arsenal Medical, Inc. and its spin out, 480 Biomedical, and in roles of increasing responsibility at Boston Scientific Corporation, a medical device company, from November 1995 to January 2008. She has served on the board of directors of PanTher Therapeutics, Inc., a privately held biotechnology company since September 2020 and of Lyra Therapeutics since January 2015. Previously, she also served on the board of directors of Arsenal Medical, Inc. from 2015 to 2018. Dr. Palasis received her B.S. and Ph.D. in Chemical Engineering from the University of Cincinnati. We believe that Dr. Palasis's extensive experience in developing medical devices and drug delivery systems qualifies her to serve on our board of directors.

Family Relationships and Other Arrangements

There are no family relationships among any of our executive officers or directors. Pursuant to our amended and restated voting agreement, which will terminate upon the closing of this offering, the following directors were designated as members of our board of directors:

- Mr. Saint, designated pursuant to his service as our Chief Executive Officer;
- Mr. Carney, designated by the holders of a majority of the outstanding shares of Series B Preferred Stock and Series B-2 Preferred Stock;

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- Ms. Jones, designated by Sands Capital Life Sciences Pulse Fund II, L.P. and its affiliates (collectively, Sands Capital);
- Mr. Dearen, designated by Omega Fund VII, L.P. and its affiliates;
- Dr. Palasis, designated by Eventide Gilead Fund and Eventide Healthcare & Life Sciences Fund and affiliates of the foregoing (collectively, Eventide); and
- Mr. Lezack, designated by mutual agreement of the other then-seated members of the board of 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 nine members with one vacancy. Dr. Damiano, Mr. Glick and Ms. Ketner resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. As a result, our board of directors consists of six members. The resignations from our board of directors and appointments to our board of directors were ordinary course transitions in connection with our public company preparedness. There were no disagreements between us and the resigning directors on any matter relating to our operations, policies or practices. 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 Sean Carney and Christy Jones whose terms will expire at our first annual meeting of stockholders to be held following this offering;
- Class II, which will consist of Sean Saint and Maria Palasis, Ph.D., whose terms will expire at our second annual meeting of stockholders to be held following this offering; and
- Class III, which will consist of Adam Lezack and Dan Dearen 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 Adam Lezack, 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 Chairperson has substantial ability to shape the work of the board of directors. We believe that separation of the positions of Chairperson 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

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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 Nasdaq, which we will post on our website, www.betabionics.com, upon the closing of this offering.

Audit Committee

Our audit committee will consist of Dan Dearen, Sean Carney and Maria Palasis, Ph.D. Dan Dearen 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 Nasdaq 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;

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- 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 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 Dan Dearen qualifies as an "audit committee financial expert" within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. 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 Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation Committee

Our compensation committee will consist of Adam Lezack, Christy Jones and Maria Palasis, Ph.D. Adam Lezack 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 Nasdaq 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;

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- 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;
- overseeing our overall compensation practices and objectives and assessing whether such practices establish appropriate incentives in light of our specific business objectives;
- 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.

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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 Nasdaq 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 will consist of Christy Jones, Dan Dearen and Adam Lezack. Christy Jones 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 Nasdaq 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 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;
- 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 Nasdaq 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.”

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Code of Business Conduct and Ethics

In connection with this offering, we have adopted 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

Under Rule 5605(a)(2) of the Nasdaq Listing Rules, independent directors must comprise a majority of our board of directors as a public company within one year of listing.

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 with the exception of Mr. Saint and Dr. Damiano, none of our directors have a relationship 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 Nasdaq Listing Rules. 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."

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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;
- Mark Hopman, our Chief Commercial Officer; and
- Stephen Feider, our Chief Financial Officer.

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 ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total ($)
Sean Saint *President and Chief Executive Officer*	2024	491,667	—	371,000	23,000	885,667
Mark Hopman *Chief Commercial Officer*	2024	365,659	432,899	170,874	23,000	992,432
Stephen Feider *Chief Financial Officer*	2024	358,333	—	278,250	23,000	659,583

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the stock options granted during 2024. These amounts have been computed in accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC) Topic 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Assumptions used in the calculation of these amounts are described in Note 2 to our financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that may be realized by our named executive officers upon vesting or exercise of the stock options or the sale of the common stock underlying such awards.

(2) The amounts disclosed represent performance bonuses earned in 2024. For additional information, please see the subsection titled "—Performance Bonus Opportunity."

(3) The amounts disclosed represent 401(k) matching contributions. For additional information, please see the subsection titled "—401(k) Plan."

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[1]	$500,000
Mark Hopman[2]	$370,800
Stephen Feider[3] .	$375,000

(1) Mr. Saint's annual base salary was effective as of March 1, 2024. Mr. Saint's annual base salary rate was $450,000 from January 1, 2024 until February 29, 2024.

(2) Mr. Hopman's annual base salary was effective as of September 10, 2024. Mr. Hopman's annual base salary rate was $367,500 from March 1, 2024 to September 9, 2024 and $350,000 from January 1, 2024 until February 29, 2024.

(3) Mr. Feider's annual base salary was effective as of March 1, 2024. Mr. Feider's annual base salary rate was $275,000 from January 1, 2024 until February 29, 2024.

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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. Our board of directors will also generally consider each named executive officer's individual contributions towards reaching our annual corporate goals.

For 2024, Mr. Saint's and Mr. Feider's target bonus was 50% of each's then-current base salary. From January 1, 2024 to September 9, 2024, Mr. Hopman's target bonus was 30% of his then-current base salary, and from September 10, 2024 to December 31, 2024, Mr. Hopman's target bonus was 50% of his then-current base salary. For 2024, the goals applicable to Mr. Saint, Mr. Feider and Mr. Hopman (prior to his appointment as the Company's Chief Commercial Officer) related to achievement of certain financial, corporate and clinical objectives and with respect to Mr. Hopman (following his appointment as the Company's Chief Commercial Officer), a Company revenue target. In January 2025, our board of directors evaluated our performance against the corporate goals applicable to our named executive officers and approved 2024 annual performance bonuses for each of our named executive officers, as reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above. Mr. Hopman's 2024 target bonus was prorated based on the part of the year that he served as our Senior Vice President of Market Access.

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.

Prior to this offering, we have granted stock options pursuant to our 2016 Plan to certain of our executives. Following this offering, we will grant equity awards under the terms of our 2025 Plan. The terms of our equity plans are described below under the subsection titled "—Equity Benefit Plans."

In January 2024 as a result of his contribution to achieving pharmacy reimbursement for the iLet in 2023, our board of directors granted an option under our 2016 Plan to purchase 17,765 shares to Mr. Hopman. The option has an exercise price of $8.52 per share, which was the fair market value per share of our Class B common stock on the date of grant, as determined by our Board, and vests in a series of 48 successive equal monthly installments after the vesting commencement date, subject to his continuous service with us as of each such vesting date.

In September 2024 and in connection with his promotion to Chief Commercial Officer, our board of directors granted an option under our 2016 Plan to purchase 39,424 shares to Mr. Hopman. The option has an exercise price of $10.74 per share, which was the fair market value per share of our Class B common stock on the date of grant, as determined by our Board, and vests in a series of 48 successive equal monthly installments after the vesting commencement date, subject to his continuous service with us as of each such vesting date.

In December 2024, our board of directors approved the following stock option grants to each of our named executive officers, which will be granted in 2025 under our 2025 Plan, contingent and effective upon execution of the underwriting agreement by and among us and the underwriters (Effective Time), subject to the continued service of our named executives through the Effective Time: 467,944 shares to Mr. Saint, 47,775 shares to Mr. Hopman and 186,203 shares to Mr. Feider. The stock options will have an exercise price per share that is equal to the initial public offering price in this offering, and shall vest starting at the Effective Time in a

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series of 48 successive equal monthly installments, subject to the executive's continuous service with us as of each such vesting date.

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.

			Option Awards[1]				
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Sean Saint	8/1/2022[4]	8/1/2022	453,774	295,671	—	$ 7.51[2]	7/31/2032
	8/1/2022[3]	8/1/2022	—	83,268	—	$ 7.51[2]	7/31/2032
	9/14/2023[3]	8/15/2022	—	54,911	—	$ 5.10	9/13/2033
	9/14/2023[4]	8/15/2022	294,488	199,710	—	$ 5.10	9/13/2033
Stephen Feider	8/1/2022[4]	8/1/2022	100,838	65,704	—	$ 7.51[2]	7/31/2032
	9/14/2023[5]	9/14/2023	35,688	74,006	—	$ 5.10	9/13/2033
Mark Hopman	7/27/2023[4]	3/20/2023	37,230	46,012	—	$ 5.10	7/26/2033
	9/14/2023[5]	9/14/2023	12,111	25,117	—	$ 5.10	9/13/2033
	1/1/2024[5]	1/1/2024	4,453	13,312	—	$ 8.51	12/31/2033
	9/30/2024[5]	9/10/2024	3,051	36,373	—	$ 10.74	9/29/2034

(1) All of the option awards were granted under the 2016 Plan, the terms of which plan is described below under "—Equity Benefit Plans—2016 Stock Incentive Plan."
(2) Reflects the option exercise price per share as of December 31, 2024. This option was amended in March 2023 to reduce the exercise price per share to $7.51.
(3) The shares subject to this option shall vest in 12 equal monthly installments measured four years after the vesting commencement date, subject to continuous service with the Company through each such vesting date.
(4) One-fourth of the shares subject to this option shall vest one year after the vesting commencement date, and thereafter 1/36th of the shares subject to this option shall vest on each monthly anniversary thereof, subject to continuous service with the Company through each such vesting date.
(5) The shares subject to this option shall vest in 48 equal monthly installments measured from the vesting commencement date, subject to continuous service with the Company through each such vesting date.

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 (Saint 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 (most recently increased to $500,000) and an annual performance bonus with an initial target percentage equal to 50% of his annual base salary based on the Company's achievement against its objectives, which target percentage may be increased to 62.5% at the discretion of our board of directors. Pursuant to his employment agreement, in August 2022 we granted two options to Mr. Saint, one to purchase 4.5% of our capital stock as of the Saint Start Date or 749,446 shares of Class B common stock, with an exercise price of $15.61 per share, which was repriced to $7.51 per share in March 2023, subject to a four-year vesting schedule, with 25% vesting on the first anniversary of the Saint Start Date and the balance vesting monthly over the remaining 36 months, subject to Mr. Saint's continued service

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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 as of the Saint Start Date or 83,268 shares of our Class B common stock, also with an exercise price of $15.61 per share, which was also repriced to $7.51 per share in March 2023, which vests in 12 equal monthly installments following the four-year anniversary of the Saint 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 Saint 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 Saint 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 549,109 shares of our Class B common stock at an exercise price per share of $5.10. 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.

