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, 2024 _____

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 001-37717

SENSEONICS HOLDINGS, INC.

(Exact name of registrant as specified in its Charter)

Delaware	**47-1210911**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

20451 Seneca Meadows Parkway
Germantown, MD 20876-7005
(301) 515-7260
(Address and telephone number, including area code, of registrant's principal executive offices)

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, par value $0.001 per share	**SENS**	**NYSE American**

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 Section 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 Act). Yes ☐ No ☒

As of June 28, 2024, the last business day of the registrant's last completed second quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $206.8 million based on the closing price of $0.40 per share as reported by the NYSE American on such date.

As of February 24, 2025, 651,850,834 shares of common stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1: "Business," Part I, Item 1A: "Risk Factors," and Part II, Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue", "target", "seek", "contemplate", and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. All statements other than statements of historical fact could be deemed forward-looking, including but not limited to statements about:

- the success of our collaboration and commercialization agreement with Ascensia Diabetes Care Holdings AG ("Ascensia");
- the timing of product launches;
- the clinical utility of Eversense;
- our ability to develop future generations of Eversense;
- our ability to service our outstanding indebtedness;
- the timing and availability of data from our clinical trials;
- the timing of our planned regulatory filings and potential regulatory approvals and CE Certificates of Conformity;
- our future development priorities;
- our ability to obtain adequate reimbursement and third-party payor coverage for Eversense;
- 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 limits;
- our expectations about the willingness of healthcare providers to recommend Eversense to people with diabetes;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to comply with applicable regulatory requirements;
- our ability to maintain our intellectual property position;
- our estimates regarding the size of, and future growth in, the market for continuous glucose monitoring systems;
- our estimates regarding the period of time for which our current capital resources will be sufficient to fund our continued operations; and
- our estimates regarding our future expenses and needs for additional financing.

Forward-looking statements are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and our management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. You should refer to "Item 1A. Risk Factors" in this Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we

undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Unless otherwise indicated or the context otherwise requires, all references in this Annual Report to "the Company," "we," "our," "ours," "us" or similar terms refer to Senseonics Holdings, Inc. and its subsidiaries. "Senseonics," the Senseonics logo, Eversense, Eversense E3 and Eversense 365 continuous glucose monitoring and other trademarks or service marks of Senseonics Holdings, Inc. appearing in this Annual Report are the property of Senseonics Holdings, Inc. This Annual Report contains additional trade names, trademarks and service marks of others, which are the property of their respective owners.

PART I

Item 1. Business

Overview

We are a commercial-stage medical technology company focused on the development and manufacturing of glucose monitoring products designed to transform lives in the global diabetes community with differentiated, long-term implantable glucose management technology. Our implantable continuous glucose monitoring ("CGM") system ("Eversense"), including Eversense E3 and Eversense 365 CGM systems are designed to continually and accurately measure glucose levels in people with diabetes via an under-the-skin sensor, a removable and rechargeable smart transmitter, and a convenient app for real-time diabetes monitoring and management for a period of up to twelve months in the case of Eversense 365 and six months in the case of Eversense E3, as compared to seven to 14 days for non-implantable CGM systems. In September 2024, the 365-day extended life Eversense E3 CGM system was approved by the FDA and Ascensia began commercializing Eversense 365 in the fourth quarter of 2024. In June 2022, we affixed the CE mark to the Eversense E3 CGM system and Ascensia began commercialization in select markets in Europe during the third quarter of 2022.

Prior to the commercialization of the current Eversense systems, we sold Eversense system measuring glucose levels for up to 180 days in the United States and prior to that 90 days in both the United States and select European markets. In September 2017, we affixed the CE mark to the Eversense XL CGM system to be sold in select markets in Europe and the Middle East. In June 2018, we obtained FDA approval for the 90-day Eversense CGM system for distribution throughout the United States. In June 2019, we received FDA approval for the non-adjunctive indication (dosing claim) for the 90-day Eversense system. With this approval and the availability of a new app in December 2019, the Eversense system can now be used as a therapeutic CGM in the United States to replace fingerstick blood glucose measurement to make treatment decisions, including insulin dosing.

