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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-42491

BETA BIONICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**47-5386878**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11 Hughes Irvine, California	**92618**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (949) 427-7785

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	BBNX	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

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

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

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 30, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the Registrant's Common Stock held by non-affiliates of the Registrant was approximately $631,998,349, based on the closing price of the Registrant's Common Stock on the Nasdaq Global Market on June 30, 2025 of $14.56 per share.

The number of shares of the Registrant's Common Stock outstanding as of February 20, 2026 was 44,382,146.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to its 2026 annual meeting of stockholders (Proxy Statement) are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) 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 Annual Report, 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 under Part I. Item 1A. "Risk Factors" and elsewhere in this Annual Report, 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 geopolitical and macroeconomic factors;

- our financial performance and capital requirements;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others;
- our expected use of our existing cash, cash equivalents and short-term investments; and
- other risks and uncertainties, including those described under Part I. Item 1A. “Risk Factors” in this Annual Report.

These risks are not exhaustive. Other sections of this Annual Report 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 Annual Report 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 Annual Report. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report 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. We intend the forward-looking statements contained in this Annual Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act).

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 Annual Report. 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 Annual Report and the documents that we reference in this Annual Report and have filed as exhibits 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.

SUMMARY OF RISKS RELATED TO OUR BUSINESS

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in Part I. Item 1A. "Risk Factors" in this Annual Report, including 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.
- We have incurred significant operating losses since inception and cannot assure you that we will be able to achieve or sustain profitability.
- Our quarterly and annual financial condition, operating results, cash flows and key business metrics 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.
- We may need to raise additional funds in the future, and these funds may not be available on acceptable terms, if at all.
- The failure of our iLet and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.
- We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration and which may allow them to develop additional products for the treatment of diabetes that compete with our iLet.
- Our results of operations will be harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.
- 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.
- 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.
- 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.
- 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.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- 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.
- Our future growth depends on the continued success, enhancement, and expanded use of the iLet. If we fail to advance the iLet platform or expand its indications, our business may be adversely affected.
- 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 system 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.
- 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.
- 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.
- Healthcare reform measures could hinder or prevent the commercial success of our solutions.
- Uncertainty related to CMS reimbursement policies could adversely affect our pricing and revenue.
- We are substantially dependent on various third parties for the continued development 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 further enhance our iLet and product candidates may be adversely affected.
- 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.
- 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.
- 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 system 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.

PART I

Item 1. 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. Our product, the iLet Bionic Pancreas (iLet), was cleared by the U.S. Food and Drug Administration (FDA) for the treatment of Type 1 diabetes in adults and children six years and older and commercially launched in May 2023 in the United States. Since we began commercializing the iLet, our installed base has grown to 35,011 iLets as of December 31, 2025.

Market Opportunity: Management of Diabetes

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.

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 1.9 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 38 million people with T2D in the United States according to the CDC, of whom an estimated 1.9 million require daily intensive insulin therapy, based on public and industry data.

According to the American Diabetes Association (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.

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 have managed to remove or reduce some "twentieth-century burdens" of disease management (e.g., logbooks, fingerstick measurements, not knowing BG levels for large stretches of the day and night), they have also added new, "twenty-first-century burdens" (e.g., bombardment with overwhelming amounts of data, constant alerts and alarms, and 24/7 information overload). The psychological, emotional and cognitive burden imposed by the continuous need for user engagement to manage the disease is substantial, unsustainable by most and unachievable by many. We believe that the iLet marks a significant breakthrough in the achievement of our ultimate goal, as it has been shown to enable clinically relevant improvements in glycemic control across broad populations of PWD, while dramatically reducing necessary user engagement.

Our Mission: Life-Changing Solutions

Our mission is to simplify and alleviate the burden of managing diabetes with life-changing solutions. Our vision is to make diabetes easier, for everyone, every day. Our goal is to establish the iLet as the standard of care for insulin delivery.

Our Solution: The iLet Bionic Pancreas

The iLet was cleared by the FDA in May 2023 for the treatment of T1D in adults and children six years and older. Unlike hybrid closed-loop systems that still require users to calculate boluses or enter carbohydrate counts, the iLet is the first and only insulin-delivery device that autonomously determines and delivers 100% of all insulin doses. This level of automation establishes an entirely new category in automated insulin delivery (AID)—true fully closed-loop dosing. The iLet's compact design integrates with leading continuous glucose monitors (CGMs) via Bluetooth and features an intuitive app-based interface that provides real-time updates and enables secure data sharing with caregivers, supporting easier and more effective glycemic control with minimal user input.

Figure 1. 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.
- 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.

Our Strategy and Future Technologies

Our strategy to achieve our mission and expand our market share focuses on driving adoption of the iLet through targeted commercialization, superior customer support, operational efficiency, and continued innovation. We are executing a focused commercial approach that leverages our internal sales force to educate PWD and healthcare providers (HCPs) on the benefits of fully autonomous insulin delivery, while building strong customer relationships through responsive service and training programs. Our initial commercial efforts are concentrated in high-volume endocrinology practices, and over time we plan to extend our outreach to primary care settings, where a significant portion of the T1D population is managed and where the iLet's minimal user input requirements may provide meaningful clinical and operational advantages.

Markets and Distribution Methods

We market and distribute the iLet in the United States through a direct commercial organization that includes sales, clinical, and customer support teams. Our commercial focus is centered on endocrinology practices that manage a high concentration of people using intensive insulin therapy, with plans to broaden over time into primary care practices that manage an estimated half of the T1D population. When we are not contracted with a specific health plan for direct fulfillment, we utilize independent distributors to support order processing, benefits investigation, and product delivery.

Our customer-facing infrastructure is designed to support onboarding, training, and long-term retention. We provide comprehensive education programs for patients and healthcare professionals, delivered through certified trainers, virtual resources, and digital tools. Our customer support team provides continuous technical assistance, order support, and product guidance throughout the life of the device. We also engage users, caregivers, and clinicians through community-focused initiatives such as the Bionic Universe, which helps share real-world experiences and informs future product refinements. This integrated commercial, training, and support model is intended to ensure a high quality user experience and strengthen long-term customer loyalty.

Multi-Channel Coverage and Reimbursement Strategy

We are pursuing a multi-channel coverage and reimbursement strategy designed to maximize access to the iLet across the T1D population and provide PWD greater flexibility and affordability in selecting their insulin delivery system. Historically, most insulin pumps have been reimbursed through the durable medical equipment (DME) channel, which continues to cover the iLet for a growing portion of payors. Under this model, patients typically make a significant upfront payment and are eligible for device replacement only after the standard four-year warranty period. While this structure ensures predictable reimbursement for payors, it can create financial and timing barriers that limit adoption of new and more effective technologies.

To expand access beyond the DME coverage, we are working with commercial and government payors to increase availability of the iLet through the pharmacy benefit plan (PBP) channel, which follows a "pay-as-you-go" model. This structure removes large upfront costs and allows more rapid adoption of new innovations, while providing payors the opportunity to capture longer-term healthcare savings through improved disease management and reduced complications. We believe this dual-channel approach improves accessibility for PWD, enhances flexibility for healthcare providers, and increases overall market penetration of the iLet, while positioning us to generate more consistent recurring revenue over the expected life cycle of the device.

Third-Party Reimbursement

In the United States, customer orders for the iLet are typically fulfilled by billing third-party payors on behalf of customers or through our network of distributors that bill payors directly. Historically, most insulin pumps, including the iLet, are eligible for insurance reimbursement for replacement approximately once every four years, though certain health plans may extend this period or impose additional restrictions. We have entered into contracts with national and regional third-party payors to establish reimbursement for the iLet and related supplies, and we continue to expand the number of payors that provide direct coverage under both the DME and PBP channels. If we are not contracted with a prospective customer's payor, and in-network status cannot otherwise be obtained, we seek to fulfill orders through alternate distribution partners where possible. A payor's decision to cover our product does not guarantee an adequate reimbursement rate, and coverage policies or reimbursement levels may change over time. Even if favorable coverage and reimbursement are achieved, future changes in payor policies or healthcare reform measures could adversely affect reimbursement terms or patient access.

Product Development Pipeline and Future Initiatives

We are committed to advancing innovation in automated insulin delivery and expanding the capabilities of the iLet platform to reach more people living with insulin-requiring diabetes. Our research and development initiatives are focused on simplifying diabetes management, improving outcomes, and expanding access through new form factors, additional therapeutic configurations, and future indication expansions.

Patch Pump (Mint)

We are developing Mint, a next-generation, tubeless insulin patch pump designed to provide the same adaptive closed-loop automation of the iLet in a discreet, wearable format. The device features a two-part design, including a reusable controller that houses the electronics and adaptive algorithm paired with a disposable cartridge. The system will be waterproof, smartphone-controlled through iOS and Android applications, and designed for efficient large-scale manufacturing with reduced environmental waste. We expect Mint to expand the addressable insulin delivery market, particularly among people seeking a tubeless form factor reimbursed through the pharmacy channel. Subject to receiving FDA 510(k) clearance as an alternate controller enabled (ACE) pump, we are targeting commercial launch by the end of 2027.

Bihormonal iLet

We are developing a first-of-its-kind bihormonal system of the iLet designed to autonomously deliver both insulin and glucagon using adaptive closed-loop algorithms that determine 100% of all dosing decisions. This system aims to transform diabetes care by actively preventing and correcting both high and low blood glucose levels, potentially eliminating the fear of hypoglycemia that affects many people with T1D. Through an exclusive collaboration and license agreement with Xeris Pharmaceuticals (Xeris), we are developing a pump-compatible, shelf-stable glucagon formulation utilizing Xeris' XeriSol technology. We plan to initiate at least one pre-pivotal and one pivotal clinical trial prior to submitting the device and algorithm for FDA 510(k) clearance and submitting a new drug application (NDA) for the glucagon formulation. If approved, the bihormonal iLet could represent a major advancement in automated glycemic control, reduce challenges associated with diabetes management and expand our reach across a broader diabetes population.

As part of our development plans, in September 2025, we completed a clinical trial in Canada assessing the pharmacokinetics (PK) and pharmacodynamics (PD) of our glucagon product candidate (also referred to as the glucagon asset, and referred to herein as the PK-PD Trial). The completion of the PK-PD Trial enables us to bridge our previous bihormonal clinical data, which tested prior formulations of glucagon in three pre-pivotal inpatient and six pre-pivotal outpatient clinical trials, to our glucagon product candidate. We believe that the results from the PK-PD Trial are supportive of the continued development of our glucagon product candidate for use in our bihormonal system of the iLet.

In the fourth quarter of 2025, we completed our first-in-human Phase 2a feasibility trial in New Zealand evaluating the integrated bihormonal system, including the glucagon formulation, pump, and dosing algorithms. This study represents an important step in the development of the complete bihormonal configuration and is part of our Phase 2 feasibility program. We observed no safety signals related to the glucagon formulation in this study. We expect to initiate an additional Phase 2a feasibility trial in the first half of 2026 to further evaluate the system as we advance development.

We intend to pursue the development of the iLet for expanded patient populations and indications, including people with T2D, which we believe represents a significant long-term opportunity.

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 1.9 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. 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.

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.

Manufacturing and Quality Assurance

We manufacture and assemble the iLet and related insulin cartridges at our facility in Irvine, California, which serves as our primary manufacturing and distribution center. Our facility is designed for scalability, enabling us to meet anticipated commercial demand while maintaining flexibility for future product iterations. Certain components and subassemblies are sourced from qualified third-party suppliers, and we maintain multi-sourcing strategies to help mitigate supply chain risk. We perform final assembly, software installation, functional testing, and quality control internally to ensure each product meets design specifications and performance standards. We believe that controlling our own manufacturing processes provides advantages in quality assurance, cost management, and the ability to rapidly implement design improvements.

We manufacture and assemble the iLet and related supplies using a quality management system designed to meet applicable FDA requirements for medical devices. We are subject to and maintain compliance with ISO manufacturing standards, including ISO 13485 certification, current good manufacturing practices (cGMP), and the relevant Quality Management System Regulation (QMSR) requirements. Our processes cover design controls, supplier oversight, production, verification and release testing, and post-market surveillance. We also utilize external suppliers for certain components and services and apply documented qualification and ongoing monitoring procedures for such suppliers. We are subject to periodic inspections and audits by regulatory authorities to assess compliance with applicable regulations.

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 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 31, 2025, our owned and licensed patent estate contains approximately 67 issued U.S. patents, 20 pending U.S. nonprovisional patent applications, 107 issued foreign patents (including at least 9 issued European patents and their national validations), and 43 pending foreign patent applications. The 107 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 43 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.

Depending on circumstances, we intend to file and prosecute patent applications for our technology in jurisdictions where we believe that patent protection is available and commercially important. Generally, for investigational devices that we believe are appropriate for patent protection, we will attempt to obtain patents in the United States, as well as key markets in Europe. However, depending on circumstances, we may not apply for patents in all or any of those jurisdictions, or we may pursue patent protection elsewhere. We plan to enforce our issued patents and our rights to proprietary information and technology as circumstances permit. We review third-party patents and patent applications in our fields of endeavor, both to shape our own patent strategy and to identify useful licensing opportunities.

Notwithstanding the foregoing, the patent positions of medical device companies, including our company, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent

application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or that any existing or future patent will not be circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. Generally, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent the subject matter covered by each of our pending U.S. patent applications or that we were the first to file either U.S. or non-U.S. patent applications for such subject matter.

If a third party files a patent application relating to an invention claimed in our patent application, we may be required to participate in an interference or derivation proceeding declared by the U.S. Patent and Trademark Office to determine who is entitled to the patent rights. Such a proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court.

Third parties may claim that our products infringe their patents and other intellectual property rights. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product designs, license rights in order to continue manufacturing and selling our products or pay substantial damages. Third party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management's time and effort. Such claims could also cause our customers or potential customers to defer or limit their purchase or use of the affected products until resolution of the claim.

In addition to patents, we rely on trademarks, trade secrets, and know-how relating to our proprietary technology and programs, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position and protect our product brands. As of December 31, 2025, our trademark portfolio consists of six (6) registered trademarks and eleven (11) 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.

These intellectual property statements are subject to a number of risks, uncertainties, factors and assumptions described under Part I. Item IA. "Risk Factors—*Risks Related to Our Intellectual Property*."

License and Collaboration Agreements

Device License Agreement with Boston University

In December 2015, we and Boston University (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 in respect of the licensed patent rights. Additionally, if we assign the Device License Agreement in connection with the sale of all or substantially all of our assets relating to the licensed patent rights, we will be required to pay BU an assignment fee to be agreed on with BU at the time of such assignment.

The Device License Agreement remains in effect for the Licensed Products and Licensed Processes on a country-by-country basis until the expiration, invalidation or termination of the last to expire, terminate, or invalidated licensed patent right, unless earlier terminated by BU. BU may terminate the Device License Agreement (i) for our uncured material breach, including our failure to meet any diligence milestone by the specified achievement date or our failure to make a payment due pursuant to the Device License Agreement, (ii) our breach of certain representations and warranties, (iii) upon our challenge of the validity of the licensed patent rights, or (iv) upon our bankruptcy or insolvency. BU may also terminate the agreement if it determines we are not diligently pursuing commercialization of the Licensed Products. We may terminate the Device License Agreement upon advance written notice to BU.

Control Algorithm License Agreement with Boston University

In December 2015, we and BU entered into a control algorithm license agreement, which was amended in December 2017, September 2020, and February 2022 (collectively, the Control Algorithm Agreement). Under the Control Algorithm Agreement, we received a royalty-bearing license (with the right to sublicense) to (i) make, use, sell, and import products, and practice processes, covered by certain of BU's patent rights related to automated control systems for treatment of T1D and similar conditions, involving monitoring and/or delivering

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

Pursuant to the Control Algorithm Agreement, we agreed to use commercially reasonable efforts to market Licensed Products in the United States and elsewhere in the world.

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, entered into a collaboration and license agreement (Collaboration and License Agreement). Under the Collaboration and License Agreement, we received a worldwide, exclusive, royalty-bearing, sublicensable license under certain patent rights and know-how related to Xeris' proprietary non-aqueous formulation technology and technology developed during the collaboration (Xeris Technology) to

develop and commercialize glucagon products that are reformulated using the Xeris Technology and developed by Xeris under a development plan under the Collaboration and License Agreement for use in a pump product or system for glycemic control (Glucagon Products) in the field of chronic glycemic control in diabetes mellitus, excluding single-dose, one-time use form for treatment of severe hypoglycemia and diagnostic uses (Field). We also received a worldwide, exclusive, sublicensable manufacturing license under the Xeris Technology to manufacture Glucagon Products in the Field following a future manufacturing transfer date to be agreed with Xeris and subject to a separate commercial supply agreement.

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

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

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

In consideration for the licenses and other rights granted to us under the Collaboration and License Agreement, we paid Xeris a one-time payment of $0.5 million for upfront fees and an additional $3.0 million upon our achievement of certain development milestone events. 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, 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.

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, 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 following the first commercial sale of the Libre-Beta System in the United States. We or Abbott may also terminate the Development and Commercialization Agreement (i) for the other party's material breach, (ii) upon the other party's bankruptcy or insolvency, or (iii) if the other party is acquired by or merges with any one of certain named competitors. In addition, if the first commercial sale of the Libre-Beta System has not occurred by a specified date, then either party may terminate the Development and Commercialization Agreement on written notice to the other party.

Government Regulation and Product Approval

Our products and operations are subject to extensive regulation by the FDA, and other federal and state authorities in the United States, as well as comparable authorities and bodies in foreign jurisdictions. Our products are subject to regulation as drugs and medical devices in the United States under the federal Food, Drug, and Cosmetic Act (FDCA), as implemented and enforced by the FDA.

FDA Regulation of Medical Devices

The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices to ensure medical devices distributed in the United States are safe and effective for their intended uses and otherwise meet the requirements of the FDCA:

- product design, development and manufacturing;
- pre-clinical and clinical testing, labeling, content and language of instructions for use and storage;
- product safety;
- marketing, sales and distribution;
- pre-market clearance or approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

FDA Pre-Market Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States must first receive 510(k) clearance, *de novo* classification, or approval of a pre-market approval (PMA) application from the FDA, unless specifically exempted. Both the 510(k) clearance and PMA processes can be resource intensive, expensive and lengthy, and require payment of significant user fees, unless an exemption is available.