Mark Hopman. We entered into an employment agreement with Mr. Hopman in March 2023 and effective March 20, 2023 (Hopman First Start Date) as the Company's Senior Vice President of Market Access (March 2023 Agreement). In September 2024 and effective September 10, 2024 (Hopman Second Start Date), Mr. Hopman was promoted to Chief Commercial Officer and we entered into a new employment agreement (September 2024 Agreement). Pursuant to his March 2023 Agreement, Mr. Hopman was entitled to an annual base salary of $350,000 and per his September 2024 Agreement, he is now entitled to an annual base salary of $370,800. Pursuant to his March 2023 Agreement, he was entitled to an annual performance bonus with a target percentage equal to 30% of his annual base salary based on the Company's achievement against its objectives and per his September 2024 Agreement, he is entitled to an annual performance bonus with a target percentage equal to 50% of his annual base salary based on the Company's achievement against its objectives, which bonus amount is capped at 100% of his salary. Pursuant to his March 2023 Agreement, in July 2023, we granted an option to Mr. Hopman to purchase 83,242 shares of Class B common stock, with an exercise price of $5.10 per share, subject to a four-year vesting schedule, with 25% vesting on the first anniversary of the Hopman First Start Date and the balance vesting monthly over the remaining 36 months, subject to Mr. Hopman's continued service with us. Pursuant to his September 2024 Agreement, in September 2024, we granted an option to Mr. Hopman to purchase 39,424 shares of Class B common stock, with an exercise price of $10.74 per share, subject to a four-year vesting schedule, vesting monthly over 48 months after the Hopman Second Start Date, subject to Mr. Hopman's continued service with us.

Stephen Feider. We entered into an employment agreement with Mr. Feider in July 2022 and effective August 1, 2022 (Feider Start Date), pursuant to which Mr. Feider was initially hired as a Senior Advisor and, effective August 15, 2022, as the Company's Chief Financial Officer. Pursuant to his July 2022 agreement, Mr. Feider is entitled to an annual base salary of $275,000 and an annual performance bonus with an initial target percentage equal to 50% of his annual base salary based on the Company's achievement against its objectives, which target percentage may be increased to 62.5% at the discretion of our board of directors. Pursuant to his employment agreement, in August 2022, we granted an option to Mr. Feider to purchase 1.0% of our capital stock or 166,542 shares of Class B common stock, with an exercise price of $15.61 per share, which was repriced to $7.51 per share in March 2023, subject to a four-year vesting schedule, with 25% vesting on the first anniversary of the Feider Start Date and the balance vesting monthly over the remaining 36 months, subject to Mr. Feider's continued service with us.

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Potential Payments Upon Termination or Change in 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 term of service, including unpaid salary and unused vacation. In addition, Mr. Saint and Mr. Feider are entitled to certain severance benefits under their respective employment agreements, subject to their 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" (as defined in Mr. Saint's employment agreement) 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 the Saint 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 the Saint 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.

Mr. Feider'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. Feider resigns for "good reason" (each, as defined in Mr. Feider'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.

For the purposes of Mr. Saint and Mr. Feider's employment agreements, "cause" for termination means (a) the executive'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 the executive by the board of directors or the Company, as applicable; (b) dishonesty to our board of directors or the Company, as applicable, with respect to any material matter; (c) misappropriation of funds or property of the Company; (d) misconduct by the executive, 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) the executive'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) the executive'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) the executive'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 the executive of the executive's employment agreement or any related agreements with the Company; or (j) the executive'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 or Company, as applicable, 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.

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For the purposes of Mr. Saint's and Mr. Feider's employment agreements, "good reason" means, subject to certain notice and cure rights, (a) any material diminution in the authority, duty or responsibilities of the executive; (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 the executive's employment agreement without his consent.

For the purposes of Mr. Saint's and Mr. Feider'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 and vision 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 100% of the amount deferred up to 6% of the participant's earnings. 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

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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.

Amended and Restated 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 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 14,317,816 shares of our Class B 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 Class B 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 Class B common stock available under the 2016 Plan. Any shares of Class B common stock that are forfeited or canceled, expire, are surrendered, or otherwise become unexercisable before the shares of Class B 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 Class B common stock that may be issued under the 2016 Plan, and such unissued shares of Class B common stock shall become available for future grant under the 2025 Plan. Shares of Class B 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 Class B common stock on the date of grant.

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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 Class B common stock underlying each such stock option must be at least equal to 110% of the fair market value of a share of our Class B 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 Class B 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 Class B 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.

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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 January 2025, our board of directors adopted, and our stockholders approved, our 2025 Plan. Our 2025 Plan became effective upon the execution of the underwriting agreement for this offering. Our 2025 Plan is a successor to our 2016 Plan. Upon effectiveness of our 2025 Plan, 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 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 will not exceed 12,016,744 shares, which is the sum of (i) 4,890,000 new shares, plus (ii) 1,467,927 shares of our common stock available for issuance under our 2016 Plan; plus (iii) a number of 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 stock award is settled in cash; are forfeited or repurchased because of the failure to vest; or are reacquired or withheld 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 5% 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 36,060,000 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;

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- 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 ISOs 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.

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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 NDAs 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.

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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 period commencing on the date of our annual meeting of stockholders for a particular year and ending on the day immediately prior to the date of our annual meeting of stockholders for the next subsequent year (Annual Period), including stock awards granted and cash fees paid by us to such non-employee director, will not exceed $750,000 in total value, or in the event such non-employee director is first appointed or elected to the board during such Annual Period, $1,000,000 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). This limitation shall apply commencing with the Annual Period that begins on our first annual meeting of stockholders following the date of execution of the underwriting agreement for this offering.

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 plan 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.

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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 January 2025. The ESPP became 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. The ESPP authorizes the issuance of 410,000 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)

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through January 1, 2035, by the lesser of (i) 1% 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) 1,230,000 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 15% 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.

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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 for service as a director. Edward Damiano, Ph.D., our Executive Chairman, is an employee, executive officer and a member of our board of directors. Dr. Damiano receives compensation as an employee and executive officer but does not receive any additional compensation for his service as a director. Effective as of the Chairman Retirement, Dr. Damiano retired as Executive Chairman and resigned as a member of the board of directors. 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."

Name	Fees Earned or Paid In Cash ($)	Option Awards ($) (1)	Total ($)
Amanda Black(2)	—	—	—
Sean Carney	60,000	—	60,000
James Parker Cassidy(2)	—	—	—
Dan Dearen	5,025	—	5,025
Francesco Draetta(3)	—	—	—
Westley Dupray(2)	—	—	—
Gilad Glick(4)	47,500	—	47,500
Lennox Ketner(4)	—	—	—
Adam Lezack	47,500	—	47,500

(1) As of December 31, 2024, the aggregate number of shares underlying outstanding options to purchase our Class B common stock held by our non-employee directors was 86,293, 39,593 and 9,137 held by Mr. Carney, Mr. Glick and Mr. Lezack, respectively. None of our other non-employee directors held any outstanding options as of December 31, 2024. In addition, as of December 31, 2024, none of our non-employee directors held any other stock awards.
(2) Ms. Black, Mr. Cassidy and Mr. Dupray resigned from our board of directors in January 2025.
(3) Mr. Draetta resigned from our board of directors in November 2024.
(4) Mr. Glick and Ms. Ketner resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Prior to this offering, we have compensated our non-investor, non-employee directors as follows: Messrs. Carney, Glick, Lezack and Dearen are entitled to an annual retainer of $40,000 for their service on our board of directors; Messrs. Glick, Lezack, and Dearen are entitled to an additional annual retainer of $7,500 for their services on the audit committee or compensation committee and Mr. Carey is entitled to an additional annual retainer of $20,000 for his service as the chair of the audit committee. Retainers are prorated for partial year of service. In addition, in December 2023, in connection with his commencement of services as a member of our board of directors, Mr. Lezack was granted an option to purchase 9,137 shares of our Class B common stock with an exercise price of $5.10 per share, that vests in 36 equal monthly installments subject to Mr. Lezack's continued service with us.

In January 2025, we appointed Christy Jones and Maria Palasis, Ph.D. to our board of directors. In connection with their appointments to our board of directors, each of Ms. Jones and Dr. Palasis are eligible for an annual retainer of $40,000 for their service on our board of directors.

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Non-Employee Director Compensation Policy

We adopted a non-employee director compensation policy (the Compensation Policy) that became effective upon the execution and delivery of the underwriting agreement related to this offering and is applicable to all of our non-employee directors. This Compensation Policy provides that each non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of $50,000;
- an additional annual cash retainer of $50,000 for service as independent chair of the board of directors;
- an additional annual cash retainer of $37,500 for service as lead independent director of the board of directors;
- an additional annual cash retainer of $10,000, $7,500 and $7,500 for service as a non-chair member of the audit committee, compensation committee, and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of $20,000, $15,000 and $10,000 for service as chair of the audit committee, chair of the compensation committee, and chair of the nominating and corporate governance committee, respectively (in lieu of the committee member retainer above);
- an initial RSU award granted upon a director's initial election or appointment to the board of directors, with a grant date value of $165,000, prorated based on the length of the director's initial term, vesting on the earlier of (i) the one-year anniversary of the date of grant and (ii) the day immediately preceding the next annual meeting; and
- an annual RSU award with a grant date value of $165,000, vesting on the earlier of (i) the one-year anniversary of the date of grant and (ii) the day immediately preceding the next annual meeting.

Each of the RSU awards described above will be granted under our 2025 Plan, the terms of which are described in more detail above under "Executive and Director Compensation—Equity Benefit Plans—2025 Equity Incentive Plan." Each such RSU award will vest subject to the director's continuous service with us, provided that each RSU award will vest in full immediately prior to a change in control (as defined in the 2025 Plan) of the Company, subject to the director's remaining in continuous service as of such date.

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.

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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.

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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 2,082,153 shares of our Series C convertible preferred stock (Series C Preferred) in our Series C convertible preferred stock financing at a purchase price of $27.40 per share for aggregate cash proceeds of approximately $57.0 million and (ii) warrants to purchase an aggregate of 520,490 shares of Series C Preferred (Series C Warrants), which effected a ten-to-one stock split that occurred in August 2023.

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.

Participants	Series C Preferred Stock (Post Stock-Split)	Total Purchase Price
Entities affiliated with Eventide Asset Management[1]	547,461	$14,999,799.57
Entities affiliated with RTW Investments[2]	437,974	$11,999,978.74
Entities affiliated with Soleus Capital[3]	310,226	$ 8,499,886.42
Zone Healthcare Holdings, LLC[4]	273,730	$ 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.

(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 Partner at Soleus Capital.

(4) Zone Healthcare Holdings, LLC, an affiliate of Farallon Capital, beneficially owns more than 5% of our outstanding capital stock.