We are in the early commercialization stages of the Eversense brand and are focused on driving awareness of our CGM system amongst people with diabetes and their healthcare providers. In both the United States and our overseas markets, we have entered into strategic partnerships and distribution agreements that allow third party collaborators with direct sales forces and established distribution systems to market and promote Senseonics CGM systems, including Eversense E3, Eversense 365 and future generation products. Our future generation products in development are our "Gemini" product variation to allow for a 2-in-1 glucose monitoring system combining the functionality of CGM and Flash Glucose Monitoring, in an implantable sensor with battery that may be utilized with a smart transmitter to get continuous glucose readings and alerts, or be utilized through a swipe over the sensor with a smart phone to get on-demand glucose reading without a smart transmitter and our "Freedom" product variation which would include Bluetooth in the sensor eliminating the on-body component.

As described in detail below, in August 2020, we entered into a collaboration and commercialization agreement ("Commercialization Agreement"), with Ascensia pursuant to which we granted Ascensia the exclusive right to distribute Eversense worldwide, with certain initial exceptions. While Ascensia is responsible for sales, marketing, market access, patient and provider onboarding and first level customer support, we remain responsible for product development and manufacturing, including regulatory submissions, approvals, conformity assessment and requests for CE Certificates of Conformity and registrations and second level customer support.

Significant Recent Developments

Global Commercialization of Eversense CGM Systems

In September 2024, the FDA approved the Eversense 365 CGM system for marketing and sale in the U.S. As described in this report, Ascensia has the exclusive right to distribute the Company's Eversense system worldwide for people with diabetes. Ascensia began commercializing Eversense 365 in the U.S. in October 2024. Prior to that, Ascensia commercialized the Eversense E3 CGM system which was approved by the FDA in February 2022. In June 2022, we affixed the CE mark to the Eversense E3 CGM system, and Ascensia began commercialization in all European Economic Area ("EEA") markets during the third and fourth quarters of 2022.

In connection with the launch of Eversense 365, Ascensia and the Company initiated a new direct to consumer U.S. marketing campaign on social and digital media platforms. 'The One Year. One CGM.' campaign expanded market awareness of the Eversense 365 system's unique benefits among people with diabetes and healthcare professionals. 'The One Year. One CGM' campaign aims to highlight the reality of the diabetes experience, through everyday complexities, successes, and challenges that people with diabetes face. The campaign demonstrates how Eversense 365 provides a differentiated CGM option, with unparalleled flexibility and long-term use that allows it to seamlessly integrate into real life. Following the launch of Eversense 365, the Company has experienced higher direct-to-consumer leads compared to pre-launch months, higher patient shipments in December 2024 compared to any previous month in company history, an increase in the number of new prescribers and prescriptions, and an increase in new patients.

The continued success of the commercial launch of the Eversense globally will continue to depend on several factors such as: (1) growing the installed base of users, (2) increasing patient awareness of Eversense above current levels in order to expand the population of Eversense users, through driving sales and marketing efforts on the Eversense system, (3) increasing awareness and adoption of Eversense by healthcare providers, including high volume CGM prescribers, through expanded targeted marketing efforts, (4) educating patients and prescribers regarding the product and its benefits relative to legacy products, (5) continuing to grow the base of the authorized inserters through geographically targeted efforts so that potential users locating a qualified inserter of Eversense is not an impediment to adoption, (6) timely establishing and maintaining favorable payor coverage for the product, including transitioning commercial payors from six month to one year coverage, (7) more effective tender participation outside the U.S. and (8) Ascensia's continued organizational development of its sales and marketing capabilities related to CGM.