The FDA classifies medical devices into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QMSR, 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 ACE insulin infusion 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 of PMA applications, or is a device that has been reclassified from Class III to either Class II or I. In rare cases, Class III devices may be cleared through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months from the date the application is submitted and filed with the FDA, but may take significantly longer, particularly for a novel type of product. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification submission, the FDA may request additional information, including clinical data, which may significantly prolong the review process.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. Once a *de novo* application is reviewed and approved, it results in the device having a Class II status and future devices from the company or a competitor may use the company's *de novo*-classified device as a 510(k) predicate.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA is obtained. Under these circumstances, the FDA may also subject a manufacturer to significant regulatory fines or other penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult and costly for manufacturers to utilize the 510(k) clearance process for their products.

De Novo Classification Process

Devices of a new type that FDA has not previously classified based on risk are automatically classified into Class III, regardless of the level of risk they pose. However, the FDA may authorize such novel devices that are low- to moderate-risk through the *de novo* classification process. A medical device may be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent or a manufacturer may request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 days following receipt of the de novo application, although in practice, the FDA's review may take significantly longer.

When FDA grants a request for de novo classification, the device is granted marketing authorization and can serve as a predicate for future devices of that type, through a 510(k) premarket notification.

Pre-market Approval Process

A PMA application must be submitted and approved prior to marketing if the medical device is in Class III (although the FDA has the discretion to continue to allow certain pre-amendment Class III devices to use the 510(k) process) or cannot be cleared through the 510(k) process. A PMA application must be supported by, among other things, extensive technical, preclinical, and clinical trials, as well as manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. In addition, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision-making process. Further, the FDA generally will conduct a pre-approval inspection of the manufacturing facility(ies) to evaluate compliance with QMSR, 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 QMSR requirements, except for the QMSR's complaint handling and recordkeeping requirements.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components, that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the device product, the FDA center responsible for premarket review of the device product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a device primary mode of action generally would be reviewed and cleared or approved pursuant to the device review processes under the FDCA. In reviewing the PMA, 510(k), or De Novo request for such a product, however, FDA reviewers in the device center could consult with their counterparts in the drug center to ensure that the drug component of the combination product met applicable requirements regarding safety and effectiveness. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the QMSR applicable to medical devices.

Clinical Trials

Clinical trials are almost always required to support a PMA or *de novo* classification and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE) regulations, which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Although the QMSR 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

The Breakthrough Devices Program, is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for PMA approval, 510(k) clearance and de novo classification.

The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients.

Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions.

Post-Market Regulation of Medical Devices

After a medical device is placed on the market, numerous FDA regulatory requirements apply, including, but not limited to the following:

- the QMSR, 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 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 QMSR 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 NDAs warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves nonclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application (IND), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically take many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not issued a clinical hold within this 30-day period, the clinical trial may begin. Clinical trials involve the administration of the investigational drug to healthy volunteers or patients

under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practice (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (iii) under protocols detailing the objectives of the trial and the criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into patients, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by confirmatory evidence.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee unless a waiver applies. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of NDAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the NDA; most applications classified as Priority Review are reviewed within six months of the date the FDA files the NDA. An NDA can be classified for Priority Review when the FDA determines the drug has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three or more additional months to consider certain late-submitted information or information intended to clarify information already provided in the NDA submission. Most innovative drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDCA, commonly referred to as a traditional or "full NDA." In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, that established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of

a traditional NDA and a generic drug application. Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing approved product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products that would require new clinical data to demonstrate safety or effectiveness. Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate or reduce the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. The FDA may also require companies to perform additional studies or measurements, including nonclinical and clinical studies, to support the change from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved NDA, including changes in indications, product labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or supplement to an approved NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original NDAs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and

surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a drug's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Regulatory Exclusivity and Approval of Follow-on Products

Hatch-Waxman Exclusivity

In addition to enacting Section 505(b)(2) of the FDCA as part of the Hatch-Waxman Amendments to the FDCA, Congress also established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA) to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD).

In order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Unlike the 505(b)(2) NDA pathway that permits a follow-on applicant to conduct and submit data from additional clinical trials or nonclinical studies in order to support the proposed change(s) to the reference product, the ANDA regulatory pathway does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data.

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

As part of the NDA review and approval process, applicants are required to list with the FDA each patent that has claims that cover the applicant's product or method of therapeutic use. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential follow-on competitors in support of approval of an ANDA or 505(b)(2) NDA.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the follow-on applicant does not challenge the innovator's listed patents, the FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

An ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivities listed in the Orange Book for the referenced product have expired. The Hatch-Waxman Amendments to the FDCA provided a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity (NCE). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of data exclusivity if an NDA or NDA supplement includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, an applicant submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

A patent claiming a prescription drug for which FDA approval is granted may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The restoration period granted on a patent covering a new FDA-

regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for premarket approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. However, the restoration period can be reduced for any time the FDA determines that the applicant did not diligently pursue approval. In addition, patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the marketing approvals. The United States Patent and Trademark Office (USPTO) reviews and approves the application for any patent term extension or restoration in consultation with the FDA. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

Foreign Government Regulation

The regulatory review processes for medical devices and drugs varies from country to country, and many countries also impose product standards, packaging requirements, environmental requirements, labeling requirements and import restrictions on devices. Each country has its own tariff regulations, duties, and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject a company to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, criminal prosecution or other consequences.

Other Healthcare Laws

Our current and future business activities are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims and healthcare professional payment transparency laws and regulations.

The federal Anti-Kickback Statute (AKS) prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual, for an item or service or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation.

Additionally, the civil False Claims Act (FCA) prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment to, or approval by, the U.S. government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the

action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of life sciences companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil FCA. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The majority of states also have analogous laws which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, which impose, among other things, requirements on certain covered HCPs, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the 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 amendments that have impacted certain aspects of the ACA. For example, on August 16, 2022, 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. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expiring ACA subsidies. It is possible that the ACA and the IRA will be subject to additional challenges and health reform measured by the second Trump administration 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. For example, the current Trump administration is pursuing policies to reduce regulations and expenditures across government including at the Department of Health and Human Services (HHS), the FDA, the Centers for Medicare & Medicaid Services (CMS), and related agencies. These actions include, for example, (1) directives to reduce agency workforce and cut programs; (2) eliminating the Biden administration's executive order that directed HHS to establish an AI task force and develop a strategic plan; and (3) directing certain federal agencies to enforce existing law regarding hospital and price plan price transparency by standardizing prices across hospitals and health plans. It is possible that certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Coverage and Reimbursement

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

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and devices they will cover and the amount of reimbursement. Coverage may be more limited than the purposes for which the drug or device is approved by the FDA or comparable foreign regulatory authorities. In the United States, CMS, an agency within HHS, determines whether and to what extent a new drug or device will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for products exists

among third-party payors. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for the iLet, in either configuration for T1D or other indications, the resulting reimbursement payment rates might not be adequate for us to maintain pricing sufficient to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations. It is also possible that CMS and other third-party payors may continue to review and modify the current coverage and reimbursement of diabetes-related products in connection with anticipated changes to the regulatory approval process for insulin pumps and related products, software applications and services. Patients are unlikely to use our devices, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. Because the iLet may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, coverage and reimbursement rates may be inadequate for us to achieve profitability. Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products. Further, it is possible that some third-party payors will not offer any coverage for iLet or our future products. For instance, it is possible that third-party payors may adopt policies in the future that designate one or more of our competitors as their preferred, in-network provider of insulin pumps and that such policies would discourage or prohibit the payors' members from purchasing our products, which would adversely impact our ability to sell the iLet.

We are pursuing a multi-channel managed care strategy through both traditional DME and PBP channels. If covered, the iLet is typically reimbursed through traditional medical benefit channels. As a medical device company, reimbursement from government and/or commercial third-party healthcare payors, including Medicare and Medicaid, is an important element of our success. Our product is eligible for Medicare coverage as DME under Medicare Part B. Coverage criteria for DME is determined by CMS under national coverage determinations as well as by local Medicare Administrative Contractors under local coverage determinations. Therefore, Medicare reimbursement for the iLet is subject to various coverage conditions. We are also offering the iLet through the PBP channel. However, the commercial opportunity in the PBP channel may be limited unless a substantial portion of the sales price for the iLet is covered by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, federal and state government healthcare agencies, intermediaries, Medicare, Medicaid and other managed care providers. Medicare Part D plan sponsors may provide coverage for iLet under the Medicare Part D prescription drug program, which requires negotiating with third-party payors in order to provide iLet through the PBP channel in the United States. Securing and retaining adequate coverage or reimbursement for the iLet and our future products by third-party payors, and expedient processing approvals by those payors, is necessary for sales and the health of our business, financial condition and operating results.

The BIOSECURE Act

The United States recently passed legislation, namely the BIOSECURE Act (BIOSECURE Act), to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service

produced or provided by a "biotechnology company of concern" or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology equipment or equipment. Specifically, on October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE Act as an amendment to the National Defense Authorization Act (NDAA) for Fiscal Year 2026. The final version of the NDAA containing this legislative language was passed by the Senate and House of Representatives and signed into law by President Trump on December 18, 2025. The BIOSECURE Act prohibits the U.S. government from procuring or obtaining biotechnology equipment or services produced or provided by a "biotechnology company of concern" (BCC); entering into, extending, or renewing government contracts with an entity that directly or indirectly uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The BIOSECURE Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. Companies designated as a BCC include those that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. government also has the ability to designate entities as BCCs through a separate designation process. Given the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology companies to the extent we would contract with, or otherwise receive funding from, the U.S. government.

Data Privacy and Security

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 Telephone Consumer Protection Act (TCPA), Children's Online Privacy Protection Act (COPPA), the Controlling the Assault of Non-Solicited Pornography and Marketing Act (CANSPAM), the California Consumer Privacy Act (CCPA), Washington's My Health My Data Act (MHMD), the European Union General Data Protection Regulation (EU GDPR) and the United Kingdom General Data Protection Regulation (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.

Moreover, cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work (including our current and future contract research organizations (CROs)). Such threats are prevalent, 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, sophisticated nation states and nation-state supported actors, including via advanced persistent threat intrusions. If we (or the third parties with whom we work)

experience a security incident or are perceived to have experienced a security incident, we could face adverse consequences.

Licensure

To distribute our product through the pharmacy channel in the United States, we rely on intermediaries that hold the pharmacy licenses required in each jurisdiction. Certain states impose professional licensure requirements on individuals who provide diabetes education and related support. We believe our certified diabetes educators operate in compliance with these requirements, but if our educators or our company were found to be non-compliant, we may be required to modify how we deliver education, clinical support, or customer service.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. individuals and corporations, as well as their representatives from, directly or indirectly offering, promising, authorizing or making corrupt payments, gifts or transfers of anything of value 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. 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.

Facilities

Our principal office is located in Irvine, California, where we lease approximately 50,000 square feet of office, laboratory and manufacturing space. We lease and sublease additional corporate offices in San Diego, California that consist of approximately 21,000 square feet of office space. We also lease corporate offices in Concord, Massachusetts that consist of approximately 13,000 square feet of office space. The lease for our office, laboratory and manufacturing space in Irvine, California expires in June 2032, the lease and sublease for our offices in San Diego, California expires in February 2027 and August 2028, respectively, 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, 2025, we had 420 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 equity incentive program, and employee stock purchase plan 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.

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. Information contained on, or accessible through, our website shall not be deemed incorporated into, and is not a part of, this Annual Report. We have included our website in this Annual Report solely as an inactive textual reference.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act are available on our website, free of charge, as soon as reasonably practicable after the reports are electronically filed or furnished to the Securities and Exchange Commission, or SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information that we file with the SEC electronically.

We intend to announce material information to the public through filings with the SEC, the investor relations page on our website, which is located at www.betabionics.com, press releases, public conference calls, and public webcasts. The information disclosed through the foregoing channels could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels. The information we post through these channels is not a part of this Annual Report. Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.

Item 1A. 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 Annual Report, 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, 2025 and 2024, our net losses were $73.2 million and $54.8 million, respectively. As of December 31, 2025, we had an accumulated deficit of $369.9 million. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing and business operations, the clinical and regulatory initiatives to maintain and obtain marketing clearance, and the research and development of our current products and product candidates.

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

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

Our quarterly and annual financial condition, operating results, cash flows and key business metrics 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, cash flows and key business metrics 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.

Furthermore, we may change our key business metrics or how we present our key business metrics from time to time, which may be perceived negatively. We regularly evaluate whether our key business metrics remain meaningful indicators of the performance of our business. As a result of these evaluations, we may make additional changes in the future to our key business metrics, including eliminating or replacing existing metrics. For example, in February 2026, we announced that we will no longer provide an exact quarterly new patient starts figure to better align our disclosure practices with industry peers. If investors or the media perceive any changes to our key business metrics disclosures negatively, our business could be adversely affected.

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 under Part II. Item 7. “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, results of operations or key business metrics 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;
- 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, 2025, our top four DME distributors represented approximately 52% 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, 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.

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 December 31, 2025, our cash, cash equivalents and short-term investments were $219.2 million. In January 2025, we completed our initial public offering and a concurrent private placement, pursuant to which we received aggregate net proceeds of approximately $190.4 million and approximately $15.6 million, respectively, in each case after deducting underwriting discounts, commissions, and other offering expenses. Based on our current and planned use of the net proceeds of our initial public 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;
- 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 system), the iLet for T2D and the patch pump;
- future revenue generated by sales of the iLet and any future products or 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 our initial public 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, 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, tariffs and other trade measurers, inflation, interest rates, liquidity concerns at, and failures of, banks and other financial institutions, changes in monetary and fiscal policy and U.S. political developments and other sources of instability. If the equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Market volatility may further adversely impact our ability to access capital as and when needed.

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

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or iLet.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our iLet, we expect to finance our future cash needs through public or private equity offerings, debt financings, strategic collaborations and other strategic arrangements with third parties, or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

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

Risks Related to Our Business, Strategy and Industry

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

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

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

- the failure of our products to achieve and maintain wide acceptance among people with insulin-dependent diabetes, their caregivers, HCPs, third-party payors and key opinion leaders in the diabetes treatment community;
- PWD experience and satisfaction of our products;
- PWD preference for management of T1D;
- lack of evidence supporting the safety, effectiveness, ease-of-use or other perceived benefits of our products over competing products or other currently available insulin treatment methodologies;
- perceived risks or uncertainties associated with the use of our products, or components thereof, or of similar products or technologies of our competitors;
- adverse regulatory or legal actions or developments relating to our insulin delivery device product or to similar products or technologies; and
- results of clinical trials relating to our existing product or product candidates or to similar competitive products.

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

If our insulin delivery device products do not achieve and maintain widespread market acceptance, we may fail to achieve sales or other business metrics 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. 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 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 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 under Part I. Item 1. "Business—Market Opportunity: Management of Diabetes." 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 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, procedures, drugs, and other therapeutics for the monitoring, treatment, and/or prevention of insulin-dependent diabetes. In addition, we face competition from a number of companies, medical researchers and pharmaceutical companies that either offer or are pursuing competing delivery devices, technologies and procedures, such as smart insulin pens and inhalable insulin products, as well as companies with approved therapeutics or in-development therapeutic candidates impacting diabetes.

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

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

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

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

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

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

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

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

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

We and the third parties with whom we work are subject to a variety of evolving threats, including, but not limited to, social-engineering attacks (including through deep fakes, are 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. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

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

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

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

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

The FDA has warned that insulin pumps may have cybersecurity vulnerabilities and could be manipulated by hackers, causing danger to PWD. Successful exploitation of any security vulnerabilities in our iLet products may allow attackers to gain access to the iLet to intercept, modify or interfere with the wireless radio frequency communications to or from our iLet products which could allow attackers to read sensitive data, change pump settings or control insulin delivery. While we take steps designed to detect, mitigate, and remediate vulnerabilities in our iLet product and information systems (such as our hardware and/or software, including that of third parties with whom we work), we have not, and may not in the future, detect and remediate all such vulnerabilities including on a timely basis. Further, we have and may in the future experience delays in deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Certain of the previously identified or similar threats have in the past and may in the future 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. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future.

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, 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 system 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, 2025, we had 420 full-time employees and 3 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 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. 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. Our future success depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of our medical device products, and for the advancement of our preclinical and clinical development programs. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty.

We source significant quantities of the iLet's components from international suppliers, with substantial reliance on foreign manufacturers, including China. While we currently benefit from tariff exemptions under the Nairobi Protocol for custom components used in the iLet and related supplies, any changes to these exemptions or broader tariff policies, particularly those affecting medical device imports from China, could materially increase our manufacturing costs and reduce our profitability, as a result of our inability to adjust pricing in formulary-based markets. Recent and potential future changes in international trade policies, particularly regarding U.S.-China trade relations and medical device-specific tariffs, present material risks to our operations and financial performance.

The ongoing trade tensions between the United States and China have resulted in multiple rounds of tariffs affecting medical device components, manufacturing equipment, and related supplies. Although tariffs on medical device components remain a risk, our current exemption for custom components under the Nairobi Protocol mitigates this exposure. However, if this exemption were to be rescinded or if new targeted tariffs were enacted that apply to our products or inputs, our manufacturing costs could increase significantly, and it would be difficult and costly to qualify alternative sources within another country with a lower tariff rate or within the United States, as developing and qualifying alternative sources takes significant time, substantial investment and regulatory approvals. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at medical device products and ingredients as part of broader healthcare cost control or national security initiatives.

Unlike many industries, our ability to pass increased costs to customers is limited by the structure of medical device pricing and reimbursement systems. Our product pricing is established through annual or multi-year contracts with commercial, third-party payors, customers and group purchase organizations, and reimbursement methodologies established by government programs, such as Medicare. These arrangements typically include fixed pricing terms that were negotiated prior to the implementation of the recently announced tariffs. As a result, and depending on the timing and scope of the implementation of these tariffs, cost increases due to tariffs may be difficult or impossible to pass through to customers until the next negotiation cycle, which could be up to 36 months away.