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 6,145,740 shares of our Series D convertible preferred stock (Series D Preferred) in our Series D convertible preferred stock financing at a purchase price of $16.55 per share for aggregate cash proceeds of approximately $101.7 million and warrants to purchase an aggregate of 4,302,009 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)	1,329,465	$ 21,999,994.80
Zone Healthcare Holdings, LLC(2)	1,136,088	$ 18,799,998.00
Entities affiliated with Eventide Asset Management(3)	604,301	$ 9,999,998.40
Entities affiliated with RTW Investments(4)	604,301	$ 9,999,998.40
Entities affiliated with Soleus Capital(5)	604,302	$ 9,999,998.40

(1) Sands Capital Life Sciences Pulse Fund II, L.P. (Sands Capital) beneficially owns more than 5% of our outstanding capital stock.
(2) Zone Healthcare Holdings, LLC, an affiliate of Farallon Capital, beneficially owns more than 5% of our outstanding capital stock.
(3) Eventide beneficially owns more than 5% of our outstanding capital stock.
(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.

Series E Preferred Stock Financing

In November 2024, we issued and sold to investors in a private placement an aggregate of 4,352,393 shares of our Series E convertible preferred stock (Series E Preferred) in our Series E convertible preferred stock financing at a purchase price of $13.79 per share for aggregate cash proceeds of approximately $60.0 million.

The following table summarizes the shares of Series E Preferred purchased by holders of more than 5% of our capital stock and entities affiliated with our directors.

Participants	Series E Preferred Stock	Total Purchase Price
Sands Capital Life Sciences Pulse Fund II, L.P.(1)	224,321	$ 3,092,381.68
Entities affiliated with Eventide Asset Management(2)	409,518	$ 5,645,428.39
Entities affiliated with RTW Investments(3)	279,890	$ 3,858,456.65
Entities affiliated with Soleus Capital(4)	207,306	$ 2,857,825.23
Wellington Hadley Harbor Aggregator IV, L.P.(5)	2,901,599	$ 40,000,001.32

(1) Sands Capital beneficially owns more than 5% of our outstanding capital stock.
(2) Eventide beneficially owns more than 5% of our outstanding capital stock.
(3) RTW Investments beneficially own more than 5% of our outstanding capital stock.
(4) 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.
(5) Wellington Hadley Harbor Aggregator IV, L.P. (Wellington) beneficially owns more than 5% of our outstanding capital stock.

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 Wellington Hadley Harbor Aggregator IV, L.P., entities affiliated with Eventide Asset Management, Sands Capital Life Sciences Pulse Fund, L.P., Zone Healthcare Holdings, LLC, entities affiliated with RTW Investments and entities affiliated with Soleus Capital. In connection with this offering, certain key investors who would beneficially own more than 9.99% of our then-outstanding common stock, may request that we restructure such investor's holdings such that any shares in excess of 9.99% be converted into non-voting shares or warrants convertible or exercisable at such investor's option only if such conversion or exercise would not result in such investor beneficially owning more than 9.99% (the Beneficial Ownership Limitation). As described below, on January 21, 2025, we entered into the Exchange Agreement with certain key investors regarding the

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Beneficial Ownership Limitation. The investors' rights, right of first refusal and co-sale and voting 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 and Selling Stockholders" for additional information regarding beneficial ownership of our capital stock.

Exchange Agreement

In January 2025, we entered into an exchange agreement with Zone Healthcare Holdings, LLC and entities affiliated with RTW Investments (the Exchange Agreement), pursuant to which we agreed to issue to such holders, immediately prior to the closing of this offering, pre-funded warrants for outstanding shares of our common stock, in an amount such that shares held by such holder, including any shares purchased in this offering, will result in such holder beneficially owning not more than 9.99% of our common stock as of immediately following the closing of this offering (the Exchange). The shares of common stock exchanged pursuant to the Exchange Agreement would cease to be issued and outstanding. No pre-funded warrants will be issued in connection with the Exchange.

Concurrent Private Placement

We have entered into a Common Stock Purchase Agreement, dated January 21, 2025, with Wellington, an existing stockholder (the Purchase Agreement). Pursuant to the Purchase Agreement, Wellington has agreed to purchase and we have agreed to sell 1,000,000 shares of our common stock (the Private Placement Shares) in a concurrent private placement exempt from the registration requirements of the Securities Act of 1933, as amended, at a per share price equal to the initial public offering price. The private placement would close concurrently with, and be contingent and conditioned upon consummation of, this offering. However, this offering is not contingent on the consummation of the concurrent private placement. The underwriters have agreed to act as placement agents in connection with the concurrent private placement and will receive a placement agent fee equal to 7.0% of the total purchase price of the Private Placement Shares.

Our Relationship with Boston University

Edward Damiano, Ph.D., our Co-Founder, was affiliated with Boston University (BU) as of the time of the original execution and the December 2017, September 2020 and February 2022 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, February 2022 and November 2024 (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 1,160 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-

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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 1,140 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, (ii) 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

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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."

Reserved Share Program

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5.0% of the shares offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale to certain of our directors, officers, employees and certain other parties related to us. See the section titled "Underwriting—Reserved Share Program."

Policies and Procedures for Related Party Transactions

Prior to the completion of this offering, we adopted 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;

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- 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.

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PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our capital stock as of December 1, 2024, as adjusted to reflect the sale of our common stock offered by us in this offering and the concurrent private placement, for:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group;
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock; and
- each of the selling stockholders.

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 and the concurrent private placement is based on 26,493,864 shares of common stock outstanding as of December 1, 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 the concurrent private placement, and excluding the automatic net exercise of the outstanding warrants and the Exchange. See the section titled "Certain Relationships and Related Party Transactions—Exchange Agreement." Applicable percentage ownership after the offering is based on (i) the automatic net exercise of all our outstanding warrants into 3,369,477 shares of common stock, and (ii) the sale of 12,000,000 shares of common stock by us in this offering and the sale of 1,000,000 shares of common stock by us in the concurrent private placement at the initial public offering price of $17.00, assuming no exercise and the full exercise by the underwriters of their option to purchase additional shares of our common stock from us and the selling stockholders. No pre-funded warrants will be issued in connection with the Exchange. 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 and warrants held by the person that are currently exercisable, or exercisable within 60 days of December 1, 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. The percentage ownership information does not reflect any potential purchases pursuant to the reserved share program or otherwise of any shares of common stock in this offering or the concurrent private placement by the beneficial owners identified in the table below. See the section titled "Underwriting—Reserved Share Program."

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.

	Shares Beneficially Owned Prior to Offering		Number of Shares Being Offered**	Shares Beneficially Owned After Offering (assuming no exercise of option)		Shares Beneficially Owned After Offering (assuming full exercise of option)**	
Name of Beneficial Owner	Number	Percentage		Number	Percentage	Number	Percentage
5% or Greater Stockholders:							
Sands Capital Life Sciences Pulse Fund II, L.P.(1)	2,484,411	9.4%	—	2,484,411	5.8%	2,484,411	5.7%
Zone Healthcare Holdings, LLC(2)	3,128,249	11.4%	—	3,127,220	7.3%	3,127,220	7.2%
Entities affiliated with Eventide Asset Management(3)	4,535,503	16.7%	—	4,534,798	10.6%	4,534,798	10.5%
Entities affiliated with RTW Investments(4)	3,099,853	11.5%	—	3,099,191	7.2%	3,099,191	7.2%
Entities affiliated with Soleus Capital(5)	2,295,955	8.5%	—	2,295,341	5.4%	2,295,341	5.3%
Omega Fund(6)	1,693,916	6.4%	—	1,693,916	4.0%	1,693,916	3.9%
Wellington Hadley Harbor Aggregator IV, L.P.(7)	2,901,599	11.0%	—	3,901,599	9.1%	3,901,599	9.0%
Named Executive Officers and Directors:							
Sean Saint(8)	751,293	2.8%	—	751,293	1.7%	751,293	1.7%
Mark Hopman(9)	58,241	*	—	58,241	*	58,241	*
Stephen Feider(10)	137,137	*	—	137,137	*	137,137	*
Sean Carney(11)	74,872	*	—	74,872	*	74,872	*
Gilad Glick(12)	25,232	*	—	25,232	*	25,232	*
Adam Lezack(13)	2,474	*	—	2,474	*	2,474	*
Edward Damiano, Ph.D.(14)**	2,540,164	9.6%	1,000,000	2,540,164	5.9%	1,540,164	3.6%
Amanda Black	—	*	—	—	*	—	*
James Parker Cassidy	—	*	—	—	*	—	*
Dan Dearen	—	*	—	—	*	—	*
Westley Dupray	—	*	—	—	*	—	*
Lennox Ketner	—	*	—	—	*	—	*
All directors and executive officers as a group (14 persons)(15)	3,798,753	13.7%	—	3,798,740	8.6%	2,798,740	6.3%
Other Selling Stockholder:							
Firas El-Khatib, Ph.D.**	1,015,228	3.8%	325,000	1,015,228	2.3%	690,228	1.6%

* Represents beneficial ownership of less than 1%.

** The selling stockholders will participate in the offering only if the underwriters exercise their option to purchase additional shares of common stock. If the underwriters exercise their option to purchase additional shares in full, and the selling stockholders will sell a total of 1,325,000 shares of our common stock in the offering.

(1) Consists of 930,625 shares of common stock, 1,329,465 shares of common stock issuable upon conversion of Series D preferred stock and 224,321 shares of common stock issuable upon conversion of Series E preferred stock held by Sands Capital Life Sciences Pulse Fund II, L.P. (Pulse Fund II). Excludes 84,489 shares of common stock issuable upon conversion of our Series B preferred stock, which were purchased by and transferred to Sands Capital pursuant to a stock purchase and transfer agreement, dated January 16, 2025, by and among Zealand Pharma A/S, Sands Capital and Omega Fund VII, L.P. (the Secondary Purchase Agreement). 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 167,510 shares of common stock, 570,614 shares of common stock issuable upon conversion of our Series B-2 preferred stock, 367,023 shares of common stock issuable upon conversion of our Series C preferred stock, 1,136,088 shares of common stock issuable upon conversion of our Series D preferred stock and 887,014 shares of common stock subject to warrants that are exercisable within 60 days of December 1, 2024. The manager of Zone Healthcare Holdings, LLC (Zone) is Farallon Capital Management, L.L.C.

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(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, Cheng Luo, 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. For purposes of the shares beneficially owned after the offering, the total number of shares of common stock issuable upon the automatic net exercise of the warrants is 885,985 shares of common stock, which represents a reduction of 1,029 shares of common stock as compared to the number of shares issuable upon exercise of the warrants prior to the offering due to the net exercise feature. Zone is a party to the Exchange Agreement and no pre-funded warrants will be issued in connection with the Exchange.