In July 2024, we began first-in-human testing for the Gemini system. The next-generation Gemini product utilizes a fully implantable self-powering system that includes a flash glucose monitor with no on-body component for people with type 2 diabetes and traditional CGM with an on-body component for people with type 1 diabetes. The Gemini product is built on the 365-day sensor platform and the clinical and regulatory work will be focused on demonstrating the battery integration and functionality rather than the sensor life. Data gathered from this first-in-human testing will be utilized for an investigational device exemption ("IDE") submission anticipated in the second half of 2025.

In April 2024 and July 2024, Eon Care Services, LLC and Eon Management Services, LLC, were formed as wholly owned subsidiaries of Senseonics, Incorporated. In November 2024, Eon Management Services, LLC entered into the Administrative Agreement with several professional corporations ("Eon Care PCs"), which are consolidated as variable interest entities ("VIEs"). The wholly owned entities and Eon Care PCs (collectively, "Eon Care") were established to support patient access to the Eversense system by providing convenient Eversense insertion and training

services. The Company expects established CPT codes associated with Eversense insertions to support this initiative in the future.

In November 2022, we announced a collaboration with the Nurse Practitioner Group (“NPG”) designed to expand U.S. patient access to Eversense by providing additional convenient in-office and at-home sensor insertion options utilizing NPG’s broad network in approximately 30 states. Under the agreement between Senseonics and NPG, NPG providers will be certified to perform Eversense procedures in the specified geographies and will offer its services for patients who have been prescribed Eversense. During 2023, we expanded the inserter network by setting up Eversense procedure capabilities in additional select geographic areas. In October 2024, we acquired the sensor insertion network assets of NPG to begin transitioning nurse practitioners to our Eon Care subsidiaries in order to further expand patient access and convenience.

Background

Diabetes is a chronic, life-threatening disease for which there is no known cure. The disease is caused by the body's inability to produce or effectively utilize the hormone insulin, which prevents the body from adequately regulating blood glucose levels. If diabetes is not managed properly, it can lead to serious health conditions and complications, including heart disease, limb amputations, loss of kidney function, blindness, seizures, coma and even death. According to the 2021 International Diabetes Federation Atlas, an estimated 537 million people worldwide had diabetes as of the date of the report. The number of people with diabetes worldwide is estimated to grow to 783 million by 2045, driven primarily by growth in type 2 diabetes and due to various reasons, including changes in dietary trends, an aging population and increased prevalence of the disease in younger people. Diabetes is typically classified into two primary types. Type 1 diabetes is an autoimmune disorder that usually develops during childhood and is characterized by the inability of the body to produce insulin, resulting from destruction of the insulin producing beta cells of the pancreas.

Type 2 diabetes is a metabolic disorder that results when the body is unable to produce sufficient amounts of insulin or becomes insulin resistant. People with type 1 diabetes must administer insulin, either by injection or insulin pump, to survive. People with type 2 diabetes may require diet and nutrition management, exercise, oral medications or the administration of insulin to regulate blood glucose levels. We expect the growth in sales of CGM systems to be driven by increased penetration of CGM in both the type 1 and type 2 patient populations.

In an attempt to maintain blood glucose levels within the normal range, many people with diabetes seek to actively monitor their blood glucose levels. The traditional self-monitoring of blood glucose, (“SMBG”), method of glucose monitoring requires lancing the fingertips, commonly referred to as fingersticks, multiple times per day and night to obtain a blood drop to be applied to a test strip inside a blood glucose meter. This method of monitoring glucose levels is inconvenient and can be painful and, because each measurement represents a single blood glucose value at a single point in time, it provides limited information regarding trends in blood glucose levels. In contrast, CGM systems are generally less painful and involve the insertion of sensors into the body to measure glucose levels in the interstitial fluid throughout the day and night, providing real-time data that shows trends in glucose measurements. As a result, CGMs improve glycemic control and quality of life, particularly in patients with type 1 diabetes treated with continuous subcutaneous insulin infusion or multiple daily insulin injection therapy, and support avoidance of hypoglycemia.