Future tariffs may also result in increased research and development expenses, including but not limited to increased costs associated with laboratory equipment and research materials. Trade restrictions affecting the import of materials, including components of the bihormonal system of the iLet and patch pump, necessary for clinical trials and manufacturing could result in delays to our timelines. Increased costs and extended timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, results of operations, financial condition and growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign

governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Annual Report.

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 system for the treatment of T1D or for any future indications we may pursue. Further, as we develop a bihormonal system 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 system. We expect that the bihormonal system 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 system for the treatment of T1D or for other indications we may pursue, or seeking initial marketing authorization or clearance for any of our other product candidates;

- receipt and maintenance of marketing authorizations or clearances from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our iLet;
- making arrangements with third-party manufacturers and ensuring such third-party manufacturers supply sufficient quantities of components of our products and product candidates;
- scaling up our manufacturing capabilities, for both commercial and clinical supplies of our products and product candidates;
- entry into collaborations to further the development of our iLet's capabilities;
- expanding sales, marketing and distribution capabilities as we continue our commercialization efforts of the iLet, whether alone or in collaboration with others;
- successfully launching commercial sales of the iLet, patch pump and any other product candidate, if authorized for marketing or cleared;
- acceptance of our products by PWD, the medical community and third-party payors;
- maintaining a continued acceptable safety profile following marketing authorization or clearance;
- maintaining regulatory compliance;
- effectively competing with other treatment options and the availability, perceived advantages, relative cost, relative safety and relative effectiveness of alternative and competing treatments;
- the emergence of competing technologies and other adverse market developments, and our need to enhance existing products and/or develop new products to maintain market share in response to such competing technologies or market developments;
- maintaining healthcare coverage and adequate reimbursement from third-party payors;
- continuing to build and maintain an organization of people who can successfully develop our products; and
- enforcing and defending intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are not successful in commercializing our iLet or obtaining marketing authorization or clearance for the iLet in its bihormonal system 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 system 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 system for the treatment of T1D or for any future indication we may pursue, the patch pump, the investigational glucagon product, or any other development-stage products. If we are unable to continue commercializing the iLet for T1D, or if we are unable to develop, or obtain marketing authorization or clearance for, or, if authorized for marketing or cleared, successfully commercialize the iLet for the treatment of any future indications, we may not be able to generate sufficient revenue to continue our business.

We are subject to a post-market surveillance order issued by the FDA for our iLet. If the FDA determines that our iLet does not perform as anticipated, or if the FDA identifies new concerns related to the safety and

effectiveness of the device, we may need to make changes to or recall or withdraw the iLet from the field, which could harm our business.

The FDA has notified us that the iLet is subject to a mandatory post-market surveillance order under Section 522 of the FDCA, which authorizes the FDA to require a manufacturer to conduct post-market surveillance for devices that meet certain criteria. 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 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. As part of the FDA's request to conduct a post-market surveillance study, the FDA set forth several criteria to evaluate the iLet in a large and diverse patient population, as well as different real-world use settings including the use of features that are unique to the iLet (i.e., lack of conventional open-loop mode, BG-run feature, body weight only initialization, handling unannounced meals, and use of the lower and higher glucose targets). The FDA accepted our post-market surveillance plan, enrollment began in April 2025, and we continued to enroll patients through December 31, 2025.

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 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 system. The FDA may ultimately determine that the 510(k) pathway is not appropriate for the bihormonal system 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 system if it proceeds into a pivotal trial. Obtaining a PMA is generally more costly and uncertain than the 510(k) clearance process or the de novo classification process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained, if ever. Additionally, even though the FDA determined that the 510(k) pathway was appropriate for the iLet for insulin-only delivery, different components of the system will require individual marketing authorizations and review of individual components can vary. For example, our iLet Dosing Decision Software utilized in the iLet required a separate 510(k) clearance. If the FDA requires us to go through a lengthier, more rigorous examination for our product candidates or for modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business. The FDA can delay, limit or deny marketing authorization or clearance of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our product candidates are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA with the design or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse effects experienced by participants in our clinical trials;

- the data from our preclinical studies and clinical trials may be insufficient to support clearance, de novo classification or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

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

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

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

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

- we may be required to submit an IDE application or 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 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 GCPs;
- unforeseen safety issues;
- malfunctioning of devices;
- inability to monitor subjects adequately during or after treatment;
- difficulty monitoring multiple trial sites;
- the FDA requiring alterations to any of the study designs, our nonclinical strategy or our manufacturing plans;
- failure of third-party clinical trial sponsors conducting studies of our products or clinical trial vendors to satisfy their contractual duties, comply with regulations, or meet expected deadlines; and
- determination by regulators that the design of a clinical trial is not adequate.

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

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

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

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

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices and drugs produced under current good manufacturing

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

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

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

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

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

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

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

The use of the iLet and any of our product candidates could be associated with adverse events or serious adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics associated with our products and product candidates. Undesirable side effects, whether observed in clinical trials or in connection with the commercial use of our products, could also affect patient

recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. The risks are associated with hypoglycemia and hyperglycemia. We report all severe hypoglycemia and all DKA events that we are aware of. Our rates of severe hypoglycemia and DKA are similar to those reported for other AID systems currently on the market and to the rates that were observed in the investigator-initiated iLet Bionic Pancreas Pivotal Trial.

Unacceptable safety concerns caused by our commercial or development-stage products could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label, or the delay or denial of required marketing authorizations or clearances.

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

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

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

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

The ability to obtain marketing authorization and to commercialize our iLet in its bihormonal system requires FDA approval of a glucagon product for chronic use and to obtain marketing authorization of the bihormonal system 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 we will develop a glucagon product utilizing Xeris’ XeriSol technology for use in our iLet in its bihormonal system. In September 2025, we completed the PK-PD Trial in Canada. We believe that the results from the PK-PD Trial are supportive of the continued development of our glucagon product candidate for use in our bihormonal system of the iLet. We are highly dependent on the approval of such glucagon product to be able to successfully commercialize our iLet in its bihormonal system 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.

We have conducted, and may conduct additional, clinical trials for our glucagon product candidate outside the United States and the FDA may not accept data from such trials.

We have conducted a clinical trial of our glucagon product candidate in Canada and we may conduct additional clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such trial data by the FDA is subject to certain conditions. For example, the clinical trial must be conducted in accordance with GCPs requirements and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted.

There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our development plan. In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- difficulties staffing and managing foreign operations;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including value-added tax, withholding and payroll taxes;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;

- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- impact of geopolitical events or a public health crisis on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- potential liability under the Foreign Corrupt Practices Act of 1977, as amended, or comparable foreign regulations; and
- diminished protection of intellectual property in some countries.

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 system of the iLet for the treatment of T1D, as described in this Annual Report. 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 system of our iLet.

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

The ability of the FDA to review and authorize the sale of new products can be affected by a variety of factors, including government budget and funding levels; its ability to hire and retain key personnel and accept the payment of user fees; statutory, regulatory, and policy changes; and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, including executive and congressional priorities, the impacts of which are 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. More recently, such agencies, including the FDA, have conducted layoffs and may, from time to time, conduct additional layoffs. If a prolonged government shutdown or significant layoffs occur, 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. In addition, the current administration has proposed substantial reductions in force at various government agencies that, if applied to the FDA in a material way, could significantly reduce the FDA's capacity to perform its functions in a manner consistent with its past practices and could negatively impact our business.

Our future growth depends on the continued success, enhancement, and expanded use of the iLet. If we fail to advance the iLet platform or expand its indications, our business may be adversely affected.

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

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

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

While we have commercialized the iLet as an automated insulin dosing system cleared for the treatment of T1D in adults and children six years of age and older, we may not be successful in expanding the configurations or indications and developing and commercializing new product enhancements. This could negatively impact our

ability to achieve and maintain market share and increase our revenue, which could have a material adverse effect on our business, financial condition and results of operations.

Maintaining regulatory clearance for our iLet as an automated insulin dosing system for the treatment of T1D and obtaining and maintaining marketing authorization or clearance for a bihormonal system 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 system 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 CMS, an agency within the 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;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

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

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

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly authorized products and, as a result, they may not cover or provide adequate payment for our commercialized devices. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We may experience pricing pressures in connection with the sale of any of our products due to the shift toward value-based healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and legislative changes, 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, and increased volatility due to international trade policies, including tariffs, sanctions and trade barriers. 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 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 amendments that have impacted certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (the IRA) was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expiring ACA subsidies. It is possible that the ACA and the IRA will be subject to additional challenges and health reform measures by the second Trump administration in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act" (OBBBA) was signed into law, which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. The OBBBA also narrows access to the ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

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. For example, the current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions include, for example, (1) directives to reduce agency workforce and cut programs; (2) eliminating the Biden administration's executive order that directed HHS to establish an AI task force and develop a strategic plan; and (3) directing certain federal agencies to enforce existing law regarding hospital and price plan price transparency by standardizing prices across hospitals and health plans. It is possible that 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.

Uncertainty related to CMS reimbursement policies could adversely affect our pricing and revenue.

CMS regularly evaluates and updates reimbursement frameworks for medical devices, and these changes can directly affect both our revenue and the broader market. On December 2, 2025, CMS issued a final rule that updates Medicare payment policies and rates for home health agencies under the Home Health Prospective Payment System Proposed Rule for calendar year 2026, which includes provisions that materially alter reimbursement policies for insulin pumps supplied to Medicare fee-for-service beneficiaries, including bundling payment for certain continuous

glucose monitors, insulin infusion pumps, and accessories on a monthly rental basis, among other changes. Because CMS reimbursement policies often serve as a benchmark for other government and commercial payors, adoption of this rule in its proposed or modified form could increase uncertainty around pricing, limit coverage or reimbursement levels for our products, and reduce utilization. Any such outcomes could negatively impact demand for our products, put downward pressure on pricing, and adversely affect our revenue and results of operations.

Risks Related to Manufacturing and Our Reliance on Third Parties

We are substantially dependent on various third parties for the continued development 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 further enhance 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 system (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. 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;

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

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

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

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

- quality or reliability defects in product components that we source from third-party suppliers, including the suppliers of our infusion sets, pump motors and cartridge connectors used in the iLet;
- our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently develop and manufacture new products or implement any necessary or desired changes in response to regulatory requirements; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facilities.

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

Following FDA clearance of the iLet as an automated insulin dosing system for the treatment of T1D in adults and children six years of age and older, we have had to invest additional resources in purchasing components, hiring

and training employees and enhancing our manufacturing processes and quality systems. We have also needed to increase our utilization of third parties to perform contracted manufacturing services for us, and have acquired additional custom designed equipment to support the expansion of our manufacturing capacity. If we fail to adequately meet commercial requirements while also maintain product quality standards, we may fail to maintain our regulatory clearance and efficiently manage costs, and our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

Further, since 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, when our current lease expires, 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, a supplier quality agreement with Maxon Precision Motors, Inc. (Maxon) for the supply of pump motors for our iLet and a supplier quality agreement with Matrix Plastic Products, Inc. (Matrix) for the supply of boards for our iLet. Unomedical, PMC, Maxon and Matrix are our main suppliers of infusion sets, cartridge connections, pump motors and boards, respectively. If any of Unomedical, PMC, Maxon or Matrix were to terminate its contract with us, or be unable to provide infusion sets, manufacture cartridge connectors, supply pump motors, or supply boards to us in the quantities ordered, we would need to identify and qualify a new supplier.

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

We do not currently have long-term supply agreements with the suppliers of most of our components, and, in most cases, we purchase these components on a purchase order basis. Although we are in active discussions to enter into long-term supply agreements for certain components, there is no assurance we will be able to enter into such agreements on commercially reasonable terms in a timely manner, if at all. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations and equipment malfunction and

environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

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

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

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

We may also have difficulty obtaining components from other suppliers that are acceptable to the FDA or other regulatory authorities and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination or interruption of distribution, operating restrictions, product seizures, delays in obtaining marketing authorization or clearance for our product candidates, suspension or withdrawal of clearances or certification, fines, civil penalties, or criminal prosecution. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional

marketing authorizations or clearances. Any disruption of this nature, or any increased expenses associated with any such disruption, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and have a material adverse impact on our operating results.

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

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

To the extent that we do not achieve and maintain our projected yields or product reliability, our business, operating results, financial condition and customer relationships would be adversely affected. We provide warranties on our product sales, and reserves for estimated warranty costs are recorded during the period of sale. The determination of such reserves requires us to make estimates of failure rates and expected costs to repair or replace the products under warranty. If actual repair and replacement costs differ significantly from our estimates, adjustments to cost of sales may be required in future periods which could have an adverse effect on our results of operations. Our customers may discover defects in our products only after initial use. In addition, some of our products include components from other vendors, which may contain defects. As a result, should problems occur, it may be difficult to identify the source of the problem. If we are unable to identify and fix defects or other problems, we could experience, among other things:

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

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

At the time revenue is recognized, we establish an accrual for estimated warranty expenses based on historical data and trends of product reliability and costs of repairing and replacing defective products. We exercise judgment in estimating the expected product warranty costs, using data such as the actual and projected product failure rates, estimated repair costs, freight, material, labor and overhead costs. While we believe that historical experience provides a reliable basis for estimating such warranty cost, unforeseen quality issues or component failure rates

could result in future costs in excess of such estimates, or alternatively, improved quality and reliability in our products, including our single-use products, could result in actual expenses that are below those currently estimated. As of December 31, 2025, we accrued approximately $3.2 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.

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

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

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

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

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

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

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

We and third-party collaborators are required to comply with all applicable regulations governing clinical research, including 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 system of the iLet. Furthermore, our third-party collaborators may be delayed in conducting trials of our iLet for reasons outside of their control.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to clinical protocols or regulatory requirements or for other reasons, the non-clinical development activities or clinical trials for our iLet for other configurations or indications may be

extended, delayed, suspended or terminated, and we may not be able to obtain marketing authorization or clearance for, or successfully commercialize, the iLet or any future investigational devices on a timely basis or other development-stage products, such as the glucagon product candidate, if at all, and our business, results of operations, financial condition and growth prospects may be adversely affected.

Risks Related to Government Regulation

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

Once we obtain marketing authorization or clearance for FDA-regulated products, such as our iLet and any future products, we and such products will be subject to continued and pervasive regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies governing, among other things, the manufacture, marketing, advertising, reporting, sale, promotion, import, export, registration, and listing of our products. For example, medical device manufacturers must submit periodic reports to the FDA as a condition of obtaining marketing authorization or clearance. These reports include information about failures and certain adverse events associated with the device after its marketing authorization or clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. In particular, unless exempt, we and our suppliers are required to comply with the FDA's QMSR 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 QMSR 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 QMSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In addition, the FDA may change its marketing authorization or clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization or clearance of any product candidate under development or impact our ability to modify any products authorized for market on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain marketing authorizations or clearances, increase the costs of compliance or restrict our ability to maintain any marketing authorizations or clearances we have obtained. For example, in February 2024, the FDA issued a final rule to amend and replace the former Quality System Regulation, which set 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 went into effect on February 2, 2026, established the 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 former Quality System Regulation, 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 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. Additionally, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects.

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. 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.

In June 2025, the FDA conducted an inspection of our Irvine, California facility. Following the inspection, the FDA issued a Form 483. We initiated remediation activities and followed our communicated plan to address the FDA's observations. We submitted our response and provided multiple updates to the FDA regarding the status of our remediation efforts. On January 29, 2026, we received a Warning Letter from the FDA following such inspection. In the Warning Letter, the FDA cited deficiencies in the response letters we sent to the FDA following the FDA's issuance of the Form 483. The Warning Letter highlights non-conformities related observed by the FDA in relation to our Quality Management System, Medical Device Reporting, and Correction and Removals, which were previously communicated by the FDA in the Form 483. The Warning Letter does not restrict our ability to produce, market, manufacture or distribute our products, nor does it restrict our ability to seek FDA 510(k) clearance of new products. We take the observations described in the Warning Letter seriously, and we are currently preparing a written response to the Warning Letter. Several corrective actions have already occurred including improvements to the processes identified in the Warning Letter. Additional corrective actions may be identified and executed based upon feedback from the FDA provided in the Warning Letter. We intend to provide regular updates to the FDA in response to the Form 483 and Warning Letter. However, we cannot provide any assurances that the FDA will be satisfied with its response or as to the expected date of the resolution of the matters included in the Warning Letter. Until the deficiencies cited in the Warning Letter are resolved to the FDA's satisfaction, additional legal or regulatory action may be taken without further notice. We do not expect the Warning Letter to materially impact our previously disclosed guidance that we expect to launch the commercialization of Mint by the end of 2027.

The FDA can also publish Safety Communications or Letters to Health Care Providers when the agency becomes aware of new issues involving a specific product or, more broadly, a product family. These communications are posted on the FDA's website and describe the FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management. If such communications occur it may harm our reputation and prevent us from generating revenue.

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

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

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

Our iLet is currently cleared only for the treatment of T1D in adults and children six years of age and older. If our iLet is authorized for marketing or cleared in a bihormonal system 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 system for the treatment of T1D or for any desired future indications, our ability to effectively market and sell our iLet may be reduced and our business may be adversely affected.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and authorized or cleared by the regulatory authorities, we are prohibited from marketing and promoting the products for indications that are not specifically cleared or approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biotechnology or medical device companies on off-label use. If the FDA determines that our promotional activities constitute promotion of an off-label use, it could request that we modify our promotional materials and subject us to FDA regulatory or enforcement actions as well as actions by other agencies, such as the Federal Trade Commission and the Department of Justice, including issuance of warning letters or untitled letters, suspension or withdrawal of a product from the market, mandatory or voluntary recalls, civil fines, disgorgement of money, operating restrictions, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, injunctions or criminal prosecution, any of which could significantly harm our business.