(3) Consists of (i) 954,984 shares of common stock issuable upon conversion of our Series B preferred stock, 337,803 shares of common stock issuable upon conversion of our Series B-2 preferred stock, 489,365 shares of common stock issuable upon conversion of our Series C preferred stock, 362,581 shares of common stock issuable upon conversion of our Series D preferred stock, 245,711 shares of common stock issuable upon conversion of Series E preferred stock and 376,147 shares of common stock subject to warrants that are exercisable within 60 days of December 1, 2024, held by Mutual Fund Series Trust on behalf of Eventide Gilead Fund (Eventide Gilead) and (ii) 477,492 shares of common stock issuable upon conversion of our Series B preferred stock, 410,841 shares of common stock issuable upon conversion of our Series B-2 preferred stock, 244,682 shares of common stock issuable upon conversion of our Series C preferred stock, 241,720 shares of common stock issuable upon conversion of our Series D preferred stock, 163,807 shares of common stock issuable upon conversion of Series E preferred stock and 230,370 shares of common stock subject to warrants that are exercisable within 60 days of December 1, 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. For purposes of the shares beneficially owned after the offering, the total number of shares of common stock issuable upon the automatic net exercise of the warrants is 605,812 shares of common stock, which represents a reduction of 705 shares of common stock as compared to the number of shares issuable upon exercise of the warrants prior to the offering due to the net exercise feature.

(4) Consists of 716,242 shares of common stock issuable upon conversion of our Series B preferred stock, 342,365 shares of common stock issuable upon conversion of our Series B-2 preferred stock, 587,244 shares of common stock issuable upon conversion of our Series C preferred stock, 604,301 shares of common stock issuable upon conversion of our Series D preferred stock, 279,890 shares of common stock issuable upon conversion of Series E preferred stock and 569,811 shares of common stock subject to warrants that are exercisable within 60 days of December 1, 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. For purposes of the shares beneficially owned after the offering, the total number of shares of common stock issuable upon the automatic net exercise of the warrants is 569,149 shares of common stock, which represents a reduction of 662 shares of common stock as compared to the number of shares issuable upon exercise of the warrants prior to the offering due to the net exercise feature. The RTW Funds are parties to the Exchange Agreement and no pre-funded warrants will be issued in connection with the Exchange.

(5) Consists of (i) 267,503 shares of common stock issuable upon conversion of our Series B-2 preferred stock, 97,872 shares of common stock issuable upon conversion of our Series C preferred stock, 120,860 shares of common stock issuable upon conversion of our Series D preferred stock and 109,069 shares of common stock subject to warrants that are exercisable within 60 days of December 1, 2024, held by Soleus BB SPV, LLC (Soleus SPV), (ii) 273,894 shares of common stock issuable upon conversion of our Series B-2 preferred stock, 97,872 shares of common stock issuable upon conversion of our Series C preferred stock and 24,467 shares of common stock subject to warrants that are exercisable within 60 days of December 1, 2024, held by Soleus Private Equity Fund I, L.P. (PE Fund I), and (iii) 220,214 shares of common stock issuable upon conversion of our Series C preferred stock, 483,442 shares of common stock issuable upon conversion of our Series D preferred stock, 207,306 shares of common stock issuable upon conversion of Series E preferred stock and 393,456 shares of common stock subject to warrants that are exercisable within 60 days of December 1, 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

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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. For purposes of the shares beneficially owned after the offering, the total number of shares of common stock issuable upon the automatic net exercise of the warrants is 526,378 shares of common stock, which represents a reduction of 614 shares of common stock as compared to the number of shares issuable upon exercise of the warrants prior to the offering due to the net exercise feature.

(6) Consists of 634,517 shares of common stock, 906,453 shares of common stock issuable upon conversion of Series D preferred stock and 152,946 shares of common stock issuable upon conversion of Series E preferred stock, held by Omega Fund VII, L.P. (Omega Fund). Excludes 84,489 shares of common stock issuable upon conversion of our Series B preferred stock, which were purchased by and transferred to Omega Fund pursuant to the Secondary Purchase Agreement. 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 2,901,599 shares of our common stock issuable upon conversion of Series E preferred stock held by Wellington. Wellington Management Company LLP, a registered investment adviser under the Investment Advisers Act of 1940, as amended, is the investment adviser to Wellington, and Wellington Alternative Investments LLC is its general partner. Wellington Management Investment, Inc. is the managing member of Wellington Alternative Investments LLC. Wellington Management Company LLP is an indirect subsidiary of Wellington Management Group LLP. Wellington Management Group LLP and Wellington Management Company LLP may be deemed beneficial owners with shared voting and investment power over the shares held by Wellington. Additional information about Wellington Management Company LLP is available in its Form ADV filed with the SEC. The address of all entities referenced in this footnote is 280 Congress Street, Boston, MA 02210.

(8) Consists of 751,293 shares of common stock subject to options held by Mr. Saint that are exercisable within 60 days of December 1, 2024.

(9) Consists of 58,241 shares of common stock subject to options held by Mr. Hopman that are exercisable within 60 days of December 1, 2024.

(10) Consists of 137,137 shares of common stock subject to options held by Mr. Feider that are exercisable within 60 days of December 1, 2024.

(11) Consists of 74,872 shares of common stock subject to options held by Mr. Carney that are exercisable within 60 days of December 1, 2024.

(12) Consists of 25,232 shares of common stock subject to options held by Mr. Glick that are exercisable within 60 days of December 1, 2024.

(13) Consists of 2,474 shares of common stock subject to options held by Mr. Lezack that are exercisable within 60 days of December 1, 2024.

(14) Consists of (i) 2,533,000 shares of common stock and (ii) 7,164 shares of common stock issuable upon conversion of our Series B preferred stock held by Dr. Damiano and Toby Milgrome, Dr. Damiano's partner.

(15) Consists of (i) the shares described in notes (8) to (14) above, (ii) (a) 38,071 shares of common stock and (b) 61,810 shares of common stock subject to options that are exercisable within 60 days of December 1, 2024 held by Steven Russell, M.D. and (iii) (a) 15,107 shares of common stock issuable upon conversion of our Series D preferred stock, (b) 83,777 shares of common stock subject to options that are exercisable within 60 days of December 1, 2024 and (c) 10,575 shares of common stock subject to a warrant that is exercisable within 60 days of December 31, 2024 held by Michael Mensinger. For purposes of the shares beneficially owned after the offering, the total number of shares of common stock issuable upon the automatic net exercise of the warrants is 10,562 shares of common stock, which represents a reduction of 13 shares of common stock as compared to the number of shares issuable upon exercise of the warrants prior to the offering due to the net exercise feature.

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DESCRIPTION OF CAPITAL STOCK

Upon the filing of our amended and restated certificate of incorporation and the closing of this offering and the concurrent private placement, our authorized capital stock will consist of 700,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 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:

- 2,939,085 shares of Class A common stock held of record by nine stockholders, all of which will automatically convert into 2,939,085 shares of common stock immediately prior to the closing of this offering;
- 3,674,858 shares of Class B common stock held of record by 20 stockholders, all of which will automatically convert into 3,674,858 shares of common stock immediately prior to the closing of this offering; and
- 48,918 shares of Class C common stock held of record by 717 stockholders, all of which will automatically convert into 48,918 shares of common stock immediately prior to the closing of this offering.

These amounts exclude our outstanding shares of convertible preferred stock, which will convert into 19,827,003 shares of common stock, which includes 4,352,393 shares of common stock issuable upon the conversion of the shares of Series E convertible preferred stock issued and sold in November 2024, immediately prior to 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 automatic net exercise of all outstanding Class B common stock warrants and the automatic net exercise and subsequent conversion of all outstanding Series C convertible preferred stock warrants into 3,369,477 shares of our common stock, (iii) the conversion of all outstanding shares of our convertible preferred stock into 19,827,003 shares of our common stock, (iv) the issuance by us of shares of common stock in this offering and concurrent private placement and (v) no exercise of the underwriters' option to purchase up to 475,000 additional shares of common stock from us, there will be 42,859,341 shares of common stock outstanding upon the closing of this offering and the concurrent private placement.

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.

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In connection with the closing of this offering and the automatic conversion of Class A common stock, Class B common stock and Class C common stock into a single class of common stock, the holders of our common stock will be entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and will not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors will be able to elect all of the directors standing for election.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of 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 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 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 12,876,561 shares of convertible preferred stock outstanding, held of record by 54 stockholders, which excludes the issuance of 4,352,393 shares of Series E convertible preferred stock issued and sold in November 2024.

Immediately prior to the closing of this offering, all outstanding shares of convertible preferred stock will automatically convert into 19,827,003 shares of our common stock, and we will not have any shares preferred stock outstanding. 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 10,000,000 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

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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, 5,658,801 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 $6.73 per share. For information regarding the terms of our equity incentive plans, see the section titled "Executive and Director Compensation—Equity Benefit Plans."

Warrants

Common B and Series C Preferred Stock Warrants

As of September 30, 2024, we had (i) 2,675,535 outstanding immediately exercisable warrants to purchase 2,675,535 shares of our common stock (Common Warrants and, together with the Series C Warrants, the Warrants), with an exercise price of $0.02 per share and (ii) 520,490 outstanding immediately exercisable warrants to purchase an aggregate of 697,874 shares of our Series C Warrants, with an exercise price of $0.02 per share. The Warrants provide that each Warrant will be deemed to have been automatically exercised pursuant to the net exercise provision of the Warrant immediately prior to such Warrant's expiration. The Warrants expire on the earliest to occur of (a) 10 years after a Warrant's issuance date, (b) immediately prior to the consummation of a Sale of the Company, (c) immediately prior to the consummation of an IPO, and (d) immediately prior to a SPAC Transaction (each term as defined in the applicable Warrant). The Warrants also include a cashless exercise feature allowing the holder to elect to receive upon exercise of the holder's Warrant (either in whole or in part) the net number of shares determined according to a formula set forth in the applicable Warrant.

Immediately prior to the completion of this offering, the Common Warrants will be automatically net exercised for the purchase of an aggregate of 2,672,422 shares of our common stock based on the initial public offering price of $17.00 per share.

Immediately prior to the completion of this offering, the Series C Warrants will be automatically net exercised for the purchase of an aggregate of 697,055 shares of our common stock based on the initial public offering price of $17.00 per share.

Pre-Funded Warrants

Immediately prior to the closing of this offering and in connection with the Exchange Agreement, we may issue pre-funded warrants in exchange for shares of our common stock in an amount such that shares held by each holder that is a party to the Exchange Agreement, including any shares purchased in this offering, will result in such holder beneficially owning not more than 9.99% of our common stock as of immediately following the closing of this offering, with an exercise price of $0.0001 per share. All or any part of the pre-funded warrants can be exercised by the holder at any time and from time to time on or after the issuance date, and such rights do not expire. The pre-funded warrants also include a cashless exercise feature allowing the holder to elect to receive upon exercise of the holder's pre-funded warrant (either in whole or in part) the net number of shares determined according to a formula set forth in the pre-funded warrant. The shares of common stock exchanged pursuant to the Exchange Agreement would cease to be issued and outstanding. No pre-funded warrants will be issued in connection with the Exchange.

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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 from holders of a majority of our outstanding registrable securities, with respect to at least 40% of our outstanding registrable securities (or a lesser percent if the anticipated aggregate offering price, net of selling expenses, would exceed $15.0 million), 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 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 $5.0 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 common stock 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;

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- 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 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);

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- 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 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

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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

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "BBNX."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock immediately prior to the closing of this offering will be Computershare Trust Company, N.A. The transfer agent and registrar's address is 150 Royall Street, Canton, Massachusetts 02021.