Historically, the FDA and other foreign regulatory authorities required that CGMs be labeled and marketed as "adjunctive" to test-strip measurements, with instructions that patients confirm CGM measurements with test-strip measurements using blood obtained from fingersticks prior to self-medicating. However, given the broader clinical indications for the use of CGM systems, including real-time alerts and multi-device integration, the FDA issued the first “non-adjunctive” label in 2016. In June 2019, an updated Eversense CGM system received a non-adjunctive label from the FDA and can now be used as a replacement to fingerstick glucose testing for treatment decisions. This non-adjunctive indication also enabled our pathway to access patients on Medicare.

In November 2019, the Eversense CGM system became the first CGM technology to be reimbursed through the Part B Medical Services benefit for Medicare beneficiaries and expanded access to our product. In November 2022, the Centers for Medicare and Medicaid Services (“CMS”) released its Calendar Year 2023 Medicare Physician Fee Schedule Proposed Rule that updated the payment amounts for the three CPT© Category III codes to account for the longer

6-month sensor. In February 2024, we announced that Medicare coverage was expanded for Eversense E3 to include all people with diabetes using insulin and non-insulin users who have a history of problematic hypoglycemia providing access to millions of Medicare patients. All of the Medicare administrative contractors ("MAC") expansions became effective in 2024. CMS provided G-codes to enable immediate access to Eversense 365 for all eligible Medicare beneficiaries. We have been working with payors to transition their policies to Eversense 365 and have confirmed immediate coverage policy transition from select payors.

We are headquartered in Germantown, Maryland. The members of our management team have held senior leadership positions at a number of medical technology and biopharmaceutical companies, including Abbott Diabetes Care and Medtronic. Members of our team have contributed to the development, regulatory approval and commercialization of several glucose monitoring systems and insulin pumps.

Commercial Strategy

We primarily sell directly to our network of distributors, strategic fulfillment partners, who provide the Eversense system to healthcare providers and patients through a prescribed request and invoice insurance payors for reimbursement. In addition, we sell our product through a consignment model through arrangements with our network of healthcare professionals. Sales of the Eversense 365 and E3 CGM system and future products are widely dependent on the ability of patients to obtain coverage and adequate reimbursement from third-party payors or government agencies. We prioritize and target regions where we have coverage decisions for patient device use and provider insertion and removal procedure payment.

Addressing reimbursement and access barriers is a top priority for us. We have reached approximately 300 million covered lives in the U.S. through positive insurance payor coverage decisions including UnitedHealthcare, the largest healthcare insurance company in the U.S. In efforts to address these priorities, Ascensia, in consultation with us, initiated the Patient Assistance and Simple Savings ("PASS") program to provide financial assistance for patients adopting Eversense. Additionally, as discussed above, we recently announced the acquisition of the insertion network assets of NPG to continue to expand U.S. patient access to the Eversense System by providing additional convenient in-office and at-home sensor insertion options utilizing the insertor network currently in approximately 30 states.

Our net revenues are derived from sales of the Eversense CGM system which includes the Eversense Sensor Pack containing the sensor, insertion tool, and adhesive patches, the Eversense Smart Transmitter Pack containing the transmitter and charger and in some cases the procedure revenue associated with insertions and removals.

Collaboration and Commercialization Agreement with Ascensia Diabetes Care Holdings AG

On August 9, 2020, we entered into a Commercialization Agreement with Ascensia pursuant to which we have granted Ascensia the exclusive right to distribute the Eversense CGM system worldwide for use in people with diabetes. Ascensia receives a portion of net revenue at specified tiered percentages ranging from the mid-teens to the mid-forties based on levels of global net revenues. Ascensia is obligated to achieve specified minimum annual revenue targets and meet specified levels of sales and marketing spend. Ascensia purchases Eversense products from us at prices which have been negotiated based on parameters set forth in the commercialization agreement. We are responsible for product development and manufacturing, including regulatory submissions, approvals, certifications and registrations and second level customer support, and Ascensia is responsible for sales, marketing, market access, patient and provider onboarding and level one customer support. We established a joint alliance committee and joint marketing committee, each with equal representation from each party, in order to collaborate.