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

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

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

payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

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

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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

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

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

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

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, 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 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 HSS Office for Civil Rights 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 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) both of which apply to our operations 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 and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work, and our customers. In addition, we may now or in the future be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act (MHMD) broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states have adopted or are in the process of adopting similar consumer health data privacy laws, including Connecticut's SB-3 which amended the Connecticut Data Privacy Act to cover consumer health data, Nevada's Consumer Health Data Privacy Law, and Virginia's amendments to the Virginia Consumer Data Protection Act addressing the processing of sensitive health data, 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). In addition, our employees and personnel are permitted to use generative AI technologies to perform their work. 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, Colorado Artificial Intelligence Act, California Bot Disclosure Law, the Utah Artificial Intelligence Policy Act, and the CCPA regulations on automated decision-making technology. Under the EU AI Act, non-compliant companies may be subject to administrative fines of up to 35 million Euros or 7% of a company's total worldwide annual turnover for the preceding financial year, whichever is the higher. 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).

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 or verifying a user's age. 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.

Additionally, the U.S. Department of Justice issued a rule titled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which imposes additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities, such as vendor engagements, data sales or sharing, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, 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 FCPA and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

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

Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the U.S. Securities and Exchange Commission (SEC) and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and

regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy

regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries could increase those uncertainties and costs and may diminish the value of our intellectual property or narrow the scope of our patent protection.

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

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

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of the new unitary patent system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the ability to opt out of the jurisdiction of the UPC and remain as national patents in the UPC countries. The UPC will provide our competitors with a new forum to centrally revoke European patents, and allow for the possibility of a competitor to obtain pan-European injunctions, since patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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

be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

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

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

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

We may not be able to detect or prevent, alone or with our future licensors, infringement, misappropriation or other violation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and, even if successful, may result in substantial costs and distract our management and other employees. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

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

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

rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of the relevant program or products, which could have a material adverse effect on our business.

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

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

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

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

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

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). For examples, certain patents and patent applications licensed from BU were made with financial assistance from the federal government. The federal government retains a "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 and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding the manufacture, use or sale of the iLet. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize the iLet and any product candidates we may develop. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

We currently and in the future may employ individuals who were previously employed at other medical device companies. Although we endeavor to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of a former employer or another third party. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these claims, and there is no guarantee of success. If we fail in defending these claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, if such intellectual property rights are found to incorporate or be derived from the trade secrets or other proprietary information of third parties. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

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

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary

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

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

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where enforcement rights are not as strong as those in the United States or Europe. These products may compete with the iLet, and our future patents or other intellectual property rights may not be effective or sufficient 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 agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

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

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

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

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

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

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

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

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

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

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

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

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our issued or future issued patents or our pending patent applications;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Ownership of 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 is likely to be volatile. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many other factors, including:

- actual or anticipated fluctuations in our financial and operating results from period to period;
- market acceptance of our current product and product candidates under development, and the recognition of our brand;
- introduction of proposed products, technologies or treatment techniques by us or our competitors, including the ongoing adoption of diabetes drugs;
- announcements of significant contracts, acquisitions, divestitures or partnerships by us, our competitors or our collaboration partners;
- regulatory marketing authorizations or clearance received for our current product or product candidates, or the products of our competitors or collaboration partners, or the failure to obtain such marketing authorizations or clearance on the projected timeline or at all;
- the announcement of a product recall, suspension or other safety notice associated with our products or the products of our competitors, or other similar regulatory enforcement actions;
- financial and operating results relative to the expectations of securities analysts and other market participants and the issuance of securities analysts' reports or recommendations;
- threatened or actual litigation, regulatory proceedings or government investigations;
- the costs and timing of manufacturing for our product, including developing our own manufacturing capabilities;
- the success of existing or new competitive therapies, products or technologies;
- development of new products that may address our markets and make our product less attractive;
- failure or discontinuation of any of our research or development programs;
- changes in the level of expenses related to any of our research or development programs;
- developments related to any existing or future collaborations;
- the recruitment or departure of key personnel;
- regulatory or legal developments in the United States and other countries;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in the structure of healthcare payment systems;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us, our executive officers, directors, 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;
- general political, economic, industry and market conditions, tariffs or other trade measures, future bank failures, increased geopolitical tensions between the United States and China, the Russia/Ukraine conflict, the Israel-Hamas war, global pandemics and global economic conditions including changes in monetary and fiscal policy, United States political developments and other sources of instability; and
- changes in accounting principles.

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. 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.

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

Our executive officers, directors and holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly control or influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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 Equity Incentive Plan (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 Employee Stock Purchase Plan (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 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.

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 our initial public 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;
- 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 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. It is possible that this may cause investors to find our common stock less attractive. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be reduced or more volatile.

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

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.

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

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and any appellate court therefrom is 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 provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action that is based upon a violation of a duty owed by any current or former director, officer, other employee or stockholder, to us or our stockholders; (iii) any claim or cause of action against us or any current or former director, officer or other employee, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any current or former director, officer or other employee, governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by applicable law and subject to the court having personal jurisdiction over the indispensable parties named as defendant; provided, however, that if the designation of such court as the sole and exclusive forum for a claim or action referred to in foregoing clauses (i) through (vi) would violate applicable law, then the United States District Court for the District of Delaware shall be the sole and exclusive forum for such claim or cause of action. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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

General Risk Factors

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

We are subject to the risks arising from adverse changes in general economic market conditions. A U.S. or global recession, could negatively impact our current and prospective customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our ability to pay our expenses and ability to obtain

financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures.

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

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

As of December 31, 2025, we had U.S. federal NOL carryforwards of $240.8 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 $229.3 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, 2025, we had state NOL carryforwards of $65.4 million, which may be available to reduce future taxable income, of which $58.8 million expire at various dates beginning in 2029, while $6.6 million do not expire. As of December 31, 2025, we also had U.S. federal and state research and development tax credit carryforwards of $5.8 million and $4.6 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2032, respectively, with $4 million of state research and development tax credits carrying forward indefinitely.

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 our initial public 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 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, the IRA and the OBBBA made many significant changes to U.S. tax laws. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. Further, existing tax laws and regulations could be interpreted, modified or applied adversely to us. In the United States, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets and could increase our future worldwide tax expense.

We have incurred and will continue to incur increased costs and become subject to additional regulations and requirements as a result of becoming a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices, which may 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 have incurred and will continue to 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 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 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.

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.

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

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

We could be subject to securities class action litigation.

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

If securities or industry analysts cease to 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. If industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

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

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

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

Our headquarters and manufacturing facility are located in Southern California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or manufacturing facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Although we do have a disaster recovery plan in place, we may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

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

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

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section under Part II. Item 7. “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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and patient and customer data (Information Systems and Data).

Our information security function is led by our Head of Information Technology, and is supported by the Chief Financial Officer and Vice President of Legal and Business Develop (the Information Security Team). Our Information Security Team works with other members of our management team to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business. It identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including: the use of manual and automated tools, subscribing to reports and services that identify cybersecurity threats, and utilizing third-party assessments to identify vulnerabilities.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, the Information Security Team works with other members of management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business. Additionally, our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the Audit Committee, as well as our Board of Directors, the latter of which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including professional services firms; cybersecurity consultants; and managed cybersecurity service providers.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, distributors, supply chain resources and other consultants. We have vendor management processes to manage cybersecurity risks associated with our use of these providers. The processes include security assessment calls with certain vendor security personnel, conducting risk assessments for certain vendors and reviewing of security assessments. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors in the section under Part I. Item 1A. "Risk Factors" of this Annual Report, including in the subsection titled "Risks Related to Our Business, Strategy and Industry."

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity management processes are implemented and maintained by our Information Security Team, in consultation with members of our cybersecurity incident management team. Our cybersecurity incident management team is led by our Head of Information Technology and includes our Chief Financial Officer, Vice President of Legal and Business Development, and relevant business departments (the "Incident Management

Team"). Our Head of Technology brings extensive experience in software development, IT, and cyber security, gained in over two decades in the consumer product and healthcare sectors.

As the leader of our Information Security Team, our Head of Information Technology is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, requesting and allocating budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policies and procedures are designed to escalate certain cybersecurity incidents to members of management who are part of the Incident Management Team. The Incident Management Team works to help mitigate and remediate cybersecurity incidents of which they are notified. In addition, the cybersecurity incident response policy and security incident handling procedure include escalating certain cybersecurity incidents to our disclosure committee and, if appropriate, to the Audit Committee.

The Audit Committee meets periodically, and receives regular reports from our Head of Information Technology and, as appropriate, other members of the Information Security Team concerning any significant cybersecurity threats and risk and the processes we have implemented to address them. The Audit Committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation, generally. The Head of Information Technology also provides regular reports to the Board of Directors of significant matters related to the Audit Committee's responsibilities.

Item 2. Properties.

The following table summarizes the facilities leased as of December 31, 2025, including the location and size of each principal facility and their designated use. We believe that these facilities are sufficient to meet our current and anticipated future needs and that suitable additional alternative spaces would be available in the future on commercially reasonable terms if deemed necessary.

Location	Primary Use	Approximate Square Footage	Lease Expiration Year
Concord, Massachusetts	General and Administrative, R&D	13,035	2026
Cincinnati, Ohio	Pharmacy and Sales	1,524	2026
San Diego California	General and Administrative, Technical Support	7,881	2027
San Diego California	General and Administrative, R&D	12,467	2028
Irvine, California	General and Administrative, R&D, Manufacturing, Warehouse	50,020	2032

Item 3. 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

On January 30, 2025, our common stock began trading on the Nasdaq Global Market under the symbol "BBNX." Prior to that time, there was no public market for our common stock.

Holders

As of February 2, 2026, there were approximately 674 holders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividends

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the development, commercialization and growth of our business, and therefore we do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors, subject to applicable laws, and would depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

On January 31, 2025, we completed our initial public offering pursuant to which we issued and sold 13,800,000 shares of our common stock, including 1,800,000 additional shares pursuant to the exercise in full by the underwriters of their option to purchase shares of common stock from the Company and the selling stockholders (consisting of 475,000 shares from the Company and 1,325,000 shares from the selling stockholders), at a price to the public of $17.00 per share. The offer and sale of all of the shares of our common stock in the initial public offering (IPO) were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-284147), which were declared effective by the SEC on January 29, 2025. BofA Securities, Piper Sandler, and Leerink Partners acted as lead bookrunners for the offering. Stifel acted as a bookrunner and Lake Street Capital Markets acted as co-manager for the IPO. Shares of our common stock began trading on The Nasdaq Global Market on January 30, 2025.

In addition to the shares sold in the IPO, we entered into a Common Stock Purchase Agreement with Wellington Hadley Harbor Aggregator IV, L.P., an existing stockholder of the Company, for the purchase of 1,000,000 shares of our common stock at a per share price equal to the IPO price of $17.00 per share (the Private Placement). The aggregate gross proceeds to the Company from the IPO, including the full exercise of the underwriter's option to purchase additional shares, and the Private Placement, were $229.1 million, before deducting underwriting discounts and commissions and offering expenses payable by us of approximately $23.1 million. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates. The Company did not receive any proceeds from the sale of the shares of common stock by the selling stockholders.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC on January 30, 2025 pursuant to Rule 424(b)(4).

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 of this Annual Report regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Item 6. [Reserved].

Item 7. 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 Annual Report on Form 10-K (Annual Report). Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, 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 people with diabetes (PWD) by utilizing advanced adaptive closed-loop algorithms to simplify and improve the treatment of their disease. Diabetes is a chronic condition that requires ongoing insulin therapy, and suboptimal glycemic control remains common despite advances in treatment technologies. Our product, the 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 users to count carbohydrate intake. We believe this represents a significant advancement over currently available insulin delivery options by combining improved glycemic control with a simplified user experience.

The iLet was designed to provide improved glycemic control relative to currently available treatment options, such as insulin pumps, partially automated insulin delivery systems, and multiple daily injections (MDI), while reducing the workload associated with achieving these outcomes. It uses adaptive closed-loop algorithms that learn each person's unique and changing insulin requirements and autonomously deliver the appropriate insulin dose every five minutes throughout the day and night. Only the user's body weight is required for initialization, unlike traditional pump and hybrid closed-loop systems that require numerous user-defined parameters. These adaptive algorithms eliminate the need to manually adjust pump settings or calculate meal and correction doses, which we believe makes the iLet easier to initiate and use than other available systems.

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 1.9 million people with T1D currently in the United States, all of whom require daily insulin replacement to manage their disease. We believe that one of the principal causes of suboptimal outcomes as it relates to disease management is the complexity of the user experience with most currently available insulin pumps and hybrid closed-loop systems, which has kept the majority of PWD from adopting them despite the improved disease management they can offer. These systems require PWD to set and to periodically adjust several insulin pump parameters, to quantify daily carbohydrate intake, and to frequently calculate proper doses of insulin for their pump to deliver. We believe this complexity, and the constant engagement that is required in order to enjoy the full therapeutic benefits that these systems can offer, limits their uptake to a subset of PWD and to subspecialty 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, 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 70% and 69% of the iLet's adoption through December 31, 2025 and 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 Continuous Glucose Monitor (CGM) sensor. An 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 (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 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 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 durable medical equipment (DME) and pharmacy benefit plans (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 years ended December 31, 2025 and 2024, PBP channel sales represented 24% and 10% of net sales, respectively.

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.

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 system 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. As part of our development plans, in September 2025, we completed a clinical trial in Canada assessing the pharmacokinetics (PK) and pharmacodynamics (PD) of our glucagon product candidate (also referred to as the glucagon asset, and referred to herein as the PK-PD Trial). The completion of the PK-PD Trial enables us to bridge our previous bihormonal clinical data, which tested prior formulations of glucagon in three pre-pivotal inpatient and six pre-pivotal outpatient clinical trials, to our glucagon product candidate. We believe that the results from the PK-PD Trial are supportive of the continued development of our glucagon product candidate for use in our bihormonal system of the iLet. In the fourth quarter of 2025, we completed our first-in-human Phase 2a feasibility trial evaluating the integrated bihormonal system and expect to initiate an additional Phase 2a feasibility trial in the first half of 2026 as development progresses. We also intend to pursue the development of the iLet for expanded patient populations and indications, such as people with type 2 diabetes (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 of certain of our license and collaboration agreements. For a more detailed description of these agreements, see the section titled "Business—Collaboration and License Agreements."

Device License Agreement with Boston University

We have the Device License Agreement with BU that requires ongoing royalty payments and other financial obligations related to products incorporating BU-licensed technology. As consideration for the license, we issued 1,160 shares of Class B common stock to BU. Under the agreement, we are required to pay (i) quarterly royalties in the mid-single-digit percentage range based on net sales of licensed products by us and our affiliates, (ii) quarterly royalties in the low double-digit percentage range based on net sales by sublicensees, which are creditable against a minimum annual royalty amount, and (iii) quarterly lump-sum payments in the low double-digit percentage range based on certain non-royalty sublicensing revenue. We are also responsible for reimbursing BU for patent-related costs and may be required to pay an assignment fee in the event of a sale of substantially all assets related to the licensed technology. Royalty and license-related costs under this agreement are recognized as cost of goods sold or operating expenses, as applicable, and increase as sales volumes grow.

Control Algorithm License Agreement with Boston University

We have the Control Algorithm license agreement with BU covering automated control system technology incorporated into the iLet. In connection with this agreement, we issued 1,140 shares of Class B common stock to BU. Under the financial terms of the agreement, we are required to pay BU (i) quarterly royalties of a mid-single-digit percentage based on net sales by us and our affiliates, (ii) quarterly royalties of a low double-digit percentage based on net sales by sublicensees, in each case of (i) and (ii) creditable against a minimum annual royalty amount, and (iii) quarterly lump-sum payments of a low double-digit percentage of certain non-royalty sublicensing revenue received from sublicensees. We are also responsible for reimbursing patent-related costs and are required to make a one-time change-of-control payment of $65,000 if such an event occurs. Royalty obligations under this agreement represent ongoing costs that are expected to increase as commercial adoption of the iLet expands.

Collaboration and License Agreement with Xeris Pharmaceuticals, Inc.

We have the Collaboration and License Agreement with Xeris Pharmaceuticals, Inc. to develop and commercialize a glucagon formulation for use in our bihormonal system. Under this agreement, we paid an upfront fee of $0.5 million and a milestone payment of $3.0 million, both of which were recognized as research and development expense when incurred. We are also obligated to pay tiered royalties in the low double-digit percentage range on future net sales of glucagon products, subject to customary reductions.

In connection with clinical development activities, we entered into the Clinical Supply Agreement with Xeris and incurred $0.9 million of costs for Phase 2 clinical materials during 2024, with the remaining balance paid in early 2025. We expect to incur up to $5.1 million in additional development and manufacturing costs related to Phase 3 activities, of which $4.0 million had been paid as of December 31, 2025. Amounts are recorded as prepaid expenses and expensed to research and development as services are performed. These agreements are expected to continue to drive research and development expense and future royalty obligations.

Development and Commercial Agreements

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

We have the Commercialization Agreement and Development and Commercialization Agreement with DexCom, Inc. and Abbott Diabetes Care Inc., respectively, related to integrated automated insulin delivery systems. These agreements primarily involve shared development responsibilities and cross-licensing of technology and trademarks and do not require upfront payments, milestone payments, or ongoing royalty obligations. As a result, these arrangements have not had a material direct impact on our results of operations or cash flows to date, though

they may affect future operating expenses associated with development, regulatory activities, and commercialization.

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 under Part I. Item 1A. "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 if we are unable to secure sufficient coverage or reimbursement from third-party payors for our current or future products, or if reimbursement structures change under our multi-channel strategy.

We are pursuing a multi-channel coverage and reimbursement strategy to maximize access to the iLet within the T1D population, provide flexibility for PWD in choosing their device and provide PWD with advantageous coverage and reimbursement terms. We are working with payors to establish coverage and reimbursement under both the DME and PBP channels as we believe this strategy increases access and optimizes the potential for better medical outcomes for PWD through the adoption of the iLet. The DME and PBP channels for the iLet and its single-use products entail different payment outlays and therefore differentially impact PWD and our financial results. When considering the overall economics over the lifetime of each iLet, sales through the DME channel generally result in higher upfront cash flows from the large, upfront payment and reimbursement for the iLet, but lead to lower cash flows 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, 2025 and 2024, PBP channel sales represented 24% and 10%, respectively, of net sales. 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 system of the iLet, as well as pursuing the development of the iLet for expanded patient populations and indications such as people with T2D.