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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 have applied to have our common stock listed on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Following the closing of this offering and the concurrent private placement, 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 and the concurrent private placement, (ii) the conversion of all outstanding shares of our Class A common stock, Class B common stock and Class C common stock into 6,662,861 shares of our common stock immediately prior to the closing of this offering, (iii) the automatic conversion of all outstanding shares of our convertible preferred stock into 15,474,610 shares of common stock, (iv) the automatic net exercise of all Class B common stock warrants outstanding as of September 30, 2024 into an aggregate of 2,672,422 shares of our common stock, (v) the automatic net exercise and subsequent conversion of all Series C convertible preferred stock warrants outstanding as of September 30, 2024 into an aggregate of 697,055 shares of our common stock, (vi) the issuance and sale of our Series E convertible preferred stock in November 2024 and the subsequent conversion into 4,352,393 shares of our common stock, which will automatically occur immediately prior to the closing of the offering, and (vii) no exercise of the underwriters' option to purchase up to 475,000 additional shares of common stock from us, we will have an aggregate of approximately 42,859,341 shares of common stock outstanding.

Of these shares, all shares of common stock sold in this offering and the concurrent private placement by us, plus any shares sold by us and the selling stockholders upon exercise, if any, of the underwriters' option to purchase additional shares of our common stock, 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, including any shares purchased by any of our affiliates pursuant to our reserved share program, 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.

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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 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 428,593 shares immediately after this offering and the concurrent private placement (calculated as of September 30, 2024 on the basis of the assumptions described above and assuming no exercise of the underwriter's option to purchase up to 475,000 additional shares from us, if any, and no exercise of outstanding options); or

- the average weekly trading volume in our common stock on Nasdaq 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."

As of September 30, 2024, options to purchase a total of 5,658,801 shares of common stock were outstanding, of which 2,645,418 were vested. Of the total number of shares of our common stock issuable under these options, substantially all are subject to contractual lock-up agreements with us or the underwriters described below under the section titled "Underwriting" and will become eligible for sale at the expiration of the restrictions set forth in those agreements unless held by an affiliate of ours.

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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, the selling stockholders, 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, certain holders 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.

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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.

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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

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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.

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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.

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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, the selling stockholders 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.	3,840,000
Piper Sandler & Co.	3,000,000
Leerink Partners LLC	2,400,000
Stifel, Nicolaus & Company, Incorporated	1,800,000
Lake Street Capital Markets, LLC	960,000
Total	12,000,000

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 offered by us and the selling stockholders 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 and the selling stockholders 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 $0.714 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 and the selling stockholders. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares from us and the selling stockholders.

	Per Share	Total	
		Without Option	With Option
Public offering price	$ 17.00	$ 204,000,000	$ 234,600,000
Underwriting discounts and commissions paid by us	$ 1.19	$ 14,280,000	$ 14,845,250
Underwriting discounts and commissions paid by the selling stockholders	$ 1.19	$ —	$ 1,576,750
Proceeds, before expenses, to us	$ 15.81	$ 189,720,000	$ 197,229,750
Proceeds, before expenses, to the selling stockholders	$ 15.81	$ —	$ 20,948,250

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The expenses of the offering, not including the underwriting discounts and commissions, are estimated at $6.2 million and are payable by us. We have agreed to reimburse the underwriters for certain of their expenses, up to $40,000.

Option to Purchase Additional Shares

The underwriters have an option to purchase up to 1,800,000 additional shares of common stock, consisting of 475,000 shares from us and 1,325,000 shares from the selling stockholders, exercisable for 30 days after the date of this prospectus, 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.

Reserved Share Program

At our request, an affiliate of BofA Securities, Inc., a participating underwriter, has reserved for sale, at the initial public offering price, up to 5.0% of the shares of common stock offered by this prospectus for sale to some of our directors, officers, employees and certain other parties related to us. Management will provide a list of potential participants to the underwriters who will administer the reserved share program. At this time, no indication of interest will be taken. Once the preliminary prospectus has been filed, an invitation package will be made available or sent to each person identified by management, which will include the preliminary prospectus and other reserved share program documentation. An invitation to participate in the reserved share program does not guarantee that the participant will receive an allocation of shares. Accordingly, we cannot provide any assurance that any director, officer, employee, or participant will receive an invitation or an allocation in the reserved share program. If a potential participant is interested in participating, that participant will be required to complete the required documentation and will be required to return such documentation to the program administrator. The program administrator will not accept funds from any participant until after the registration statement for this offering is declared effective, this offering is priced, and the participants are notified of their final allocation and given an opportunity to confirm that they wish to purchase the shares allocated to them. After the registration statement has been declared effective and this offering is priced, we and the program administrator will prepare a final approved list of allocations. The program administrator will notify each participant who has been allocated shares of the number of shares that have been allocated and the total purchase price due upon confirmation of their participation. Thereafter, participants will be required to wire or transfer their funds to the program administrator. The shares under the reserved share program will be allocated following pricing and settle in the same manner as the shares sold to the general public. Except for any shares purchased by our directors and officers, shares purchased pursuant to the reserved share program will not be subject to the 180-day lock-up restriction described in this section. If these persons purchase reserved shares, it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.

No Sales of Similar Securities

We, the selling stockholders, 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;

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- 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

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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

Our shares have been approved for listing on the Nasdaq Global Market under the symbol “BBNX”.

Before this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price were:

- 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.

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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 from us and the selling stockholders as 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 Nasdaq Global Market, 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

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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.

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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, 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

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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

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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

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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.

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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. Whalen LLP is acting as counsel for the selling stockholders in connection with this offering.

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.

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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. 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, except for the fifth paragraph of Note 20, as to which the date is January 22, 2025

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BETA BIONICS, INC.

BALANCE SHEETS

(In thousands, except number of shares)

	December 31, 2022	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 27,675	$ 26,566
Short-term investments	—	70,179
Accounts receivable, net	—	4,448
Inventories, net	—	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	$ 35,527	$ 110,040
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	22,527	51,432
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; 6,730,821 and 12,876,561 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; 10,000,000 and 6,000,000 shares authorized at December 31, 2022 and 2023, respectively; 2,989,847 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; 1,989,383 shares and 2,982,562 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; 48,918 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	(170,034)	(203,105)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 35,527	$ 110,040

The accompanying notes are an integral part of these financial statements.

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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 revenues	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	$ (12.96)	$ (8.31)
Weighted-average common shares outstanding, basic and diluted	4,997,244	5,303,684

The accompanying notes are an integral part of these financial statements.

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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	4,648,668	$138,049	4,905,833	$ 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	2,082,153	44,985	—	—	—	—	—	—
Stock option exercises	—	—	122,315	—	389	—	—	389
Stock-based compensation expense	—	—	—	—	6,100	—	—	6,100
Net loss	—	—	—	—	—	—	(64,751)	(64,751)
Balance at December 31, 2022	6,730,821	183,034	5,028,148	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	6,145,740	78,679	—	—	—	—	—	—
Common B warrant exercises	—	—	991,957	—	5,223	—	—	5,223
Stock option exercises	—	—	1,222	—	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	12,876,561	$261,713	6,021,327	$ 1	$ 26,421	$ 137	$ (229,664)	$ (203,105)

The accompanying notes are an integral part of these financial statements.

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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	(60,208)	(32,445)
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	(769)	(69,693)
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	56,782	101,029
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	$ 27,775	$ 26,666
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	$ 27,775	$ 26,666

The accompanying notes are an integral part of these financial statements.

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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 closed-loop 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.

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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:

	Total Sales Year Ended December 31, 2023	Accounts Receivable, net December 31, 2023
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.

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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

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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.

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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.

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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.

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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.

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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.

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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 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.

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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 $0.02. 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.

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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.

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3. Revenue

Net Sales

The Company disaggregates net sales by product category and reimbursement channel, which the Company believes provides a meaningful depiction of how the nature, timing and uncertainty of net sales are affected by economic factors.

During the year ended December 31, 2023, the Company's revenues were predominantly generated from sales of the iLet. The iLet requires the use of separately purchased single-use products which include cartridges for storing and delivering insulin, and infusion sets that connect the iLet to the user's body. These single-use products generate recurring revenue for the Company, as these are typically replaced by the end-user every 2-3 days or as directed by a healthcare provider.

The Company's customers are distributors and pharmacies who sell these products to insulin-requiring PWD, through the durable medical equipment ("DME") and the pharmacy benefit plan ("PBP") reimbursement channels, which entail differing payment outlays. For the year ended December 31, 2023, the majority of the Company's sales were through the DME channel.

The following table summarizes the Company's disaggregated revenues:

	Year Ended December 31, 2023 (in thousands)
DME channel	
iLet	$ 10,169
Single-use products	1,091
Total DME channel	11,260
PBP channel	
iLet	535
Single-use products	200
Total PBP channel	735
Total net sales	$ 11,995

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.

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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.

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:

	Fair Value Measurements at December 31, 2022			
Assets	**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	$24,751	$ —	$ —	$24,751
Liabilities				
Series C warrant liabilities	$ —	$ —	$10,497	$10,497
Total liabilities	$ —	$ —	$10,497	$10,497

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	Fair Value Measurements at December 31, 2023			
Assets	**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	$94,693	$ —	$ —	$94,693
Liabilities				
Series C warrant liabilities	$ —	$ —	$ 9,447	$ 9,447
Common B warrant liabilities	—	—	28,126	28,126
Total liabilities	$ —	$ —	$37,573	$37,573

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 4,302,009 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 $0.02 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 (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 520,490 shares of Series C Preferred Stock at a price per share equal to $0.02 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.

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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	$20.15	$ 18.16
Strike price	$ 0.02	$ 0.02
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%

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	$ 5.20	$ 8.51
Strike price	$ 0.02	$ 0.02
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.

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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	$ 9,447

	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	$ 28,126

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			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
		(in thousands)		
Short-term investments				
U.S. Treasury bills	$ 70,042	$ 137	$ —	$ 70,179
Total	$ 70,042	$ 137	$ —	$ 70,179

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	$ 4,448

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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	$ 46

The Company did not have accounts receivable, net or an allowance for credit losses at December 31, 2022.

7. Inventories

Inventories consisted of the following:

	December 31, 2023
	(in thousands)
Raw materials	$ 803
Work in process	34
Finished goods	408
Inventories	$ 1,245

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	$ 792	$ 1,183

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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	$ 3,319	$ 2,476

Depreciation and amortization expense for the years ended December 31, 2022 and 2023 was $1.3 million and $1.2 million, respectively.

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	$6,327	$8,128

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	$ 22

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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 6,145,740 shares of Series D Preferred Stock, at a price of $16.55 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 price of $0.02 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 991,957 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 $16.55.

In February 2022, the Company issued and sold 2,082,153 shares of Series C Preferred Stock, at a price of $27.40 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 520,490 shares of Series C Preferred Stock (the "Series C Warrants"). The Series C Warrants are exercisable at any time, at an exercise price of $0.02 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 $27.40.