Clinical Development and Regulatory Pathway

Overview

We conduct pivotal trials, primarily in the United States, to gather the data that supports submission to the FDA as a Premarket Approval ("PMA") application, PMA supplement or 510(k) submission and to our Notified Body for issue of a CE Certificate of Conformity allowing us to commercialize our products.

We are also continuing to conduct a number of post-approval and feasibility studies.

United States Pivotal Trials

PRECISE II Trial

In 2016, we conducted our U.S. 90-day pivotal trial. The trial was a prospective, single-arm, multi-center trial designed to determine the accuracy and safety of the Eversense system. Ninety subjects were enrolled in eight centers across the United States.

The purpose of this clinical trial was to evaluate the accuracy of Eversense measurements, measured by the mean absolute relative difference ("MARD"), when compared with bed-side blood glucose measurements obtained using the YSI glucose analyzer over successive periods of 30 days through 90 days, as well as to assess the safety of Eversense. YSI in vitro analyzers are bed-side instruments used in hospitals and clinics to accurately measure blood glucose levels and are commonly used as comparators of glucose monitoring systems in clinical trials. MARD is a statistical calculation that measures the average absolute value of the differences, expressed as a percentage, between glucose measurements taken from interstitial fluid based on our CGM system and blood glucose measurements from YSI. The lower the MARD of a glucose monitoring system, the more accurate the system and, therefore, the more reliable the system's readings.

In the trial, we observed a MARD of 8.8% for Eversense across the 40-400 mg/dL range when compared to YSI blood reference values during the 90-day continuous wear period. We conducted a second study, the PRECISION study, to collect supplementary data early in sensor life with two additional in-clinic visits in the first 30 days after insertion. Study participants were able to see their real-time glucose readings during this study. The accuracy and safety observed in PRECISE II was confirmed in this study. In addition, the data from PRECISE II study was also analyzed using an updated glucose calculation algorithm which improved the MARD to 8.5%. Based on the data from both of these trials, we submitted a PMA application to the FDA to market Eversense in the United States for 90-day use. On June 21, 2018, we received PMA approval from the FDA for the 90-day Eversense system and received Category III CPT codes for the insertion and removal of the Eversense sensor.

PROMISE Trial

In December 2018, we began enrollment for the U.S. 180-day pivotal trial. The trial is a prospective, single-arm, multi-center trial designed to evaluate the accuracy and safety of the Eversense system up to six months using the methods described above for the 90-day system. Over 180 subjects were enrolled in eight centers across the United States.

In the trial, we observed performance matching that of the 90-day Eversense system available in the United States, with MARD of 8.5%-9.6%. This result was achieved with reduced calibration, down to one per day, while also doubling the sensor life to 180 days. Following the results of the PROMISE trial, on September 30, 2020, a Premarket Approval Application Supplement, or PMA supplement to extend the wearable life of the Eversense CGM System to six months was submitted to the FDA.

On February 26, 2020, we announced that the FDA approved a subgroup of PROMISE trial participants to continue for a total of 365 days to gather feasibility data on the safety and accuracy of a 365-day sensor. This sub-set of 30 participants who all had sensors with the modified chemistry were left undisturbed for 365 days with the goal of measuring accuracy and longevity over the full 365 days. Information gathered from this sub-set and continued development efforts provided us the confidence to start the pivotal study for the Eversense 365-day System.