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

Regulatory Approvals and Actions

The medical devices we manufacture are subject to laws and regulation by numerous regulatory bodies, including the FDA. The laws and regulations govern, among other things, the research and development, design, testing, manufacture, packaging, storage, recordkeeping, approval, labeling, promotion, post-approval monitoring and reporting, distribution and import and export of medical devices. Any adverse event involving any products that we distribute could result in future corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. In the future, we also intend to pursue additional products, such as a patch pump and bihormonal system 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, including tariffs or other trade measures, future bank failures, increased geopolitical tensions and conflicts, global pandemics, global economic conditions, including changes in monetary and fiscal policy, U.S. political developments and other sources of instability.

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 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. For additional information regarding the risks of our reliance on these suppliers, please

see the section under Part I. Item 1A. “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

Net Sales

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

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, 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 include engineering and clinical trial activities for the iLet, regulatory efforts, personnel costs such as salaries, bonuses, stock-based compensation and benefits, payments under third-party license agreements, supplies, development prototypes, design and testing services, depreciation and allocated facilities and information technology expenses, all of which are expensed as incurred. We track research and development expenses by individual product candidate. We expect research and development expenses to

increase significantly for the foreseeable future as we advance clinical development, pursue new products and indications including the bihormonal system, patch pump, and potential T2D use, expand technical and operational staffing, make required payments under license arrangements, and establish commercial scale manufacturing capabilities.

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 primarily include personnel costs for our sales and clinical teams, the development of customer support infrastructure, marketing and branding activities, healthcare conference and market research costs, payer education and market access initiatives, data purchases, website and consulting fees, and facilities, travel, and other related operating expenses. We anticipate a significant increase in sales and marketing expenses for the foreseeable future to support the continued commercialization of the iLet and our future products.

General and Administrative

General and administrative expenses include personnel-related costs, including salaries, bonuses, stock-based compensation expense and benefits for our personnel in executive, legal, finance, accounting, human resources, information technology, quality assurance and other administrative functions, as well as expenses for patent filings, legal services, accounting and tax services, insurance, travel, facilities and depreciation. We expect these expenses to increase significantly as we continue operating as a public company, driven by higher professional services costs, director and officer insurance, investor and public relations activities and compliance with SEC and stock exchange listing requirements. We anticipate a significant increase in general and administrative expenses for the foreseeable future in order to continue to scale the business and support future demand.

Other Income (Expense)

Our other income (expense) consists of (i) interest income, (ii) other income (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 and long-term investment balances.

Other Income (Expense)

Other income (expense) consists of miscellaneous income and expenses unrelated to our core operations.

Change in Fair Value of Warrant Liabilities

In connection with our February 2022 Series C preferred stock financing, we granted warrants (Series C Warrants) to certain investors to purchase additional shares of our Series C convertible preferred stock. 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 through their exercise in January 2025. Changes in the fair value were recognized as a component of other income (expense), net. We continued to recognize changes in fair value of the warrant liabilities until the Warrants were exercised prior to the completion of our IPO. The Warrants are no longer outstanding. For additional information, see Part II. Item 8. Note 4 of our audited financial statements included elsewhere in this Annual Report.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,		Change	
	2025	2024	$	%
	(in thousands, except percentages)			
Net sales	$ 100,251	$ 65,124	$ 35,127	54%
Cost of sales[(1)]	44,714	29,236	15,478	53%
Gross profit	55,537	35,888	19,649	55%
Operating expenses:				
Research and development[(1)]	34,789	26,184	8,605	33%
Sales and marketing[(1)]	61,404	37,086	24,318	66%
General and administrative[(1)]	31,025	17,869	13,156	74%
Total operating expenses	127,218	81,139	46,079	57%
Loss from operations	(71,681)	(45,251)	(26,430)	58%
Other income (expense):				
Interest income	10,932	3,909	7,023	*
Other expense	(1)	(2)	1	*
Change in fair value of warrant liabilities	(12,450)	(13,412)	962	*
Total other expense, net	(1,519)	(9,505)	7,986	*
Net loss	$ (73,200)	$ (54,756)	$ (18,444)	34%

* Not meaningful

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

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Cost of sales	$ 542	$ 275
Research and development	3,205	1,144
Sales and marketing	4,625	1,661
General and administrative	8,012	3,304
Total stock-based compensation expense	$ 16,384	$ 6,384

Net Sales

Net sales for the year ended December 31, 2025 was $100.3 million, compared to $65.1 million for the year ended December 31, 2024. The increase in net sales of $35.2 million was primarily driven by higher sales volumes, reflecting an increase in the number of single-use products sold as a result of the expansion of our installed customer base and growth in new patient starts. The increase in net sales was driven predominantly by volume, with pricing and reimbursement changes having a limited impact on the year-over-year increase. For the year ended December 31, 2025, single-use products accounted for 47% of net sales, up from 25% for the year ended December 31, 2024. For the year ended December 31, 2025, there were 19,713 new patient starts, up from 12,994 for the year ended December 31, 2024.

For the year ended December 31, 2025, 76% of net sales were generated through the DME channel and 24% through the PBP channel, compared to 90% and 10%, respectively, for the year ended December 31, 2024. The shift toward the PBP channel was driven by expanded pharmacy benefit coverage, resulting in a larger percentage of new patient starts reimbursed through this channel.

Cost of Sales

Cost of sales for the year ended December 31, 2025 was $44.7 million, compared to $29.2 million for the year ended December 31, 2024. The $15.5 million increase was primarily driven by higher volumes of single-use products and iLets sold through the PBP channel.

Gross Profit and Margin

Gross profit for the year ended December 31, 2025 was $55.5 million, compared to $35.9 million for the year ended December 31, 2024. Gross margin was 55% for the year ended December 31, 2025, compared to 55% in the year ended December 31, 2024. The $19.6 million increase in gross profit was primarily driven by higher sales volume. Gross margin remained consistent year over year, as benefits from increased production scale and improved cost absorption were offset by a shift in revenue mix toward the PBP channel, which recognizes less revenue upfront compared to the DME channel.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2025 were $34.8 million, compared to $26.2 million during the year ended December 31, 2024. This increase of $8.6 million was primarily attributable to a net increase of $5.4 million in payroll-related expenses, including stock-based compensation, driven by an increase in headcount focused on supporting our innovation activities. The remaining increase is attributable to materials and clinical trial related expenses incurred for the development of our patch pump, bihormonal system of the iLet and incremental software and product updates.

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

	Year Ended December 31,		Change	
	2025	2024	$	%
	(in thousands, except percentages)			
External research and development[(1)]	$ 5,573	$ 6,722	$ (1,149)	(17)%
Internal research and development[(2)]	26,011	17,818	8,193	46%
Stock-based compensation	3,205	1,144	2,061	180%
Licensing fees and other	—	500	(500)	(100)%
Total research and development expense	$ 34,789	$ 26,184	$ 8,605	33%

(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.

Sales and Marketing Expenses

Sales and marketing expenses for the year ended December 31, 2025 were $61.4 million, compared to $37.1 million for the year ended December 31, 2024. This increase of $24.3 million was primarily attributable to an increase of $16.3 million in payroll-related expenses, 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 expansion of our sales territories within the United States. The remaining increase includes HCP-related marketing, training and travel-related expenses attributable to our continued efforts to grow our install base and support sales expansion.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2025 were $31.0 million, compared to $17.9 million for the year ended December 31, 2024. This increase of $13.1 million was primarily attributable to an

increase of $7.1 million in payroll-related expenses, driven by an increase in headcount following our IPO as well as increased corporate bonus incentives provided to management level employees and stock-based compensation. The remaining increase is partially attributable to professional fees, including legal, recruiting, and accounting services, software-related expenses, non-recurring expenses related to FDA-compliance, and increased insurance premiums primarily related to operating as a public company.

Other Income (Expense)

Total other expense, net for the year ended December 31, 2025 was $1.5 million, compared to $9.5 million for the year ended December 31, 2024. This decrease of $8.0 million was attributable to a $7.0 million increase in interest income from our short-term and long-term investments due to the investment of our IPO proceeds during the first quarter of 2025 as well as a $1.0 million decrease in expense from the change in fair value of our warrant liabilities due to changes in inputs associated with the fair value measurement immediately prior to our IPO compared to December 31, 2024.

Selected Quarterly Financial Information

The following table sets forth our selected unaudited quarterly consolidated statements of operations data for each of the eight quarters in the period ended December 31, 2025. The information for each of these quarters has been prepared in accordance with generally accepted accounting principles in the United States (GAAP), on a basis consistent with our audited consolidated financial statements included elsewhere in this Annual Report and include, in our opinion, all normal recurring adjustments necessary for the fair presentation of the results of operations for the periods presented, with the exception of Adjusted earnings before interest, taxes, depreciation and amortization (EBITDA), which is a non-GAAP financial measure discussed below. 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 Annual Report.

The following table sets forth our selected unaudited quarterly statements of operations data for the periods presented:

	Three Months Ended			
	March 31, 2025	June 30, 2025	September 30, 2025	December 31, 2025
	(unaudited)			
	(in thousands, except percentages)			
Net sales	$ 17,639	$ 23,238	$ 27,253	$ 32,121
Cost of sales[1]	8,668	10,735	12,134	13,177
Gross profit	8,971	12,503	15,119	18,944
Gross margin	50.9%	53.8%	55.5%	59.0%
Operating expenses:				
Research and development[1]	7,590	8,873	8,195	10,131
Sales and marketing[1]	13,402	15,623	16,045	16,334
General and administrative[1]	6,621	7,879	7,922	8,603
Total operating expenses	27,613	32,375	32,162	35,068
Loss from operations	(18,642)	(19,872)	(17,043)	(16,124)
Other income (expense):				
Interest income	2,436	3,005	2,833	2,658
Other income (expense), net	—	(2)	1	—
Change in fair value of warrant liabilities	(12,450)	—	—	—
Total other income (expense), net	(10,014)	3,003	2,834	2,658
Net loss	$ (28,656)	$ (16,869)	$ (14,209)	$ (13,466)
Adjusted EBITDA	$ (15,535)	$ (14,526)	$ (12,179)	$ (10,512)

	Three Months Ended			
	March 31, 2024	June 30, 2024	September 30, 2024	December 31, 2024
	(unaudited)			
	(in thousands, except percentages)			
Net sales	$ 12,933	$ 15,046	$ 16,705	$ 20,440
Cost of sales[1]	5,732	6,962	7,791	8,751
Gross profit	7,201	8,084	8,914	11,689
Gross margin	55.7%	53.7%	53.4%	57.2%
Operating expenses:				
Research and development[1]	5,479	6,350	5,141	9,214
Sales and marketing[1]	7,663	8,974	9,645	10,804
General and administrative[1]	3,512	4,544	5,105	4,708
Total operating expenses	16,654	19,868	19,891	24,726
Loss from operations	(9,453)	(11,784)	(10,977)	(13,037)
Other income (expense):				
Interest income	1,139	993	826	951
Other income (expense), net	4	(2)	(4)	—
Change in fair value of warrant liabilities	(4,139)	(3,670)	419	(6,022)
Total other income (expense), net	(2,996)	(2,679)	1,241	(5,071)
Net loss	$ (12,449)	$ (14,463)	$ (9,736)	$ (18,108)
Adjusted EBITDA	$ (7,805)	$ (9,985)	$ (8,672)	$ (11,254)

[1] Includes stock-based compensation expense as follows:

	Three Months Ended			
	March 31, 2025	June 30, 2025	September 30, 2025	December 31, 2025
	(unaudited)			
	(in thousands)			
Cost of sales	$ 106	$ 153	$ 140	$ 143
Research and development	502	924	893	886
Sales and marketing	801	1,314	1,273	1,237
General and administrative	1,395	2,408	2,172	2,037
Total stock-based compensation expense	$ 2,804	$ 4,799	$ 4,478	$ 4,303

	Three Months Ended			
	March 31, 2024	June 30, 2024	September 30, 2024	December 31, 2024
	(unaudited)			
	(in thousands)			
Cost of sales	$ 71	$ 61	$ 69	$ 74
Research and development	263	287	294	300
Sales and marketing	288	390	472	511
General and administrative	735	762	1,141	666
Total stock-based compensation expense	$ 1,357	$ 1,500	$ 1,976	$ 1,551

The following table sets forth our selected unaudited quarterly key business metrics for the periods presented:

	Three Months Ended			
	March 31, 2025	June 30, 2025	September 30, 2025	December 31, 2025
	(unaudited)			
% of Total Net Sales:				
Durable Medical Equipment (DME) Channel	78%	80%	77%	70%
Pharmacy Benefit Plan (PBP) Channel	22%	20%	23%	30%
Total	100%	100%	100%	100%
% of New Patient Starts (NPS) Reimbursed Through Pharmacy	Low 20s %	High 20s %	Low 30s %	Low 30s %

	Three Months Ended			
	March 31, 2024	June 30, 2024	September 30, 2024	December 31, 2024
	(unaudited)			
% of Total Net Sales:				
Durable Medical Equipment (DME) Channel	94%	95%	87%	88%
Pharmacy Benefit Plan (PBP) Channel	6%	5%	13%	12%
Total	100%	100%	100%	100%
% of New Patient Starts (NPS) Reimbursed Through Pharmacy	Mid-single digit %	Mid-single digit %	High-single digit %	Low-teens %

Adjusted EBITDA

In addition to our financial results determined in accordance with GAAP, we believe the following adjusted EBITDA non-GAAP measure is useful in evaluating our operating performance. We use adjusted EBITDA to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that this non-GAAP financial measure, 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. 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 adjusted EBITDA 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 this non-GAAP financial measure to its most directly comparable GAAP financial measure, and not to rely on any single financial measure to evaluate our business.

The following table presents a reconciliation of adjusted EBITDA from the most comparable GAAP measure, net loss, for the eight quarters in the period ended December 31, 2025:

	Year Ended December 31,	
	2025	2024
	(unaudited) (in thousands)	
Net loss	$ (73,200)	$ (54,756)
Add:		
Depreciation expense	1,573	1,151
Stock-based compensation expense	16,384	6,384
Interest income	(10,932)	(3,909)
Income tax expense	1	2
Litigation settlement and other related expense	410	—
Other non-recurring	562	—
Change in fair value of warrant liabilities	12,450	13,412
Adjusted EBITDA	$ (52,752)	$ (37,716)

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, 2025:

	Three Months Ended			
	March 31, 2025	June 30, 2025	September 30, 2025	December 31, 2025
	(unaudited) (in thousands)			
Net loss	$ (28,656)	$ (16,869)	$ (14,209)	$ (13,466)
Add:				
Depreciation expense	303	347	386	537
Stock-based compensation expense	2,804	4,799	4,478	4,303
Interest income	(2,436)	(3,005)	(2,833)	(2,658)
Income tax expense (benefit)	—	2	(1)	—
Litigation settlement and other related expense	—	200	—	210
Other non-recurring	—	—	—	562
Change in fair value of warrant liabilities	12,450	—	—	—
Adjusted EBITDA	$ (15,535)	$ (14,526)	$ (12,179)	$ (10,512)

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, 2024:

	Three Months Ended			
	March 31, 2024	June 30, 2024	September 30, 2024	December 31, 2024
	(unaudited) (in thousands)			
Net loss	$ (12,449)	$ (14,463)	$ (9,736)	$ (18,108)
Add:				
Depreciation expense	287	299	333	232
Stock-based compensation expense	1,357	1,500	1,976	1,551
Interest income	(1,139)	(993)	(826)	(951)
Income tax expense	—	2	—	—
Change in fair value of warrant liabilities	4,139	3,670	(419)	6,022
Adjusted EBITDA	$ (7,805)	$ (9,985)	$ (8,672)	$ (11,254)

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 expense, (ii) stock-based compensation expense, (iii) interest income, (iv) income tax expense (benefit), (v) litigation settlement and other related expense, and (vi) change in fair value of warrant liabilities.

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 expense includes 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.

Selected Quarterly Trends

Net sales

Net sales increased from the first quarter of 2025 to the fourth quarter of 2025, benefiting from favorable seasonality and continued growth in new patient starts, leading to higher net sales of both iLets and supplies. This followed a decline from the fourth quarter of 2024 to the first quarter of 2025, primarily due to seasonal factors. From the first quarter of 2024 through the fourth quarter of 2024, net sales steadily increased, driven primarily by growth in our installed customer base as more patients adopted the iLet. This expansion also contributed to higher recurring sales of single-use products, which are replaced every 2–3 days.

Cost of sales

Cost of sales increased from the first quarter of 2025 to the fourth quarter of 2025, largely due to increased volume, particularly in sales of iLets through the PBP channel, and higher product warranty costs. This followed a decline from the fourth quarter of 2024 to the first quarter of 2025, primarily due to product mix and lower volume due to seasonal factors. From the first quarter of 2024 through the fourth quarter of 2024, cost of sales steadily increased, reflecting higher iLet sales and a growing installed base, which drove increases in material cost and royalties expense.

Gross Margin

Gross margin improved from the first quarter of 2025 to the fourth quarter of 2025, reflecting higher sales volumes and improved manufacturing cost absorption. Margins also strengthened as production volumes increased and fixed costs were absorbed more efficiently. Gross margin decreased from the fourth quarter of 2024 to the first quarter of 2025 driven by lower volume and a shift in channel mix of new patient starts toward the PBP channel—which recognizes less revenue upfront compared to the DME channel. Prior to that, gross margin increased from the first quarter of 2024 to the fourth quarter of 2024 due to higher sales volumes and improved manufacturing cost absorption. PBP-reimbursed patient starts represented a low-30% share of new patients in the third and fourth quarter of 2025, compared to the high-20% range in the second quarter of 2025, the low-20% range in the first quarter of 2025, and the low-teens in the fourth quarter of 2024. Although the mix shift toward the PBP

channel continues, the adverse margin impact was more than offset by higher unit volumes and improved manufacturing efficiencies during the period.