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 6,145,740 shares were designated as Series D Preferred Stock.

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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	253,807	$ 6,589	$ 5,000	253,807
Series A-2 Preferred Stock	500,000	253,807	6,626	5,000	253,807
Series B Preferred Stock	4,200,000	2,130,910	61,606	63,053	2,232,758
Series B-2 Preferred Stock	4,500,000	2,010,144	63,228	63,360	2,124,082
Series C Preferred Stock	5,500,000	2,082,153	44,985	57,049	2,082,153
	15,200,000	6,730,821	$ 183,034	$ 193,462	6,946,607

	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	253,807	$ 6,589	$ 5,000	317,040
Series A-2 Preferred Stock	500,000	253,807	6,626	5,000	317,040
Series B Preferred Stock	4,200,000	2,130,910	61,606	63,053	3,010,683
Series B-2 Preferred Stock	4,000,000	2,010,144	63,228	63,360	2,892,318
Series C Preferred Stock	5,127,250	2,082,153	44,985	57,049	2,791,789
Series D Preferred Stock	12,107,140	6,145,740	78,679	101,700	6,145,740
	26,434,390	12,876,561	$ 261,713	$ 295,162	15,474,610

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.

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BETA BIONICS, INC.

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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 $14.60 (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 $19.70 per share for Series A Preferred Stock, $19.70 per share for Series A-2 Preferred Stock, $29.59 per share for Series B Preferred Stock, $31.52 per share for Series B-2 Preferred Stock, $27.40 per share for share for Series C Preferred Stock and $16.55 per share for Series D Preferred Stock. The Conversion Price is $15.77 per share for Series A Preferred Stock, $15.77 per share for Series A-2 Preferred Stock, $20.94 per share for Series B Preferred Stock, $21.91 per share for Series B-2 Preferred Stock, $20.43 per share for Series C Preferred Stock and $9.73 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).

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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.

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

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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.

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 $14.60 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	15,474,610
Common stock options granted and outstanding	5,202,905
Shares available for issuance under the 2016 Stock Incentive Plan	834,508
Total common stock reserved for future issuance	21,512,023

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 128,046 shares, from 6,037,413 to 6,165,458.

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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 6,165,458 shares as of December 31, 2023, of which 834,508 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 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 2,273,054 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 regranted 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 $7.51 per share. Aside from the reduced strike price, all regranted 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.

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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	$ 7.51	$ 8.51
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	3,417,646	$ 12.61	7.4	$ 1,870
Granted	4,396,507	6.44		
Exercised	(1,222)	7.80		
Forfeited or cancelled	(2,610,026)	13.95		
Outstanding at December 31, 2023	5,202,905	$ 6.30	8.1	$ 535
Vested and expected to vest at December 31, 2023	5,202,905	$ 6.30	8.1	$ 535
Options exercisable at December 31, 2023	2,078,712	$ 6.67	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.

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2022 and 2023 was $5.38 per share and $4.26 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	1,742,227	$ 14.67
Non-vested options, December 31, 2023	3,124,193	$ 6.06

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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	$6,100	$5,658

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 participant's earnings. 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	0.0%	0.0%

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	$ —	$ —

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

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Company 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.

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	$ 43,632	$ 51,903

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.

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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	$ 1,053

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)	6,946,607	15,474,610
Stock options to purchase Class B common stock	3,417,646	5,202,905
Warrants to purchase Series C convertible preferred stock	520,490	697,885
Warrants to purchase Class B common stock	—	3,310,052
Total	10,884,743	24,685,452

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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	2,997,344	2,989,847
Weighted-average Class B common stock outstanding, basic and diluted	1,950,982	2,264,919
Weighted-average Class C common stock outstanding, basic and diluted	48,918	48,918
Weighted-average Class A, Class B, Class C common stock outstanding, basic and diluted	4,997,244	5,303,684
Net loss per share attributable to Class A, Class B and Class C common stockholders, basic and diluted	$ (12.96)	$ (8.31)

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.

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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	$4,223

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.

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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 1,160 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.

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

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BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

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 1,140 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, (ii) 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.

As of December 31, 2022 and 2023, $0.2 million and $0.3 million, respectively, was due to BU from the Company.

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BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

20. Subsequent Events

The Company evaluated subsequent events through September 13, 2024, which represents the date the financial statements were issued, for events requiring adjustment to or disclosure in the financial statements. The Company has further evaluated subsequent events for disclosure purposes through January 22, 2025. Except as discussed in the footnotes or below, there are no events that require adjustment to or disclosure in the financial statements.

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.

Reverse Stock Split

On January 21, 2025, the Company effectuated a 1-for-1.970 reverse stock split of the Company's issued and outstanding shares of Class A, Class B and Class C common stock, Series A, Series A-2, Series B, Series B-2, Series C, Series D, and Series E preferred stock, as well as stock option awards to purchase shares of

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BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

Class B common stock and warrants to purchase shares of Class B common stock and Series C preferred stock. Consequently, all issued and outstanding shares of stock, stock option awards, warrants, and per share data have been retroactively adjusted in these financial statements to reflect the reverse stock split for all periods presented. The authorized shares and par value of the common stock and preferred stock remain unchanged. As the number and issuance price of all outstanding preferred stock were adjusted, the conversion ratios for each series of the Company's preferred stock were unchanged. Stockholders entitled to fractional shares as a result of the reverse stock split received cash payment in lieu of receiving fractional shares.

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BETA BIONICS, INC.
CONDENSED BALANCE SHEETS
(In thousands, except number of shares)

	December 31, 2023	September 30, 2024 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 26,566	$ 17,481
Short-term investments	70,179	43,416
Accounts receivable, net	4,448	7,464
Inventories	1,245	11,291
Prepaid expenses and other current assets	1,183	2,903
Total current assets	103,621	82,555
Property and equipment, net	2,476	4,321
Operating lease right-of-use asset	3,722	6,715
Restricted cash	100	100
Deferred offering costs	—	3,096
Other long-term assets	121	151
Total assets	$ 110,040	$ 96,938
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,166	$ 2,848
Accrued expenses and other current liabilities	8,128	13,031
Operating lease liabilities	1,224	1,450
Deferred revenue	87	550
Total current liabilities	10,605	17,879
Operating lease liabilities, net of current portion	2,999	5,851
Deferred revenue, net of current portion	255	1,466
Warrant liabilities	37,573	38,876
Total liabilities	51,432	64,072
Commitments and contingencies (Note 17)		
Convertible preferred stock (Series A, A-2, B, B-2, C and D), par value of $0.0001 per share; 26,434,390 shares authorized at December 31, 2023 and September 30, 2024; 12,876,561 shares issued and outstanding at December 31, 2023 and September 30, 2024; liquidation preference of $295,162 at December 31, 2023 and September 30, 2024	261,713	261,713
Stockholders' deficit:		
Class A common stock, par value of $0.0001 per share; 6,000,000 shares authorized at December 31, 2023 and September 30, 2024; 2,989,847 and 2,939,085 shares issued and outstanding at December 31, 2023 and September 30, 2024, respectively	1	1
Class B common stock, par value of $0.0001 per share; 65,000,000 shares authorized at December 31, 2023 and September 30, 2024; 2,982,562 shares and 3,674,858 shares issued and outstanding at December 31, 2023 and September 30, 2024, respectively	—	—
Class C common stock, par value of $0.0001 per share; 100,000 shares authorized at December 31, 2023 and September 30, 2024; 48,918 shares issued and outstanding at December 31, 2023 and September 30, 2024	—	—
Additional paid-in capital	26,421	49,723
Accumulated other comprehensive income	137	58
Accumulated deficit	(229,664)	(278,629)
Total stockholders' deficit	(203,105)	(228,847)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 110,040	$ 96,938

The accompanying notes are an integral part of these unaudited condensed financial statements.

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BETA BIONICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except number of shares and per share data)

	Nine Months Ended September 30,	
	2023	2024
Net sales	$ 3,645	$ 44,684
Cost of sales	2,399	20,485
Gross profit	1,246	24,199
Operating expenses:		
Research and development	13,483	16,970
Sales and marketing	6,372	26,282
General and administrative	8,874	13,161
Total operating expenses	28,729	56,413
Loss from operations	(27,483)	(32,214)
Other income (expense), net:		
Interest income	526	2,958
Interest and other expense	(13)	(2)
Change in fair value of warrant liabilities	1,719	(7,390)
Total other income (expense), net	2,232	(4,434)
Net loss	$ (25,251)	$ (36,648)
Other comprehensive income (loss):		
Unrealized loss on short-term investments	—	(79)
Comprehensive loss	$ (25,251)	$ (36,727)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.98)	$ (5.86)
Weighted-average common shares outstanding, basic and diluted	5,062,429	6,264,162

The accompanying notes are an integral part of these unaudited condensed financial statements.

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BETA BIONICS, INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except number of shares)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	6,730,821	$183,034	5,028,148	$ 1	$ 15,530	$ —	$ (185,565)	$ (170,034)
Issuance of Series D preferred stock, net of issuance costs of $700 and net of warrant liability of $22,321	6,145,740	78,679	—	—	—	—	—	—
Common B warrant exercises	—	—	972,926	—	5,122	—	—	5,122
Stock option exercises	—	—	45	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	4,082	—	—	4,082
Net loss	—	—	—	—	—	—	(25,251)	(25,251)
Balance at September 30, 2023	12,876,561	$261,713	6,001,119	$ 1	$ 24,735	$ —	$ (210,816)	$ (186,080)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	12,876,561	$261,713	6,021,327	$ 1	$ 26,421	$ 137	$ (229,664)	$ (203,105)
Adoption of ASU 2020-06	—	—	—	—	12,317	—	(12,317)	—
Common B warrant exercises	—	—	634,513	—	6,100	—	—	6,100
Stock option exercises	—	—	7,021	—	52	—	—	52
Stock-based compensation expense	—	—	—	—	4,833	—	—	4,833
Unrealized loss on short-term investments	—	—	—	—	—	(79)	—	(79)
Net loss	—	—	—	—	—	—	(36,648)	(36,648)
Balance at September 30, 2024	12,876,561	$261,713	6,662,861	$ 1	$ 49,723	$ 58	$ (278,629)	$ (228,847)

The accompanying notes are an integral part of these unaudited condensed financial statements.