ENHANCE Trial

In March 2022, we began enrollment for the U.S. 365-day pivotal trial. The trial is a prospective, single-arm, multi-center trial designed to evaluate the accuracy and safety of the Eversense system up to one year using the methods

described above for the 90-day and 180-day systems. Over 165 adult subjects were inserted with Eversense systems in four centers across the United States. In mid-2023, the data gathered in this trial were used to submit an application to the FDA for the integrated continuous glucose monitoring ("iCGM") designation. The iCGM designation will enable our ability to integrate with insulin delivery devices like pens and pumps to create systems that would use Eversense for autonomous control and we received approval in April 2024. In 2022, we submitted and received approval for an IDE for an extension of the trial to allow for pediatric patients and we began enrolling patients in the first half of 2023. The ENHANCE pivotal study for the Eversense 365-day system has been fully enrolled, the last patient of the adult cohort completed the study, and we completed analysis of the data. Based on this analysis we determined to advance the next generation sensor platform as the underlying technology used in the 365-day and future products. In May 2024 this data supported an FDA 510(k) submission for a new product with a 365-day duration and once per week calibration. The 510(k) submission was approved by the FDA on September 17, 2024 and our 365-day product was cleared for sale in the United States. In February 2025, the data supported the Eversense 365-day product CE Mark submission in compliance with the EU Medical Device Regulation (MDR) and, upon approval, would enable the commercialization of Eversense 365 in European Union (EU) member countries.

Our Technology

Eversense consists of three primary components: a small sensor inserted subcutaneously under the skin by a healthcare provider; an external removable smart transmitter that receives, assesses and relays data from the sensor and provides vibratory alerts; and a mobile app that receives data from the transmitter and provides real-time glucose readings, alerts and other data on the person's mobile device. All of these components work together to provide sensor glucose values, trends and alerts to a user's mobile device within 20 milliseconds. We have designed this reliable, long-term and implantable CGM system to continually and accurately measure a person's glucose levels for up to one year. Eversense 365 requires once weekly fingerstick calibrations after day 13. In June 2019, we received FDA approval for the non-adjunctive indication for the Eversense system. With this approval, the Eversense system can be used as a therapeutic CGM to replace fingerstick blood glucose measurement for dosing decisions.

We believe our implantable CGM system offers the following advantages to support the management of diabetes:

- Duration: Longest available sensor duration at up to one year.
- Convenience: Our Eversense CGM system supports the patient's lifestyle; the smart transmitter can be removed and replaced without disturbing the sensor, strong but gentle-on-skin adhesive patches, wireless communication to patient's mobile device or Apple Watch ®, including readings every five minutes whether the patient has their mobile device or not, remote monitoring that can be shared friends, family, and health care providers, and tracking of meals and workouts for further diabetes treatment management.
- Accuracy: Exceptional accuracy particularly in the low glucose range throughout the sensor life.
- Vibe Alerts: Added safety of an on-body vibration alert when low or high glucose threshold is reached, or importantly before low or high threshold is reached, even when the mobile device is not nearby.
- Continuous Support: Patient and healthcare provider hotline support 24/7.

Sensor

The sensor is approved and CE marked to be inserted under the skin, in the upper arm, and measures the glucose in the interstitial fluid. These glucose levels are then communicated wirelessly to the smart transmitter. We have designed the sensor to last up to one year, as compared to other currently available CGM sensors labeled for use for between seven and 14 days.

The sensor consists of an optical system, known as a micro-fluorometer, encased in a rigid, translucent polymer capsule, which is 3.3 mm in diameter and 15 mm in length. The capsule is coated with a glucose-indicating hydrogel that is bound to the surface of the capsule through polymerization. This hydrogel is energized, or excited, by a light-emitting diode ("LED"), contained in the optical system of the sensor, causing the hydrogel to fluoresce, or glow. Two photodiodes within the optical system of the sensor measure the degree of fluorescence of the hydrogel, which is proportional to the level of glucose present in the interstitial fluid. The sensor then communicates the amount of

fluorescence via a near field communication ("NFC") interface to the transmitter. NFC is a high frequency wireless communication technology that enables the exchange of data and energy between devices over a short range. The sensor does not have a power source and remains electrically dormant (powered off) between readings every five minutes, and it is remotely and discretely powered, as needed, by an inductive NFC link between the sensor and the transmitter. On power-up, the LED source is energized for approximately five milliseconds to excite the hydrogel.