Operating expenses

Our quarterly research and development expenses increased in all periods presented, except the third quarters of 2024 and 2025 and the first quarter of 2025, primarily due to increases in payroll-related expenses, materials and clinical trial 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 fourth quarter of 2024, primarily due to increases in payroll-related expenses driven by headcount increases in our quality assurance team, and public company costs, including accounting and audit services, insurance premiums and legal expenses, as well as expenses incurred for operational overhead expenses to meet the growing demand for the iLet.

Adjusted EBITDA

Adjusted EBITDA improved from the first quarter of 2025 to the fourth quarter of 2025 due to higher revenue, improved margins, and increased operating leverage despite continued headcount increases. The decline from the third quarter of 2024 to the first quarter of 2025 was primarily driven by product mix, lower volume due to seasonal factors as well as a $3.0 million milestone payment made to Xeris in the fourth quarter of 2024 for the achievement of certain developmental milestones. Adjusted EBITDA improved from the second quarter of 2024 to the third quarter of 2024 due to favorable timing of research and development expenses. Adjusted EBITDA declined from the first quarter of 2024 to the second quarter of 2024 primarily due to increases in sales and marketing and research and development expenses.

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, although we may change our key business metrics or how we present our key business metrics from time to time.

We believe that the following metrics are representative of our current business:

	Year Ended December 31,	
	2025	2024
New patient starts	19,713	12,994
New patient starts from MDI as a percentage of total new patient starts	70%	69%
Installed customer base	35,011	15,298

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.

In the year ended December 31, 2025, a high-twenties percentage of our new patient starts were reimbursed through the PBP channel. In the year ended December 31, 2024, a high-single digit percentage of our new patient starts were reimbursed through the PBP channel. The increase in new patient starts through the PBP channel reflects

enhanced formulary access and broader pharmacy coverage for iLet. These improvements are primarily attributable to the execution of contracts with key PBMs.

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

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

Installed Customer Base

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

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 system 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. In January 2025, we completed our IPO and a concurrent private placement, pursuant to which we received aggregate net proceeds of approximately $190.4 million and approximately $15.6 million, respectively, in each case after deducting underwriting discounts, commissions, and other offering expenses. We have also received payments in connection with collaboration agreements and government grants, receiving $6.1 million to date from these types of arrangements, as well as from the sale of the iLet and single-use products utilized with the iLet from our contracts with customers. As of December 31, 2025, we had cash and cash equivalents and short-term and long-term investments of $264.7 million.

Cash Flows

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

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (50,925)	$ (48,273)
Net cash used in investing activities	(162,805)	(3,476)
Net cash provided by financing activities	214,874	55,615
Net increase in cash, cash equivalents and restricted cash	$ 1,144	$ 3,866

Operating Activities

Net cash used in operating activities was $50.9 million for the year ended December 31, 2025, compared to $48.3 million the year ended December 31, 2024. The increase in net cash used in operating activities was primarily

driven by an increase of $18.4 million in net loss year over year. This was partially offset by an increase in non-cash charges of $12.7 million, primarily attributable to changes in fair value of our warrant liabilities and higher stock-based compensation expense due to increased headcount to support innovation activities, the expansion of our sales territories and our business operations as a public company. Working capital to support the growth of our commercial operations required cash of $9.9 million in 2025, compared to $12.1 million in 2024. The working capital outflow in 2025 was primarily driven by a $9.9 million increase in inventories, reflecting higher production levels to support anticipated future demand as commercial sales continue to grow, a $5.8 million increase in prepaid expenses and other current assets attributable to directors and officers insurance premiums, prepaid material components, and software license renewals, and a $5.2 million increase in accounts receivable due to higher sales volume. These cash requirements were offset by a $6.6 million increase in accrued expenses and other current liabilities primarily due to the payout of the 2024 corporate bonus offset by the twelve months of accrual for 2025 corporate bonus based on company goals, a $2.1 million increase to accounts payable due to the timing of vendor payments, and a $2.0 million increase in deferred revenue due to an increase in sales and unsatisfied performance obligations.

Investing Activities

Net cash used in investing activities increased to $162.8 million for the year ended December 31, 2025 compared to $3.5 million for the year ended December 31, 2024. The increase in net cash used in investing activities was primarily driven by the investment of net proceeds from our IPO in January 2025. The Company used $282.0 million in purchases of short-term investments and $45.5 million in purchases of long-term investments during 2025, partially offset by $170.0 million in proceeds from maturities and redemptions of short-term investments. Capital expenditures increased modestly to $5.3 million in 2025 compared to $3.4 million in 2024, reflecting continued investment in property and equipment for additional manufacturing equipment to support commercial growth.

Financing Activities

Net cash provided by financing activities was $214.9 million for the year ended December 31, 2025 compared to $55.6 million for the year ended December 31, 2024. The increase in net cash provided by financing activities was primarily driven by the completion of the Company's IPO in January 2025. During 2025, financing activities primarily consisted of $195.4 million in net proceeds from the IPO, $15.6 million in proceeds from the private placement, and $4.8 million from stock option exercises. By comparison, financing activities in 2024 primarily consisted of $59.7 million from the issuance and sale of shares of our Series E convertible preferred stock, offset by $4.1 million in payments of deferred offering costs associated with our IPO.

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 system), 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 system 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;
- 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; and
- the impact of geopolitical and macroeconomic events, including tariffs or other trade measures, future bank failures, increased geopolitical tensions and conflict, global pandemics, global economic conditions including changes in monetary and fiscal policy, U.S. political developments and other sources of instability that may impact our ability to access capital on acceptable terms, if at all.

Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term and long-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 for at least the next 12 months. 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 and we may seek additional capital to support future growth initiatives.

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, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or strategic alliances with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or investigational devices, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

Leases

We have entered into various non-cancelable operating leases for certain office, laboratory and manufacturing space. The leases have varying initial lease terms of approximately 1-6 years. For additional information, see Note 17 to our audited financial statements included elsewhere in this Annual Report.

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 entering into Phase 2 of the collaboration, we ordered and paid for clinical material totaling $0.9 million. In connection with entering into Phase 3 of the collaboration, we expect to incur development and manufacturing costs, including ordering clinical materials and technical transfer, development, and testing of the product, totaling $5.1 million. As of December 31, 2025, we have completed payments totaling $4.0 million. The payments were initially recognized in prepaid expense and other current assets in the balance sheets and a portion of the payment was expensed to research and

development related to the services completed. 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. We may continue to incur costs as we progress into Phase 2 and Phase 3 clinical trials. For additional information, see the section under Part I. Item 1. "Business—License and Collaboration Agreements."

Royalty Obligations

In connection with the development, production and sale of the iLet, we have entered into certain agreements that obligate us to pay royalties based on specific production or net sales metrics. Among other obligations, certain license agreements with BU require us to pay quarterly royalties of a mid-single-digit percentage based on net sales (and royalties of a low double-digit percentage of net sales by sublicensees), of any products licensed under the agreements, which royalties are creditable against the minimum royalty amount. For additional information on these license agreements with BU, see the section under Part I. Item 1. "Business—License and Collaboration Agreements."

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

While our significant accounting policies are described in more detail in Part II. Item 8. Note 2 to our audited financial statements included elsewhere in this Annual Report, 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. The fair value of stock options is estimated using the Black-Scholes option pricing model, while the fair value of restricted stock units ("RSUs") is based on the closing price of our common stock on the grant date. Stock-based compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award for employees and directors and the period during which services are performed for non-employees. Stock-based compensation expense for non-employee awards is recognized in the same manner as if we had paid cash in exchange for the goods or services, which is generally the vesting period of the award. We have issued awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We have not issued any stock-based awards with performance-based or market-based vesting conditions.

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

- *Fair Value of Our Class B Common Stock*—Prior to our initial public 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 titled "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 Part II. Item 8. Note 13 of our audited financial statements included elsewhere in this Annual Report 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.

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 Part II. Item 8. Note 2 to our audited financial statements included elsewhere in this Annual Report.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups (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 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 our initial public 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 by Rule 12b-2 of the Exchange Act because both the market value of our stock held by non-affiliates is less than $700 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. 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. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company" as defined by Item 10(f)(1) of Regulation S-K, the Company is not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required pursuant to this item are incorporated by reference herein from the applicable information included in Item 15(a)(1) and (2) of this Annual Report on Form 10-K and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Annual Report. Based on such evaluation, our principal executive officer and our principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financing reporting, as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of our financial reporting for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our consolidated financial statements; providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our consolidated financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our consolidated financial statements would be prevented or detected.

Management assessed the effectiveness of the Company's internal control over financial reporting based on the framework in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2025.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's assessment of internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

We have adopted a written code of business conduct and ethics ("Code of 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. A copy of our Code of Ethics is available on the Leadership & Governance section of the Investors section of our website, www.betabionics.com. We intend to disclose on our website or by filing a Current Report on Form 8-K any future amendments of our Code of Ethics or waivers that exempt any of the principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in our Code of Ethics. The information contained on, or accessible through, our website is not incorporated by reference into this Annual Report, and you should not consider any information contained in, or that can be accessed through, our website as part of this Annual Report.

The information required by this item that is not set forth above will be set forth in our definitive proxy statement for our 2026 Annual Meeting of Stockholders ("Proxy Statement"), under the sections headed "Proposal 1: Election of Directors," "Executive Officers," "Delinquent Section 16(A) Reports" and "Insider Trading Policy," and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement, under the sections headed "Executive and Director Compensation" and "Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to Release of Material Nonpublic Information," and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in our Proxy Statement, under the sections headed "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management," and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in our Proxy Statement, under the sections headed "Proposal 1: Election of Directors" and "Certain Relationships and Related Person Transactions," and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in our Proxy Statement, under the section headed "Proposal 2: Ratification of Appointment of Independent Registered Public Accounting Firm," and is incorporated herein by reference.

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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, 2025 and 2024, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, 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

February 24, 2026

BETA BIONICS, INC.

BALANCE SHEETS

(In thousands, except number of shares)

	December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 31,576	$ 30,432
Restricted cash, current	100	—
Short-term investments	187,549	73,143
Accounts receivable, net	17,118	11,996
Inventories	21,722	13,320
Prepaid expenses and other current assets	9,840	4,032
Total current assets	267,905	132,923
Property and equipment, net	8,600	4,776
Operating lease right-of-use asset	6,627	6,645
Restricted cash, noncurrent	—	100
Deferred offering costs	—	5,051
Long-term investments	45,431	—
Other long-term assets	180	150
Total assets	328,743	$ 149,645
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,998	$ 2,852
Accrued expenses and other current liabilities	22,431	15,828
Operating lease liabilities	1,938	1,529
Deferred revenue	1,557	939
Total current liabilities	30,924	21,148
Operating lease liabilities, net of current portion	5,365	5,726
Deferred revenue, net of current portion	3,297	1,860
Warrant liabilities	—	44,898
Other long-term liabilities	1,547	—
Total liabilities	41,133	73,632
Commitments and contingencies (Note 18)		
Convertible preferred stock (Series A, A-2, B, B-2, C, D and E), par value of $0.0001 per share; no and 34,966,547 shares authorized at December 31, 2025 and December 31, 2024, respectively; no and 17,228,954 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively; liquidation preference of $0 and $355,162 at December 31, 2025 and December 31, 2024, respectively	—	321,373
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value, 700,000,000 shares authorized; 44,360,873 and 6,667,793 issued and outstanding at December 31, 2025 and 2024, respectively	4	1
Additional paid-in capital	657,140	51,311
Accumulated other comprehensive income	403	65
Accumulated deficit	(369,937)	(296,737)
Total stockholders' equity (deficit)	287,610	(245,360)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 328,743	$ 149,645

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

BETA BIONICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except number of shares and per share data)

	Year Ended December 31,	
	2025	2024
Net sales	$ 100,251	$ 65,124
Cost of sales	44,714	29,236
Gross profit	55,537	35,888
Operating expenses:		
Research and development	34,789	26,184
Sales and marketing	61,404	37,086
General and administrative	31,025	17,869
Total operating expenses	127,218	81,139
Loss from operations	(71,681)	(45,251)
Other income (expense):		
Interest income	10,932	3,909
Other expense	(1)	(2)
Change in fair value of warrant liabilities	(12,450)	(13,412)
Total other expense, net	(1,519)	(9,505)
Net loss	$ (73,200)	$ (54,756)
Other comprehensive income (loss):		
Unrealized gain (loss) on short-term and long-term investments	338	(72)
Comprehensive loss	$ (72,862)	$ (54,828)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.81)	$ (8.60)
Weighted-average common shares outstanding, basic and diluted	40,529,051	6,365,064

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

BETA BIONICS, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except number of shares)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (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
Issuance of Series E preferred stock, net of issuance costs of $340	4,352,393	59,660	—	—	—	—	—	—
Stock option exercises	—	—	11,953	—	89	—	—	89
Stock-based compensation expense	—	—	—	—	6,384	—	—	6,384
Unrealized loss on short-term investments	—	—	—	—	—	(72)	—	(72)
Net loss	—	—	—	—	—	—	(54,756)	(54,756)
Balance at December 31, 2024	17,228,954	$ 321,373	6,667,793	$ 1	$ 51,311	$ 65	$ (296,737)	$ (245,360)
Conversion of convertible preferred stock into common stock on initial public offering	(17,228,954)	(321,373)	19,827,003	2	321,371	—	—	321,373
Issuance of common stock in initial public offering, net of underwriting discounts and commissions and offering costs of $21.7 million	—	—	12,475,000	1	190,378	—	—	190,379
Issuance of common stock under private placement offering, net of offering costs of $1.4 million	—	—	1,000,000	—	15,591	—	—	15,591
Reclassification of convertible preferred stock and common stock warrants into common stock upon initial public offering	—	—	3,369,473	—	57,348	—	—	57,348
Vesting of restricted stock units	—	—	275,919	—	—	—	—	—
Stock option exercises	—	—	745,685	—	4,757	—	—	4,757
Stock-based compensation expense	—	—	—	—	16,384	—	—	16,384
Unrealized gain on short-term and long-term investments	—	—	—	—	—	338	—	338
Net loss	—	—	—	—	—	—	(73,200)	(73,200)
Balance at December 31, 2025	—	$ —	44,360,873	$ 4	$ 657,140	$ 403	$ (369,937)	$ 287,610

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

BETA BIONICS, INC.

STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (73,200)	$ (54,756)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,573	1,151
Provision for expected credit losses	40	70
Stock-based compensation expense	16,384	6,384
Net provision for excess and obsolete inventory	1,478	(636)
Change in fair value of warrant liabilities	12,450	13,412
Accretion of discount on short-term investments	(2,054)	(2,905)
Amortization of premium on long-term investments	63	—
Amortization of operating lease right-of-use asset	1,302	1,132
Loss on disposal of property and equipment	31	23
Changes in operating assets and liabilities:		
Accounts receivable	(5,162)	(7,618)
Inventories	(9,880)	(11,439)
Prepaid expenses and other current assets	(5,808)	(2,849)
Other long-term assets	(30)	(29)
Accounts payable	2,098	1,515
Accrued expenses and other current liabilities	7,424	6,838
Other long-term liabilities	1,547	—
Operating lease liability	(1,236)	(1,023)
Deferred revenue	2,055	2,457
Net cash used in operating activities	(50,925)	(48,273)
Cash flows from investing activities:		
Purchases of short-term investments	(282,035)	(72,131)
Purchases of long-term investments	(45,473)	—
Proceeds from maturities and redemptions of short-term investments	170,000	72,000
Proceeds on disposal of property and equipment	—	50
Purchases of property and equipment	(5,297)	(3,395)
Net cash used in investing activities	(162,805)	(3,476)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of underwriting discounts, commissions and issuance costs	194,526	—
Proceeds from the issuance of common stock from private placement, net of issuance costs	15,591	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	59,660
Payments for deferred offering costs	—	(4,147)
Proceeds from stock option exercises	4,757	89
Proceeds from common stock warrants exercise	—	13
Net cash provided by financing activities	214,874	55,615
Net increase in cash, cash equivalents and restricted cash	1,144	3,866
Cash, cash equivalents and restricted cash at beginning of period	30,532	26,666
Cash, cash equivalents and restricted cash at end of period	$ 31,676	$ 30,532
Supplemental disclosure of non-cash investing and financing information:		
Deferred offering costs included in accrued expenses	$ —	$ 862
Reclassification of long-term investments to short-term investments	$ 171,104	$ —
Conversion of convertible preferred stock upon initial public offering	$ 321,373	$ —
Conversion of warrants net exercise upon initial public offering	$ 57,348	$ —
Reclassification of deferred offering costs to equity upon initial public offering	$ 5,051	$ —
Operating lease right-of-use asset obtained in exchange for operating lease obligations	$ 1,284	$ 4,055
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 31,576	$ 30,432
Restricted cash	100	100
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 31,676	$ 30,532

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

BETA BIONICS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

Beta Bionics, Inc. (the "Company") is a commercial-stage medical device company engaged in the design, development, and commercialization of innovative solutions to improve the health and quality of life of insulin-requiring people with diabetes ("PWD") by utilizing advanced adaptive closed-loop algorithms to simplify and improve the treatment of their disease. The Company was incorporated as a Massachusetts benefit corporation in October 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 utilizes an adaptive closed-loop insulin dosing algorithm designed to automate insulin delivery without requiring users to manually calculate insulin doses.

From its inception to December 31, 2025, 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 and single-use products.

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 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"), Series D convertible preferred stock (the "Series D Preferred Stock"), and Series E convertible preferred stock (the "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.

Initial Public Offering

On January 31, 2025, the Company completed its initial public offering ("IPO") pursuant to which the Company issued 13,800,000 shares of its common stock, including 1,800,000 additional shares pursuant to the exercise in full of the underwriters of their option to purchase shares of common stock from the Company and other selling stockholders (consisting of 475,000 shares from the Company and 1,325,000 shares from the selling stockholders), at a public offering price of $17.00 per share (the "IPO Price"). The aggregate net proceeds from the offering, after deducting underwriting discounts, commissions, and other offering expenses, were approximately $190.4 million. In addition, upon the closing of the IPO, all 6,671,174 shares of Class A, Class B, and Class C Common Stock were converted into an equal number of shares of common stock, all 17,228,954 outstanding shares of convertible preferred stock were converted into 19,827,003 shares of common

stock, and all 3,196,025 outstanding warrants to purchase shares of Series C Preferred Stock and Class B Common Stock were converted into 3,373,409 shares of common stock.