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BETA BIONICS, INC.
STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2023	2024
Cash flows from operating activities:		
Net loss	$ (25,251)	$ (36,648)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	934	919
Provision for expected credit losses	—	44
Stock-based compensation expense	4,082	4,833
Provision for excess and obsolete inventory	(23)	(184)
Change in fair value of warrant liabilities	(1,719)	7,390
Accretion of discount on short-term investments	—	(2,286)
Amortization of operating lease right-of-use asset	613	835
Loss on disposal of property and equipment	5	8
Changes in operating assets and liabilities:		
Accounts receivable	(2,017)	(3,060)
Inventories	(271)	(9,862)
Prepaid expenses and other current assets	(115)	(1,721)
Other long-term assets	1	(30)
Accounts payable	36	1,575
Accrued expenses and other current liabilities	(673)	3,269
Funded R&D liability—related party	(1,140)	—
Operating lease liability	(664)	(750)
Deferred revenue	104	1,674
Net cash used in operating activities	(26,098)	(33,994)
Cash flows from investing activities:		
Purchases of short-term investments	—	(27,030)
Proceeds from maturities and redemptions of short-term investments	—	56,000
Proceeds on disposal of property and equipment	4	50
Purchases of property and equipment	(89)	(2,834)
Net cash (used in) provided by investing activities	(85)	26,186
Cash flows from financing activities:		
Proceeds from the issuance of convertible preferred stock, net of issuance costs	101,000	—
Payments for deferred offering costs	—	(1,341)
Proceeds from stock option exercises	1	52
Proceeds from common stock warrants exercise	19	12
Net cash provided by (used in) financing activities	101,020	(1,277)
Net increase (decrease) in cash, cash equivalents and restricted cash	74,837	(9,085)
Cash, cash equivalents and restricted cash at beginning of period	27,775	26,666
Cash, cash equivalents and restricted cash at end of period	$ 102,612	$ 17,581
Supplemental disclosure of non-cash investing and financing information:		
Purchases of property and equipment included in accounts payable	$ —	$ 7
Deferred offering costs included in accrued expenses	$ —	$ 1,634
Deferred offering costs included in accounts payable	$ —	$ 120
Unrealized loss on short-term investments	$ —	$ (79)
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	$ 160	$ 3,828
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 102,512	$ 17,481
Restricted cash	100	100
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 102,612	$ 17,581

The accompanying notes are an integral part of these unaudited condensed financial statements.

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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 closed-loop 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 September 30, 2024, 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 unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission applicable to interim financial information. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles in the United States ("GAAP") have been condensed or omitted pursuant to such rules and regulations. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC").

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period(s). These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and accompanying notes for the years ended December 31, 2022 and 2023, from which the balance sheet information herein was derived.

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. The impact of the change has been given retroactive effect in the unaudited condensed 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

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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.

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 unaudited condensed 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 judgments 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.

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 unaudited condensed 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 unaudited condensed 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 nine months ended September 30, 2023 and 2024. All short-term investments are classified as current based on the nature of the investments and their availability for use in current operations.

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.

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The Company is exposed to concentration risk as it relates to its customers. The following table summarizes the percentages of net sales and accounts receivable, net for customers who accounted for 10% or more of the respective amounts for the periods presented:

	Net Sales Nine Months Ended September 30,		Accounts Receivable, net	
	2023	2024	December 31, 2023	September 30, 2024
Distributor A	25.3%	13.6%	28.9%	19.5%
Distributor B	12.6%	18.6%	24.5%	10.1%
Distributor C	11.3%	12.0%	12.3%	12.5%
Distributor D	22.8%	16.6%	*	*
Distributor E	*	*	*	18.1%

* Amount related to the respective customer represented less than 10% for the period presented.

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 September 30, 2024 (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.

Leases

In accordance with ASC 842, *Leases*, 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 (see Note 16).

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The Company's leases have non-cancelable initial lease terms of approximately two to seven years, with some including options to extend for up to five additional years. 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 decision to exercise of lease renewal options is at the Company's sole discretion. Variable lease costs, including maintenance and utilities, real estate taxes, and insurance are expensed as incurred and excluded from the measurement of the lease liability. Lease agreements that include lease and non-lease components are accounted for as a single lease component. 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. The Company does not have any leases that are classified as financing leases.

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 unaudited condensed 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 unaudited condensed balance sheets as these warrants are freestanding financial instruments that are not indexed to the Company's common stock (see Note 4).

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.

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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. 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.

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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 unaudited condensed 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 unaudited condensed statements of operations and comprehensive loss.

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 $0.02. 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

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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.

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 unaudited condensed financial statements.

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)*, which simplifies the accounting for convertible instruments and equity-linked financial instruments in addition to amending the EPS guidance in ASC 260 to improve the consistency of the diluted EPS calculation. The standard addresses issues identified as a result of the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. The standard eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. 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 standard is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company adopted ASU 2020-06 on January 1, 2024, using the modified retrospective method for its convertible preferred instruments. Consequently, prior period comparatives have not been restated to align with the current period presentation. The cumulative effect of the adoption of ASU 2020-06 resulted in an adjustment to accumulated deficit as of January 1, 2024 of $12.3 million with a corresponding adjustment to additional paid in capital. In the period of adoption there was no impact in the net loss per share.

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

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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.

3. Revenue

The Company disaggregates net sales by product category and reimbursement channel, which the Company believes provides a meaningful depiction of how the nature, timing and uncertainty of net sales are affected by economic factors.

During the nine months ended September 30, 2024, the Company's revenues were predominantly generated from sales of the iLet. The iLet requires the use of separately purchased single-use products which include cartridges for storing and delivering insulin, and infusion sets that connect the iLet to the user's body. These single-use products generate recurring revenue for the Company, as these are typically replaced by the end-user every 2-3 days or as directed by a healthcare provider.

The Company's customers are distributors and pharmacies who sell these products to insulin-requiring PWD, through the durable medical equipment ("DME") and the pharmacy benefit plan ("PBP"), which entail differing payment outlays. For the nine months ended September 30, 2024, the majority of the Company's sales were through the DME channel.

The following table summarizes the Company's disaggregated revenues:

	Nine Months Ended September 30,	
	2023	2024
	(in thousands)	
DME channel		
iLet	$3,024	$33,105
Single-use products	288	7,740
Total DME channel	3,312	40,845
PBP channel		
iLet	276	1,748
Single-use products	57	2,091
Total PBP channel	333	3,839
Total net sales	$3,645	$44,684

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. Revenue recognized during the nine months ended September 30, 2024 that was included in the deferred revenue balance as of December 31, 2023 was approximately $0.1 million.

At September 30, 2024, $2.0 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, $0.6 million is expected to be recognized as revenue in the next 12 months, with the remainder expected to be recognized thereafter. The $2.0 million relates to amounts deferred associated with the unspecified software updates promised to users and the user's access to the mobile application.

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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:

	Fair Value Measurements at December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets				
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	$94,693	$ —	$ —	$94,693
Liabilities				
Series C warrant liability	$ —	$ —	$ 9,447	$ 9,447
Common B warrant liability	—	—	28,126	28,126
Total liabilities	$ —	$ —	$37,573	$37,573

	Fair Value Measurements at September 30, 2024			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets				
Cash equivalents:				
Money market fund	$13,710	$ —	$ —	$13,710
Restricted cash:				
Money market fund	100	—	—	100
Short-term investments				
U.S. Treasury bills	43,416	—	—	43,416
Total assets	$57,226	$ —	$ —	$57,226
Liabilities				
Series C warrant liability	$ —	$ —	$ 9,607	$ 9,607
Common B warrant liability	—	—	29,269	29,269
Total liabilities	$ —	$ —	$38,876	$38,876

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 nine months ended September 30, 2024. 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 nine months ended September 30, 2024.

Warrant Liabilities

In connection with the August 2023 Series D Preferred Stock financing (see Note 11), the Company granted warrants to purchase up to 4,302,009 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 $0.02 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 (iii) immediately prior to the consummation of a qualifying initial public offering or a SPAC Transaction (as

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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 520,490 shares of Series C Preferred Stock at a price per share equal to $0.02 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, 2023 and September 30, 2024:

	December 31, 2023	September 30, 2024
Fair value of Series C Preferred Stock	$ 18.16	$ 18.48
Strike price	$ 0.02	$ 0.02
Risk-free interest rate	4.69%	4.39%
Expected term (in years)	1.30	1.00
Expected volatility	78.00%	65.00%
Expected dividend yield	0%	0%

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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 December 31, 2023 and September 30, 2024:

	December 31, 2023	September 30, 2024
Fair value of Class B common stock	$ 8.51	$ 10.95
Strike price	$ 0.02	$ 0.02
Risk-free interest rate	3.88%	3.74%
Expected term (in years)	9.70	8.90
Expected volatility	74.64%	75.70%
Expected dividend yield	0%	0%

The Company recognizes changes in the fair value of the warrant liabilities as a component of other income (expense), net in its unaudited condensed 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, 2023	$ 9,447
Change in fair value	160
Balance at September 30, 2024	$ 9,607

	Common B Warrant Liability (in thousands)
Balance at December 31, 2023	$ 28,126
Common B warrant exercises	(6,087)
Change in fair value	7,230
Balance at September 30, 2024	$ 29,269

5. Short-Term Investments

The following represents a summary of the estimated fair value of short-term investments at December 31, 2023 and September 30, 2024:

	At December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Short-term investments				
U.S. Treasury bills	$ 70,042	$ 137	$ —	$ 70,179
Total	$ 70,042	$ 137	$ —	$ 70,179

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	At September 30, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Short-term investments				
U.S. Treasury bills	$ 43,358	$ 58	$ —	$ 43,416
Total	$ 43,358	$ 58	$ —	$ 43,416

6. Accounts Receivable, Net

Accounts receivable, net consisted of the following:

	December 31, 2023	September 30, 2024
	(in thousands)	
Accounts receivable	$ 4,494	$ 7,554
Less: allowance for credit losses	(46)	(90)
Accounts receivable, net	$ 4,448	$ 7,464

The following table provides a reconciliation of the changes in the allowance for estimated credit losses for the nine months ended September 30, 2024:

	Nine Months Ended September 30, 2024
	(in thousands)
Balance at beginning of period	$ 46
Provision for expected credit losses	44
Balance at end of period	$ 90

The Company did not have an allowance for credit losses at September 30, 2023.

7. Inventories

Inventories consisted of the following:

	December 31, 2023	September 30, 2024
	(in thousands)	
Raw materials	$ 803	$ 4,536
Work in process	34	775
Finished goods	408	5,980
Inventories	$ 1,245	$ 11,291

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8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2023	September 30, 2024
	(in thousands)	
Prepaid expenses	$ 908	$ 2,598
Other current assets	275	305
Prepaid expenses and other current assets	$ 1,183	$ 2,903

9. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31, 2023	September 30, 2024
	(in thousands)	
Manufacturing equipment	$ 4,386	$ 6,291
Leasehold improvements	951	810
Furniture	924	924
Computer equipment	468	308
Construction in progress	167	1,011
Total cost	6,896	9,344
Less: Accumulated depreciation and amortization	(4,420)	(5,023)
Property and equipment, net	$ 2,476	$ 4,321

Depreciation and amortization expense for the nine months ended September 30, 2023 and 2024 was $0.9 million for each period.