Smart Transmitter

The removable smart transmitter is a rechargeable, external device that is worn over the sensor implantation site using a daily adhesive patch. The transmitter supplies wireless power to the sensor through an inductive NFC link, which activates a measurement sequence every five minutes. The transmitter then receives data from the sensor and calculates glucose concentrations and trends. Based on these calculations and on the user's individual settings for glucose levels, the transmitter determines if an alert condition exists, in which case the transmitter communicates the condition to the user through the mobile app and through on-body vibration. The information from the transmitter is also transmitted for display to the user's mobile device via Bluetooth Low-Energy ("BLE"). Our transmitter is functional for at least 24 hours following a full charge and can be fully charged in approximately fifteen minutes.

Mobile App

Our mobile app is a software application that runs on both platforms; iOS mobile devices, including iPhones, iPads and Apple Watches, and Android mobile devices. The mobile app receives information from the transmitter via BLE and displays that information discreetly to the user. This user-friendly, intuitive app provides real-time glucose readings, alerts, trends, and graphs. Within the mobile app, users can set alerts based on, among other things, glucose levels. The mobile app also allows for cloud-based storage.

Future Product Development

We intend to continue to expand our line of product offerings to benefit people with diabetes and healthcare providers. We expect these product development initiatives to include system modifications and next generation enhancements that we believe will further increase the convenience and appeal of our products to the diabetes community.

We are focusing our future development efforts on enhancing current product offerings by incorporating first a power source and then Bluetooth in the sensor to remove the need for an on-body component of our system. We are performing feasibility studies with our "Gemini" product variation to allow for a 2-in-1 glucose monitoring system combining the functionality of CGM and Flash Glucose Monitoring, in an implantable sensor with battery that may be utilized with a smart transmitter to get continuous glucose readings and alerts, or be utilized through a swipe over the sensor with a smart phone to get on-demand glucose reading without a smart transmitter. We are also developing our "Freedom" product variation which would include Bluetooth in the sensor eliminating the on-body component. We are seeking to ensure that we meet the growing and unique needs of people with diabetes utilizing our core and proprietary sensor technology. The company's technology also has potential applications measuring analytes other than glucose, such as oxygen, and the company may consider opportunities for the development or out-licensing of such applications.

Sales and Marketing

We are in the early commercialization stages of Eversense and are focused on driving awareness and adoption of our CGM system amongst people with diabetes and their healthcare providers with our commercial partner Ascensia.

As described above, we are party to a commercialization agreement with Ascensia, pursuant to which we have granted Ascensia the exclusive right to distribute our Eversense CGM system worldwide for use in people with diabetes,

with certain exceptions. Pursuant to the Commercialization Agreement, in the United States, Ascensia began providing sales support for Eversense on October 1, 2020 and Ascensia ramped up sales activities and assumed commercial responsibilities during the second quarter of 2021.

As a result of our strategic partnership, Ascensia is responsible for sales, marketing, market access, patient and provider onboarding and level one customer support. We have established a joint alliance committee and joint marketing committee, each with equal representation from each party, in order to collaborate.