Private Placement Offering

On January 21, 2025, the Company entered into a Common Stock Purchase Agreement (the "Private Placement Offering") with an existing accredited investor pursuant to which the Company sold 1,000,000 shares of its common stock at a per share price equal to the IPO Price. The Private Placement Offering closed concurrently with the IPO on January 31, 2025. The aggregate net proceeds from the Private Placement Offering, after deducting underwriting discounts, commissions, and other offering expenses, were approximately $15.6 million.

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").

The Reverse Stock Split became effective on January 21, 2025. Accordingly, all share and per share data included for all periods presented in these financial statements and the accompanying notes have been adjusted retroactively to reflect the impact of the Reverse Stock Split.

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.

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 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.

Cash and Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash and all highly liquid investments purchased with original maturities of three months or less. Restricted cash relates to a letter of credit maintained in connection with the

Company's lease agreement entered into in May 2019. The Company is required to maintain a letter of credit in the amount of $0.1 million for the benefit of the landlord. The lease is expected to expire within the next twelve months, at which time the letter of credit is expected to be released. As of December 31, 2025 and 2024, this amount was guaranteed by a deposit in a money market fund and classified as restricted cash on the balance sheets.

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' equity (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, 2025 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.

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 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, restricted cash, short-term investments and long-term investments 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 the balance sheet date (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.

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.

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:

	Net Sales		Accounts Receivable, net	
	Year Ended December 31,		December 31,	December 31,
	2025	2024	2025	2024
Distributor A	13.8%	12.8%	14.7%	13.7%
Distributor B	12.9%	18.3%	*	13.3%
Distributor C	10.8%	11.6%	*	10.6%
Distributor D	12.0%	16.3%	*	13.0%
Distributor E	*	*	14.0%	14.8%
Distributor F	*	*	19.4%	*
Distributor G	13.2%	*	10.9%	*
Distributor H	11.7%	*	16.0%	*

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

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.

Valuation of 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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is 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.

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, 2025 or 2024.

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 17).

The Company's leases have initial lease terms of approximately one to six 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.

Deferred Offering Costs

The Company capitalized as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's IPO. As of December 31, 2025, the Company did not have a balance in deferred offering costs. As of December 31, 2024, the Company had $5.1 million in deferred offering costs, of which $0.9 million were in accrued expenses. The deferred offering costs were offset against the IPO proceeds upon the closing the IPO in January 2025 (see Note 1).

Long-Term Investments

Long-term investments include U.S. Treasury notes with maturities of 12 months or more. The Company classifies its U.S. Treasury securities as available-for-sale and carries them at fair value. If a U.S. treasury note has an unrealized loss and the Company either intends to sell the security or it is more likely than not that the Company will be required to sell the security before its anticipated recovery, the Company will record an impairment charge to investment and other income (expense), net for the entire amount of the unrealized loss and adjust the amortized cost basis of the security. The Company has not recognized any impairment losses related to its long-term investments during the years ended December 31, 2025 and 2024. All long-term investments are classified as noncurrent based on the nature of the investments.

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, 2025 and 2024, no liabilities were recorded for loss contingencies (see Note 18).

Warrant Liabilities

Preferred Stock Warrants

Prior to the IPO, the Company 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).

In connection with the completion of the IPO, all outstanding preferred stock warrants were exercised or otherwise extinguished. As a result, there were no preferred stock warrants outstanding or recorded as warrant liabilities as of December 31, 2025.

Common Stock Warrants

Prior to the IPO, the Company 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).

In connection with the completion of the IPO, all outstanding common stock warrants were exercised or otherwise extinguished. Accordingly, there were no common stock warrant liabilities outstanding as of December 31, 2025.

Classification and Accretion of Convertible Preferred Stock

The Company's convertible preferred stock is classified outside of stockholders' equity (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 Preferred Stock, the Series A-2 Preferred Stock, the Series B Preferred Stock, the Series B-2 Preferred Stock, the Series C Preferred Stock, the

Series D Preferred Stock and the Series E 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.

Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's Chief Executive Officer is the Company's CODM. The CODM reviews financial information presented on a total company basis for purposes of making operating decisions, allocating resources, and evaluating financial performance. As such, the Company has determined that it operates as one operating segment. The measure of segment assets is presented as total assets on the balance sheets. The Company has concluded that gross profit and net income (loss) are the primary measures of segment profit or loss used by the CODM. The CODM assesses performance for the Company, monitors budget versus actual results, and determines how to allocate resources based on net income (loss) as reported in the statements of operations and comprehensive loss. There are no other expense categories regularly provided to the CODM that are not already included in the primary financial statements herein. During the years ended December 31, 2025 and 2024, the Company did not generate any international revenues and the Company did not have a material amount of assets located outside of the United States.

Revenue Recognition

Net Sales

Revenue is generated primarily from sales of the iLet and its associated single-use products, such as cartridges for insulin storage and delivery, and infusion sets that connect the iLet to a user's body. These products are distributed through a network of distributors and pharmacies, which then 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 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 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. Actual rebates and chargebacks have not differed materially from estimated amounts recorded in the accompanying financial statements.

Sales Returns

The Company offers a 90-day right of return 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. 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. Warranty expense is recorded as a component of cost of sales in the statements of operations and comprehensive loss.

Reconciliations of the changes in the Company's product warranty liability, which is included in accrued expenses and other current liabilities and other long-term liabilities, were as follows:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Product warranty liability at beginning of period	$ 657	$ 22
Warranty expense	4,537	1,689
Warranty fulfillment	(2,040)	(1,054)
Product warranty liability at end of period	$ 3,154	$ 657

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.

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 RSUs is based on the closing price of our common stock on the grant date. The fair value of stock options is estimated using the Black- Scholes option pricing model, which requires the input off 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 common stock only recently became publicly traded in January 2025, there is limited historical trading data to estimate expected volatility. Accordingly, 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.

Prior to the IPO, 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. For stock options granted subsequent to the Company's IPO, the fair value of the underlying common stock is based on the closing market price of the Company's publicly traded common stock on the date of grant.

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 Income (Loss)

Comprehensive loss includes net loss as well as other changes in stockholders' equity (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, 2025 and 2024, the unrealized gain (loss) on short-term and long-term investments, approximately $0.3 million and $(0.1) million, respectively, was recorded in other comprehensive income (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. Subsequent to the Company's IPO, all outstanding shares of Class A, Class B and Class C common stock were converted into a single class of common stock.

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.

Recently Adopted Accounting Pronouncements

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. 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.

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 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard retrospectively for the period ending December 31, 2025. The adoption impacted the disclosures and did not impact the financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03")*, and in January 2025, the FASB issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date* ("ASU 2025-01"). ASU 2024-03 requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03, as clarified by ASU 2025-01, is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact that this guidance may have on its financial statements.

In July 2025, FASB issued ASU 2025-05, *Credit Losses (Topic 326) – Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient to assume that the current conditions as of the balance sheet date will remain unchanged for the remaining life of the asset when developing a reasonable and supportable forecast as part of estimating expected credit losses on current accounts receivable and current contract assets arising from transactions accounted for under ASC 606. The

amendments are effective for fiscal years beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact that this guidance may have on its financial statements.

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 year ended December 31, 2025 and 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") reimbursement channels, which entail differing payment outlays. For the year ended December 31, 2025 and 2024, 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,	
	2025	2024
	(in thousands)	
DME channel		
iLet[(1)]	$ 52,055	$ 46,617
Single-use products	23,765	12,189
Total DME channel	75,820	58,806
PBP channel		
iLet[(1)]	692	2,099
Single-use products	23,739	4,219
Total PBP channel	24,431	6,318
Total net sales	$ 100,251	$ 65,124

(1) iLet includes the over-time recognition software updates and mobile app access.

The Company recognizes revenue at a point in time once control has transferred to the customer, as well as over time for performance obligation to provide ongoing services such as unspecified software updates. Revenue recognized during the year ended December 31, 2025 that was included in the deferred revenue balance as of December 31, 2024 was approximately $0.8 million.

At December 31, 2025 and 2024, $4.9 million and $2.8 million, respectively, was allocated to performance obligations that were not yet satisfied and is recorded in deferred revenue on the balance sheet. These are primarily associated with the unspecified software updates promised to users and the user's access to the mobile application. At December 31, 2025 and 2024, of the performance obligations not yet satisfied, $1.6 million and $0.9 million, respectively, is expected to be recognized as revenue in the next 12 months, with the remainder expected to be recognized thereafter.

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, 2025			
	Level 1	Level 2	Level 3	Total
Assets	(in thousands)			
Cash equivalents:				
Money market fund	$ 26,249	$ —	$ —	$ 26,249
Restricted cash:				
Money market fund	100	—	—	100
Short-term investments				
U.S. Treasury bills	187,549	—	—	187,549
Long-term investments				
U.S. Treasury notes	45,431	—	—	45,431
Total assets	$ 259,329	$ —	$ —	$ 259,329

	Fair Value Measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets	(in thousands)			
Cash equivalents:				
Money market fund	$ 27,107	$ —	$ —	$ 27,107
Restricted cash:				
Money market fund	100	—	—	100
Short-term investments				
U.S. Treasury bills	73,143	—	—	73,143
Total assets	$ 100,350	$ —	$ —	$ 100,350
Liabilities				
Series C warrant liabilities	$ —	$ —	$ 9,935	$ 9,935
Common B warrant liabilities	—	—	34,963	34,963
Total liabilities	$ —	$ —	$ 44,898	$ 44,898

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, 2025 and 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 years ended December 31, 2025 and 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 IPO 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 IPO 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, 2024:

	December 31, 2024
Fair value of Series C Preferred Stock	$ 19.11
Strike price	$ 0.02
Risk-free interest rate	4.39%
Expected term (in years)	0.38
Expected volatility	65.00%
Expected dividend yield	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, 2024:

	December 31, 2024
Fair value of Class B common stock	$ 13.08
Strike price	$ 0.02
Risk-free interest rate	4.53%
Expected term (in years)	8.70
Expected volatility	75.77%
Expected dividend yield	0%

The Company recognizes changes in the fair value of the warrant liabilities as a component of other income (expense) in its statements of operations and comprehensive loss. The Company recognized changes in the fair value of the warrant liabilities through December 31, 2024, and up until immediately prior to the net exercise of the warrants, which took place concurrently with the IPO on January 31, 2025 (see Note 1).

Upon the closing of the IPO, the Company revalued the convertible preferred stock warrants and common stock warrants and reclassified the liability to stockholders' equity (deficit). As the warrants were net exercised at the IPO, they are no longer outstanding.

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	488
Balance at December 31, 2024	9,935
Change in fair value	1,929
Net exercise and conversion into common stock upon closing of IPO	(11,864)
Balance at December 31, 2025	$ —

	Common B Warrant Liability (in thousands)
Balance at December 31, 2023	$ 28,126
Change in fair value	6,837
Balance at December 31, 2024	34,963
Change in fair value	10,521
Net exercise and conversion into common stock upon closing of IPO	(45,484)
Balance at December 31, 2025	$ —

5. Short-Term and Long-Term Investments

The following represents a summary of the estimated fair value of short-term and long-term investments at December 31, 2025 and 2024:

	Fair Value Measurements at December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Short-term investments				
U.S. Treasury bills	$ 187,167	$ 382	$ —	$ 187,549
Long-term investments				
U.S. Treasury notes	45,411	20	—	45,431
Total	$ 232,578	$ 402	$ —	$ 232,980

	Fair Value Measurements at December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
	(in thousands)			
Short-term investments				
U.S. Treasury bills	$ 73,078	$ 65	$ —	$ 73,143
Total	$ 73,078	$ 65	$ —	$ 73,143

The following represents the contractual maturities of available-for-sale debt securities as of December 31, 2025:

	Fair Value Measurements at December 31, 2025			
	Years to Maturity			
	Within One Year	One to Two Years	More Than Two Years	Estimated Fair Value
	(in thousands)			
U.S. Treasury bills	$ 187,549	$ —	$ —	$ 187,549
U.S. Treasury notes	—	45,431	—	45,431
Total	$ 187,549	$ 45,431	$ —	$ 232,980

6. Accounts Receivable, Net

Accounts receivable, net consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Accounts receivable	$ 17,274	$ 12,112
Less: allowance for credit losses	(156)	(116)
Accounts receivable, net	$ 17,118	$ 11,996

Accounts receivable are stated at the amount expected to be collected. The allowance for credit losses reflects expected losses on accounts receivable based primarily on historical experience and customer credit

quality. The allowance for credit losses and related write-offs were not material for the years ended December 31, 2025 and 2024.

7. Inventories

Inventories consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Raw materials	$ 8,556	$ 6,737
Work in process	2,750	637
Finished goods	10,416	5,946
Total inventories	$ 21,722	$ 13,320

8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Prepaid expenses	$ 7,064	$ 2,982
Interest receivable	2,511	233
Income tax receivable and other current assets	265	817
Prepaid expenses and other current assets	$ 9,840	$ 4,032

9. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Manufacturing equipment	$ 9,247	$ 6,252
Leasehold improvements	830	810
Furniture	939	924
Computer equipment	—	308
Construction in progress	3,339	1,735
Total cost	14,355	10,029
Less: Accumulated depreciation and amortization	(5,755)	(5,253)
Property and equipment, net	$ 8,600	$ 4,776

Depreciation expense was $1.6 million and $1.2 million for the years ended December 31, 2025 and 2024, respectively.

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Employee compensation and benefits	$ 12,656	$ 9,942
Sales returns, rebates and patient assistance	3,161	1,502
Inventory in transit	1,961	530
Professional fees	1,713	2,119
Warranty	1,607	657
Royalties	1,005	741
Other	328	337
Accrued expenses and other current liabilities	$ 22,431	$ 15,828

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, and Series E 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 but did identify contingent beneficial conversion features on each class of Preferred Stock related to the down round protective provisions. Although down round protection was triggered with the issuance of the Series C and Series D Preferred Stock, the contingent beneficial conversion features were not triggered requiring recognition by the Company. Upon the adoption of ASU 2020-06, the Company recorded an adjustment to reflect the cumulative effect of the down rounds triggered with the issuance of the Series C and Series D Preferred Stock, resulting in a $12.3 million adjustment to retained earnings (see Note 1 for further details). In November 2024, the Company issued and sold 4,352,393 shares of Series E Preferred Stock, at a price of $13.79 per share, for gross proceeds of $60.0 million. The Company incurred issuance costs in connection with this transaction of $0.3 million. The Series E Preferred Stock has an Original Issuance Price and Conversion Price (each as defined in the Company's certificate of incorporation) per share of $13.79.

From August to September 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 IPO or a SPAC Transaction. 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.

As part of the Series E Preferred Stock issuance, the Company increased the number of shares of Class B common stock authorized for issuance from 65,000,000 shares to 70,000,000 shares and increased the number of shares of preferred stock authorized for issuance from 26,434,390 shares to 34,966,547 shares, of which 8,574,227 shares were designated as Series E Preferred Stock.

As of 12/31/2024, Preferred Stock consisted of the following:

	December 31, 2024				
	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	4,197,930	2,130,910	61,606	63,053	3,010,683
Series B-2 Preferred Stock	3,960,000	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
Series E Preferred Stock	8,574,227	4,352,393	59,660	60,000	4,352,393
	34,966,547	17,228,954	$ 321,373	$ 355,162	19,827,003

On January 31, 2025 upon the closing of the IPO, all 17,228,954 outstanding shares of the Company's convertible preferred stock were converted into 19,827,003 shares of common stock, and the carrying value of $321.4 million was reclassified to stockholders' equity (deficit). All 3,196,025 outstanding warrants to purchase shares of Series C Preferred Stock and Class B Common Stock were converted into 3,369,473 shares of common stock, and the carrying value of $57.3 million was reclassified to stockholders' equity (deficit).

Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

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. The holders of Class C common stock do not have voting rights.

Per the certificate of incorporation, the events requiring the automatic conversion of all shares of outstanding Class A common stock, Class B common stock, and Class C common stock into common stock are defined as (i) the closing of a firm-commitment underwritten public offering of common stock, (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 voting common stock.

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 $100.0 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.

Common stock reserved for future issuance consists of the following:

	December 31,	
	2025	2024
Convertible preferred stock	—	19,827,003
Common stock options granted and outstanding	6,453,036	5,667,555
RSUs outstanding	753,885	—
Shares available for issuance under the 2016 Stock Incentive Plan	—	1,600,371
Shares available for issuance under the 2025 Stock Incentive Plan	4,136,115	—
Shares available for issuance under the ESPP	410,000	—
Total common stock reserved for future issuance	11,753,036	27,094,929

On January 31, 2025, the Company completed its IPO and as a result, all 6,671,174 shares of Class A, Class B, and Class C Common Stock were converted into an equal number of shares of common stock, and all outstanding shares of convertible preferred stock were converted into shares of common stock in accordance with the certificate of incorporation. Following the IPO, the Company amended and restated its certificate of incorporation to authorize a single class of common stock. See Note 1 for further details.

As of December 31, 2025, the Company had 700,000,000 shares of common stock authorized, par value $0.0001 per share, of which 44,360,873 shares were issued and outstanding. As of December 31, 2024, the Company was authorized to issue 75,886,910 shares of common stock, par value $0.0001 per share, consisting of Class A, Class B, and Class C common stock, of which 6,667,793 shares were issued and outstanding.

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 exercise prices, vesting conditions, and other terms of awards granted under the 2016 Plan are determined by the Board or its designated committee.

Following the Company's IPO in January 2025 and the conversion of all outstanding shares of Class A, Class B, and Class C common stock into a single class of common stock, the Company grants equity classified stock options for the purchase of shares of the Company's 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. As of December 31, 2025, 4,768,461 shares of common stock were available for issuance under the 2016 Plan. 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 under the 2016 Plan may not be less than the fair value of the Company's common stock on the date of grant.