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2023	September 30, 2024
	(in thousands)	
Accrued employee compensation and benefits	$ 5,475	$ 8,025
Accrued professional fees	963	2,556
Accrued sales returns, rebates and patient assistance	592	787
Accrued inventory in transit	342	290
Accrued royalties	294	588
Other current liabilities	462	785
Accrued expenses and other current liabilities	$ 8,128	$ 13,031

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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	Nine Months Ended September 30, 2024
	(in thousands)	
Product warranty liability at beginning of period	$ —	$ 22
Warranty expense	84	1,114
Changes in estimates	—	—
Warranty fulfillment	(62)	(704)
Product warranty liability at end of period	$ 22	$ 432

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 6,145,740 shares of Series D Preferred Stock, at a price of $16.55 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 price of $0.02 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 nine months ended September 30, 2024, a total of 634,517 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 $16.55.

In February 2022, the Company issued and sold 2,082,153 shares of Series C Preferred Stock, at a price of $27.40 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 520,490 shares of Series C Preferred Stock (the "Series C Warrants"). The Series C Warrants are exercisable at any time, at an exercise price of $0.02 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 $27.40.

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

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number of shares of preferred stock authorized for issuance from 15,200,000 shares to 26,434,390 shares, of which 6,145,740 shares were designated as Series D Preferred Stock.

At both December 31, 2023 and September 30, 2024, Preferred Stock consisted of the following:

	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	253,807	$ 6,589	$ 5,000	317,040
Series A-2 Preferred Stock	500,000	253,807	6,626	5,000	317,040
Series B Preferred Stock	4,200,000	2,130,910	61,606	63,053	3,010,683
Series B-2 Preferred Stock	4,000,000	2,010,144	63,228	63,360	2,892,318
Series C Preferred Stock	5,127,250	2,082,153	44,985	57,049	2,791,789
Series D Preferred Stock	12,107,140	6,145,740	78,679	101,700	6,145,740
	26,434,390	12,876,561	$ 261,713	$ 295,162	15,474,610

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 $14.60 (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 $19.70 per share for Series A Preferred Stock, $19.70 per share for Series A-2 Preferred Stock, $29.59 per share for Series B Preferred Stock, $31.52 per share for Series B-2 Preferred Stock, $27.40 per share for share for Series C Preferred Stock and $16.55 per share for Series D Preferred Stock. The

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Conversion Price is $15.77 per share for Series A Preferred Stock, $15.77 per share for Series A-2 Preferred Stock, $20.94 per share for Series B Preferred Stock, $21.91 per share for Series B-2 Preferred Stock, $20.43 per share for Series C Preferred Stock and $9.73 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 September 30, 2024, 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.

Through September 30, 2024, no dividends had been declared on any series or class of shares.

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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.

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12. Stock-Based Compensation

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:

	Nine Months Ended September 30,	
	2023	2024
Fair value of common stock	$ 6.42	$10.95
Risk-free interest rate	4.34%	4.08%
Expected term (in years)	5.89	6.02
Expected volatility	82.09%	86.57%
Expected dividend yield	0%	0%

The following table summarizes stock option activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	5,202,905	$ 6.30	8.1	$ 535
Granted	884,460	$ 9.17		
Exercised	(7,021)	$ 7.43		
Forfeited or cancelled	(386,453)	$ 9.21		
Expired	(35,090)	$ 7.47		
Outstanding at September 30, 2024	5,658,801	$ 6.73	7.8	$ 22,000
Vested and expected to vest at September 30, 2024	5,658,801	$ 6.73	7.8	$ 22,000
Options exercisable at September 30, 2024	2,645,418	$ 6.82	6.6	$ 9,742

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 during the nine months ended September 30, 2023 and 2024 were not significant.

The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2023 and 2024 was $9.38 per share and $6.84 per share, respectively. The total fair value of shares vested during the nine months ended September 30, 2023 and 2024, was $1.3 million and $1.8 million, respectively.

The following table summarizes the non-vested stock options that were outstanding as of December 31, 2023 and September 30, 2024:

	Number of Options	Weighted-Average Exercise Price
Non-vested Options, December 31, 2023	3,124,193	$ 6.06
Non-vested Options, September 30, 2024	3,013,383	$ 6.71

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Stock-Based Compensation Expense

Stock-based compensation expense related to the stock options was included in the Company's unaudited condensed statements of operations and comprehensive loss as follows:

	Nine Months Ended September 30,	
	2023	2024
	(in thousands)	
Cost of sales	$ 149	$ 201
Research and development	1,411	844
Sales and marketing	362	1,150
General and administrative	2,160	2,638
Total stock-based compensation expense	$4,082	$4,833

As of September 30, 2024, total unrecognized stock-based compensation expense related to the unvested stock-based awards was $14.8 million, which is expected to be recognized over a weighted-average period of 2.87 years.

13. 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 participant's earnings. During the nine months ended September 30, 2023 and 2024, the Company contributed $0.8 million and $1.6 million, respectively, to the 401(k) Plan.

14. Income Taxes

During the nine months ended September 30, 2023 and 2024, the Company did not record income tax benefits for the net operating losses 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 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 September 30, 2024, there were no pending tax examinations. The Company is open to future tax examination under statute by the IRS 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.

15. 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

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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):

	Nine Months Ended September 30,	
	2023	2024
Convertible preferred stock (as converted into shares of Class B common stock)	15,474,597	15,474,610
Stock options to purchase Class B common stock	5,075,232	5,658,801
Warrants to purchase Series C convertible preferred stock	697,874	697,874
Warrants to purchase Class B common stock	3,329,083	2,675,535
Total	24,576,786	24,506,820

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:

	Nine Months Ended September 30,	
	2023	2024
	(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	$ (25,251)	$ (36,648)
Denominator:		
Weighted-average Class A common stock outstanding, basic and diluted	2,989,847	2,956,500
Weighted-average Class B common stock outstanding, basic and diluted	2,023,664	3,258,744
Weighted-average Class C common stock outstanding, basic and diluted	48,918	48,918
Weighted-average Class A, Class B, Class C common stock outstanding, basic and diluted	5,062,429	6,264,162
Net loss per share attributable to Class A, Class B and Class C common stockholders, basic and diluted	$ (4.98)	$ (5.86)

16. 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.

In September 2024, the Company amended its lease for office space and a manufacturing facility in Irvine, California to include two renewal options. The Company is reasonably certain it will exercise one of these options, extending the lease term from May 2027 to June 2032, which has been factored into the lease liability. As the amendment only resulted in the extension of the lease term, it did not meet the criteria to be accounted for as a separate contract. Accordingly, the right-of-use asset and lease liability were remeasured as of the effective date of the amendment, resulting in the recording of an additional right-of-use asset and lease liability of $3.8 million.

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The components of lease expense were as follows:

	Nine Months Ended September 30,	
	2023	2024
	(in thousands)	
Operating lease cost – fixed	$ 732	$ 964
Operating lease cost – variable	102	123
Short-term lease expense	7	13
Total lease expense	$ 841	$ 1,100

Cash paid for amounts included in the measurement of operating lease liabilities was $0.8 million and $0.9 million, respectively, for the nine months ended September 30, 2023 and 2024.

The weighted-average remaining lease term and discount rate were as follows:

	September 30, 2024
Weighted-average remaining lease term	6.57 years
Weighted-average discount rate	6.67%

Future lease payments under non-cancellable leases as of September 30, 2024 were as follows:

(in thousands) Year Ending December 31,	
2024	$ 371
2025	1,484
2026	1,431
2027	904
2028	1,050
Thereafter	4,010
Total future lease payments	9,250
Less: imputed interest	(1,949)
Total lease liabilities	$ 7,301

17. Commitments and Contingencies

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.

Xeris Agreements

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

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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, which was included as a component of research and development expenses in the Company's unaudited condensed statements of operations and comprehensive loss and the Company will pay Xeris a one-time milestone payment of $3.0 million upon its achievement of a certain development milestone event. The milestone was achieved and the payment of $3.0 million was made in November 2024. 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.

In connection with entering into phase 2 of the collaboration, during the nine months ended September 30, 2024, under its clinical supply arrangement the Company ordered clinical material totaling $0.9 million for phase 2 clinical trials and has paid a deposit equal to 30% of the estimated clinical material costs, which is recognized in prepaid expense and other current assets in the unaudited condensed balance sheets.

18. Related Party Transactions

Boston University

Edward Damiano, Ph.D., the Co-Founder and Executive Chairman of the Company, was affiliated with Boston University ("BU") during the execution and amendments of key agreements and currently serves as a volunteer research professor. Under the agreements, BU and Dr. Damiano are entitled to a specified percentage of royalties from net sales of licensed products.

In December 2015, the Company executed hardware and software license agreements with the Trustees of BU under which the Company received exclusive, non-transferable, sublicensable, worldwide, royalty-bearing licenses to certain patent rights and copyrights.

The Company incurred $0.1 million and $1.5 million, respectively, of royalties expense under the control algorithm agreement during the nine months ended September 30, 2023 and 2024, which was included as a component of cost of sales in the Company's unaudited condensed 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 nine months ended September 30, 2023 and 2024, the Company paid BU $0.1 million and $0.2 million, respectively, for reimbursed legal costs in connection with the agreements.

As of December 31, 2023 and September 30, 2024, $0.3 million and $0.6 million, respectively, was due to BU from the Company.

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19. Subsequent Events

The Company evaluated subsequent events through November 22, 2024, which represents the date the condensed financial statements were issued, for events requiring adjustment to or disclosure in the condensed financial statements. The Company has further evaluated subsequent events for disclosure purposes through January 22, 2025. Except as discussed in the footnotes or below, there are no events that require adjustment to or disclosure in the condensed financial statements.

Series E Preferred Stock Issuance

On November 8, 2024, the Company issued a total of 4,352,393 shares of convertible Series E Preferred Stock to multiple investors at a purchase price of $13.79 per share for gross proceeds of approximately $60.0 million.

Xeris Collaboration and License Agreement

On November 8, 2024, the development milestone related to our Collaboration and License Agreement with Xeris was achieved and the Company paid a one-time milestone payment of $3.0 million.

Reverse Stock Split

On January 21, 2025, the Company effectuated a 1-for-1.970 reverse stock split of the Company's issued and outstanding shares of Class A, Class B and Class C common stock, Series A, Series A-2, Series B, Series B-2, Series C, Series D, and Series E preferred stock, as well as stock option awards to purchase shares of Class B common stock and warrants to purchase shares of Class B common stock and Series C preferred stock. Consequently, all issued and outstanding shares of stock, stock option awards, warrants, and per share data have been retroactively adjusted in these financial statements to reflect the reverse stock split for all periods presented. The authorized shares and par value of the common stock and preferred stock remain unchanged. As the number and issuance price of all outstanding preferred stock were adjusted, the conversion ratios for each series of the Company's preferred stock were unchanged. Stockholders entitled to fractional shares as a result of the reverse stock split received cash payment in lieu of receiving fractional shares.

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Through and including February 23, 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.

12,000,000 Shares

Beta Bionics

Common Stock

PROSPECTUS

BofA Securities

Piper Sandler

Leerink Partners

Stifel

Lake Street

January 29, 2025