2025 Equity Incentive Plan

On January 21, 2025, the Company's board of directors adopted and the Company's stockholders approved the 2025 Equity Incentive Plan (the "2025 Plan"), which became effective on the date immediately preceding the date on which the Company's registration statement was declared effective by the U.S. Securities and Exchange Commission ("SEC"). The 2025 Plan replaced the 2016 Plan, as the Company's board of directors has determined to not make additional grants under the 2016 Plan following the closing of the IPO. However, the 2016 Plan will continue to govern outstanding equity awards granted under the 2016 Plan. The 2025 Plan allows the Company to grant incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards ("RSUs"), performance awards and other awards. The number of shares initially available for issuance under awards granted pursuant to the 2025 Plan is 12,016,744.

Stock Options

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,	
	2025	2024
Fair value of common stock	$ 14.38	$ 13.08
Risk-free interest rate	4.25%	4.09%
Expected term (in years)	5.97	6.02
Expected volatility	100.01%	86.80%
Expected dividend yield	0%	0%

The following table summarizes stock option activity for the twelve months ended December 31, 2025:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding at December 31, 2024	5,667,555	$ 6.98	7.6	$ 22,929
Granted	1,731,539	$ 17.85		
Exercised	(745,685)	$ 6.38		
Forfeited or cancelled	(184,977)	$ 10.45		
Expired	(15,396)	$ 7.09		
Outstanding at December 31, 2025	6,453,036	$ 9.87	7.4	$ 141,925
Vested and expected to vest at December 31, 2025	6,453,036	$ 9.87	7.4	$ 141,925
Options exercisable at December 31, 2025	3,612,259	$ 8.03	6.7	$ 86,092

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 twelve months ended December 31, 2025 and 2024 were $12.1 million and not significant, respectively.

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $14.38 per share and $6.92 per share, respectively. The total fair value of shares vested during the years ended December 31, 2025 and 2024 was $6.7 million and $3.1 million, respectively.

The following table summarizes the non-vested stock options that were outstanding as of December 31, 2025 and 2024:

	Number of Options	Weighted-Average Exercise Price
Non-vested options, December 31, 2025	2,840,777	$ 12.21
Non-vested options, December 31, 2024	2,779,877	$ 7.07

Restricted Stock Units

The following table summarizes RSU activity under the Company's incentive plans for the twelve months ended December 31, 2025:

	Number of Shares	Weighted-Average Grant Date Fair Value
RSUs outstanding, December 31, 2024	—	$ —
Granted	1,083,312	$ 14.96
Vested	(275,919)	$ 14.61
Cancelled	(53,508)	$ 14.49
RSUs outstanding, December 31, 2025	753,885	$ 15.12

Stock-Based Compensation Expense

Stock-based compensation expense by type and financial statement line is included in the Company's statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Options	$ 11,691	$ 6,384
RSUs	4,693	—
Total stock-based compensation expense	$ 16,384	$ 6,384

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Cost of sales	$ 542	$ 275
Research and development	3,205	1,144
Sales and marketing	4,625	1,661
General and administrative	8,012	3,304
Total stock-based compensation expense	$ 16,384	$ 6,384

As of December 31, 2025, total unrecognized stock-based compensation expense related to the unvested stock-based awards was $25.8 million, which is expected to be recognized over a weighted-average period of 2.5 years. As of December 31, 2025, total unrecognized stock-based compensation expense related to the unvested RSUs was $10.7 million, which is expected to be recognized over a weighted-average period of 2.3 years.

Employee Stock Purchase Plan

The Company's Employee Stock Purchase Plan ("ESPP") was approved by the Board in January 2025. The ESPP enables eligible employees to purchase shares of the Company's common stock using their after-tax payroll deductions, subject to certain conditions. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Eligible employees may contribute, through payroll deductions, up to 15% of their earnings for the purchase of common stock under the ESPP. The purchase price of common stock under the ESPP is the lesser of: (a) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (b) 85% of the fair market value of a share of the Company's common stock on the last date of the offering, limited to the maximum number of shares that may be purchased on any single purchase date. Each offering under the ESPP has a six-month duration, beginning on January 1 and July 1 of each year, with purchases occurring on June 30 and December 31, respectively. The Company has not conducted any offerings under the ESPP as of December 31, 2025. The first offering under the ESPP commenced on January 1, 2026.

14. Employee Benefit Plan

The Company maintains a 401(k) retirement plan (the "401(k) Plan") for the benefit of eligible employees. Each participant may elect to contribute up to 100% of his or her compensation to the 401(k) Plan each year, subject to certain Internal Revenue Service limitations. Under the terms of the Plan, the Company matches 100% of the first 6% of employee contributions. During the years ended December 31, 2025 and 2024, the Company contributed $3.0 million and $2.2 million, respectively, to the 401(k) Plan.

15. Income Taxes

During the years ended December 31, 2025 and 2024, 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. Cash paid for income taxes, net of refunds, was not material for the years ended December 31, 2025 and 2024 and was paid in the United States.

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,			
	2025		2024	
	Amount (in thousands)	Percentage	Amount (in thousands)	Percentage
Income taxes (benefit) at statutory federal rate	$ (15,301)	21.0 %	$ (11,514)	21.0 %
State and local income taxes, net of federal benefit[1]	(195)	0.3 %	(105)	0.2 %
Tax credits				
Research and development	(1,754)	2.4 %	(1,074)	2.0 %
Changes in valuation allowance	11,874	(16.3)%	8,199	(15.0)%
Nontaxable or nondeductible items				
Loss on revaluation of warrant liability	2,614	(3.6)%	2,817	(5.1)%
Stock based compensation	(927)	1.3 %	1,146	(2.1)%
Officer's compensation	2,841	(3.9)%	—	— %
Other	316	(0.4)%	203	(0.4)%
Changes in unrecognized tax benefits	546	(0.7)%	320	(0.6)%
Other Adjustments				
Other	(14)	0.0 %	8	(0.0)%
Provision / (benefit) for income taxes	$ —	— %	$ —	— %

(1) The state(s) that contribute to the majority (greater than 50%) of the tax effect in this category is California for year ending December 31, 2025.

The Company's net deferred tax assets consisted of the following:

	December 31,	
	2025	2024
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 54,762	$ 39,470
Capitalized research and development expenditures	8,205	10,728
Research and development credit carryforwards	7,609	5,425
Stock-based compensation	1,484	2,892
Lease liability	1,751	1,687
Accruals and other temporary differences	3,336	2,429
Total deferred tax assets	77,147	62,631
Valuation Allowance	(75,307)	(61,023)
Deferred tax assets	1,840	1,608
Deferred tax liabilities:		
Operating lease right-of-use asset	(1,589)	(1,545)
Other	(251)	(63)
Total deferred tax liabilities	(1,840)	(1,608)
Net deferred tax assets	$ —	$ —

As of December 31, 2025, the Company had U.S. federal net operating loss carryforwards of $240.8 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 $229.3 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, 2025, the Company had state net operating loss carryforwards of $65.4 million, which may be available to reduce future taxable income, of which $58.8 million expire at various dates beginning in 2029, while $6.6 million do not expire. As of December 31, 2025, the Company also had U.S. federal and state research and development tax credit carryforwards of $5.8 million and $4.6 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2032, respectively, with $4 million of state research and development tax credits carrying forward indefinitely.

Utilization of the U.S. federal and state net operating loss 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, 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, 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, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, 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 net operating loss 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, 2025 and 2024. 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 net operating loss carryforwards and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Valuation allowance as of beginning of year	$ 61,023	$ 51,903
Increases	14,284	9,120
Valuation allowance as of end of year	$ 75,307	$ 61,023

The changes in the Company's unrecognized tax benefits are summarized as follows:

	December 31,	
	2025	2024
	(in thousands)	
Beginning balance	$ 1,401	$ 1,053
Increases related to current year tax positions	568	348
Ending balance	$ 1,969	$ 1,401

As of December 31, 2025 and 2024, the Company had unrecognized tax benefits of $2.0 million and $1.4 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, 2025 and 2024, 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 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, 2025 and 2024, there were no pending tax examinations. The Company is open to future tax examination under statute by the IRS from 2022 to present and by most state tax authorities from 2021 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.

On July 4, 2025, the U.S. President signed into law H.R.1, the legislation commonly known as the One Big Beautiful Bill (OBBB). This legislation extended, modified, or made permanent many of the tax provisions which were initially enacted as part of the Tax Cuts and Jobs Act (TCJA) of 2017. The OBBB contains a number of tax provisions including, but not limited to, immediate expensing of domestic research and experimental expenditures. These tax provisions apply to either tax years beginning after December 31, 2024 or December 31, 2025. The Company has reflected the effect of OBBB within the provision for income taxes and the deferred taxes as of December 31, 2025.

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,	
	2025	2024
Convertible preferred stock (as converted into shares of common stock)	—	19,827,003
Stock options to purchase common stock	6,453,036	5,667,555
Warrants to purchase Series C convertible preferred stock	—	697,874
Warrants to purchase Class B common stock	—	2,675,535
RSUs	753,885	—
Total	7,206,921	28,867,967

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders:

	Year Ended December 31,	
	2025	2024
	(in thousands, except share and per share data)	
Numerator:		
Net loss attributable to common stockholders, basic and diluted	$ (73,200)	$ (54,756)
Denominator:		
Weighted-average Class A common stock outstanding, diluted	—	2,952,123
Weighted-average Class B common stock outstanding, diluted	—	3,364,023
Weighted-average Class C common stock outstanding, diluted	—	48,918
Weighted-average common stock outstanding, basic and diluted	40,529,051	—
Net loss per share attributable to common stockholders, basic and diluted	$ (1.81)	$ (8.60)

17. Leases

In May and November 2023, the Company entered into two separate lease agreements for a total of approximately 8,500 square feet of office space in San Diego, California. These leases expire in January 2026 and February 2027, respectively, with the February 2027 lease including an 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 the Company determined at lease commencement that the option was not reasonably certain to be 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.

In October 2024, the Company entered into a lease agreement for an additional office suite to expand its office space in San Diego, California, which expires in March 2027. As a result, the Company recognized operating lease right-of-use asset and associated operating lease liability of $0.2 million.

In September 2025, the Company entered into a sublease agreement for an additional office building in San Diego, California, which expires in August 2028. As a result, the Company recognized operating lease right-of-use asset and associated operating lease liability of $1.3 million.

The components of lease expense were as follows:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Operating lease cost–fixed	$ 1,803	$ 1,375
Operating lease cost–variable	195	209
Short-term lease expense	42	17
Total lease expense	$ 2,040	$ 1,601

Cash paid for amounts included in the measurement of operating lease liabilities was $1.7 million and $1.3 million, respectively, for the years ended December 31, 2025 and 2024.

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

	December 31, 2025
Weighted-average remaining lease term	5.26
Weighted-average discount rate	6.80%

Future lease payments under non-cancellable leases as of December 31, 2025 were as follows:

(in thousands) Year Ending December 31,	
2026	2,006
2027	1,418
2028	1,384
2029	1,092
2030	1,136
Thereafter	1,782
Total future lease payments	$ 8,818
Less: imputed interest	(1,515)
Total lease liabilities	$ 7,303

18. 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 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 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 twelve months ended December 31, 2024, under its clinical supply arrangement the Company ordered clinical material totaling $0.9 million for Phase 2 clinical trials and paid a deposit equal to 30% of the estimated clinical material costs, which was recognized in prepaid expense and other current assets in the balance sheets. As of March 2025, the clinical materials had been delivered to the Company and the remaining payment of $0.6 million was made.

In connection with entering into Phase 3 of the collaboration, under its clinical supply arrangement, the Company expects to incur development and manufacturing costs, including ordering clinical materials and technical transfer, development, and testing of the product, totaling $5.1 million. As of December 31, 2025, the Company has completed payments totaling $4.0 million. The payments were initially recognized in prepaid expense and other current assets in the balance sheets and a portion of the payment was expensed to research and development as it related to the services completed.

19. 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 $3.2 million and $2.2 million of royalties expense under the Control Algorithm Agreement during the twelve months ended December 31, 2025 and 2024, respectively, 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 twelve months ended December 31, 2025 and 2024, the Company paid BU $0.2 million and $0.2 million, respectively, for reimbursed legal costs in connection with the agreements.

As of December 31, 2025 and 2024, $1.1 million and $0.7 million, respectively, were due to BU from the Company. As of January 30, 2025, Edward Damiano no longer held board or management positions and no longer has the ability to significantly influence the Company. Therefore, Edward Damiano and BU are not considered a related party under ASC 850, "Related Party Disclosures" as of December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

(1) Financial Statements

See Index to Financial Statements under Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

Schedules not listed above have been omitted because they are not required, not applicable, or the required information is otherwise included.

(3) Exhibits

Exhibit Number	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-42491	3.1	01/31/25	
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-284147	3.4	01/06/25	
4.1	Form of Common Stock Certificate.	S-1/A	333-284147	4.1	01/22/25	
4.2†	Amended and Restated Investor Rights Agreement, dated November 8, 2024, by and among the Registrant and certain of its stockholders.	S-1	333-284147	4.2	01/06/25	
4.3	Description of Capital Stock.	10-K	001-42491	4.3	03/25/25	
10.1*	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1	333-284147	10.1	01/06/25	
10.2*	Beta Bionics, Inc. Amended and Restated 2016 Stock Incentive Plan.	S-1	333-284147	10.2	01/06/25	
10.3*	Forms of Option Agreement, Notice of Stock Option Grant and Exercise Notice under the Beta Bionics, Inc. Amended and Restated 2016 Stock Incentive Plan.	S-1	333-284147	10.3	01/06/25	
10.4*	Beta Bionics, Inc. 2025 Equity Incentive Plan.	S-8	333-284655	99.3	02/03/25	
10.5*	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Beta Bionics, Inc. 2025 Equity Incentive Plan.	S-1	333-284147	10.5	01/06/25	
10.6*	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Beta Bionics, Inc. 2025 Equity Incentive Plan.	S-1	333-284147	10.6	01/06/25	
10.7*	Forms of Stock Option Grant Double Trigger Grant Notice and Award Agreement under the Beta Bionics, Inc. 2025 Equity Incentive Plan	S-1/A	333-284147	10.7	01/22/25	
10.8*	Forms of Restricted Stock Unit Double Trigger Grant Notice and Award Agreement under the Beta Bionics, Inc. 2025 Equity Incentive Plan.	S-1/A	333-284147	10.8	01/22/25	
10.9*	Beta Bionics, Inc. 2025 Employee Stock Purchase Plan.	S-8	333-284655	99.8	02/03/25	
10.10*	Non-Employee Director Compensation Policy.					X
10.11*	Employment Agreement, dated August 1, 2022, between the Registrant and Sean Saint.	S-1	333-284147	10.9	01/06/25	
10.12*	Employment Agreement, dated August 1, 2022, between the Registrant and Stephen Feider.	S-1	333-284147	10.10	01/06/25	
10.13*	Employment Agreement, dated November 14, 2022, between the Registrant and Steven Russell, M.D.	S-1	333-284147	10.11	01/06/25	
10.14*	Employment Agreement, dated August 1, 2023, between the Registrant and Mike Mensinger.	S-1	333-284147	10.12	01/06/25	
10.15*	Employment Agreement, dated September 10, 2024, between the Registrant and Mark Hopman.	S-1	333-284147	10.13	01/06/25	
10.16#	Lease Agreement, dated February 3, 2020, by and between Pacific Industrial Partners, LLC and the	S-1	333-284147	10.14	01/06/25	

	Registrant, as amended by Amendment No. 1 dated May 19, 2020, Amendment No. 2 dated March 12, 2024 and Amendment No. 3 dated September 13, 2024.					
10.17#	Device License Agreement, dated December 16, 2015, by and between Trustees of Boston University and the Registrant, as amended by the First Amendment dated December 11, 2017, the Second Amendment dated September 21, 2020, the Third Amendment dated February 14, 2022 and the Fourth Amendment dated November 8, 2024.	S-1	333-284147	10.15	01/06/25	
10.18#	Control Algorithm License Agreement, dated December 23, 2015, by and between Trustees of Boston University and the Registrant, as amended by the First Amendment dated December 11, 2017, the Second Amendment dated September 21, 2020, and the Third Amendment dated February 14, 2022.	S-1	333-284147	10.16	01/06/25	
10.19#	Collaboration and License Agreement, dated May 2, 2024, by and between Xeris Pharmaceuticals, Inc. and the Registrant.	S-1	333-284147	10.17	01/06/25	
10.20#	Commercialization Agreement, dated July 25, 2023, by and between DexCom, Inc. and the Registrant.	S-1	333-284147	10.18	01/06/25	
10.21#	Development and Commercialization Agreement, dated April 2, 2024, by and between Abbott Diabetes Care Inc. and the Registrant.	S-1	333-284147	10.19	01/06/25	
10.22#	Amendment No. 1 to Development and Commercialization Agreement, dated May 9, 2025, by and between Abbott Diabetes Care Inc. and the Registrant.	10-Q	001-42491	10.1	07/29/25	
19	Beta Bionics, Inc. Insider Trader Policy.					X
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.					X
24.1	Power of Attorney (included on the signature page to this Annual Report).					X
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
97*	Beta Bionics, Inc. Incentive Compensation Recoupment Policy	10-K	001-42491	97	03/25/25	

Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, portions of this exhibit (indicated by [***]) have been omitted because the Registrant has determined that the information is both not material and is the type that the Registrant treats as private or confidential. The Registrant hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

† Certain schedules, annexes and exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule, annex and/or exhibit will be furnished to the SEC upon request.

* Indicates a management contract or any compensatory plan, contract or arrangement.

+ The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

BETA BIONICS, INC.

Date: February 24, 2026

By: /s/ Sean Saint
Sean Saint
President and Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Sean Saint and Stephen Feider, and each of them, as his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Sean Saint **Sean Saint**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 24, 2026
/s/ Stephen Feider **Stephen Feider**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 24, 2026
/s/ Adam Lezack **Adam Lezack**	Chairperson of the Board of Directors	February 24, 2026
/s/ Sean Carney **Sean Carney**	Director	February 24, 2026
/s/ Dan Dearen **Dan Dearen**	Director	February 24, 2026
/s/ Christy Jones **Christy Jones**	Director	February 24, 2026
/s/ Gerard Michel **Gerard Michel**	Director	February 24, 2026
/s/ Maria Palasis **Maria Palasis, Ph.D.**	Director	February 24, 2026

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