Building strong adoption with an implantable device requires a strong network of healthcare providers trained on the Eversense sensor placement procedure. In the first few quarters of our commercial launch, our focus was ensuring the Endocrinology providers obtained the necessary training needed to support their diabetes patients. In 2019, we began our second phase of establishing a large network of Eversense proceduralists with the launch of the Certified Eversense Specialist ("CES") network. This group of healthcare providers includes specialists who have strong familiarity with conducting in-office procedures such as dermatologists and plastic surgeons. The CES network offers an alternative for healthcare providers who want to prescribe Eversense for their patients but prefer to refer the procedure to a specialist. In 2022, we announced a collaboration with NPG designed to expand U.S. patient access to Eversense by providing additional convenient in-office and at-home sensor insertion options utilizing NPG's broad network in approximately 30 states. In October 2024, we acquired the sensor insertion network assets of NPG to begin transitioning nurse practitioners to our Eon Care subsidiaries. We will continue to expand the inserter network by setting up Eversense procedure capabilities in additional select geographic areas.

As people with diabetes often consult with their healthcare providers about treatment options, we believe that educating healthcare providers regarding the benefits of Eversense compared to SMBG and other currently available CGM systems is an important step in promoting its use in people with diabetes. Our United States and European experience indicate healthcare providers highly value the accuracy and sensor duration of our CGM system and the majority of physicians surveyed considered the insertion process to be fairly simple or feasible. We intend to continue educating healthcare providers and people with diabetes on the advantages of Eversense compared to SMBG and other currently available CGM systems.

In October 2024, Ascensia and the Company launched a new direct to consumer U.S. marketing campaign on social and digital media platforms. 'The One Year. One CGM.' campaign expanded market awareness of the Eversense 365 system's unique benefits among people with diabetes and healthcare professionals. 'The One Year. One CGM' campaign aims to highlight the reality of the diabetes experience, through everyday complexities, successes, and challenges that people with diabetes face. The campaign demonstrates how Eversense 365 provides a differentiated CGM option, with unparalleled flexibility and long-term use that allows it to seamlessly integrate into real life. Following the launch of Eversense 365 in October 2024, the Company has experienced higher direct-to-consumer leads compared to pre-launch months, higher patient shipments in December 2024 compared to any previous month in company history, an increase in the number of new prescribers and prescriptions, and an increase in new patients.

Reimbursement

Coverage in the United States

In the U.S. market, it is essential to obtain third-party payor coverage policies, coding mechanisms, and adequate payment for medical technology to expand market acceptance and adoption. CGM as a class of products has been broadly accepted by commercial third-party payors, such as health insurers and health maintenance organizations, and more recently by Medicare for patients who require the use of insulin to manage their diabetes. We approach the U.S. commercial third-party payor community in efforts to establish coverage for Eversense. To date, approximately 300 million people in the United States may have coverage and access to Eversense via commercial (for example, UnitedHealthcare) or government (for example, Medicare) payors.

Some commercial payors have denied coverage deeming Eversense as an "experimental and investigational" technology electing to wait for further clinical evidence, more safety data, or time in market. We disagree with this

position as the CGM class has already proven to improve health outcomes and Eversense is another product that fits into the class. Additionally, in 2019 we published several sets of real-world data, which show Eversense provides the same clinical benefits as other CGM systems and has a favorable safety profile. However, until payment for the Eversense sensor placement becomes consistent, some patients will be required to bear the financial cost for the placement of the sensor by their healthcare provider. As a result, some patients and their healthcare provider may choose not to use Eversense on a widespread basis. Patient access programs and patient appeals support have been key initiatives to expanding payor policy and acceptance through case-by-case review and eventual denial overturn and Ascensia has continued similar programs for this purpose. This can be a long process with varying results in each case but is a prudent step to challenge payor positions of non-coverage given the strong evidence that supports CGM and Eversense. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Coverage Outside the United States

In countries outside the United States, coverage for CGM systems is obtained from various sources, including governmental authorities, national healthcare systems, private health insurance plans, and hospital funds. Coverage systems in international markets vary significantly by country and, within some countries, by region. Coverage approvals must be obtained on a country-by-country, region-by-region or, in some instances, a case-by case basis. The responsibility for securing this coverage resides with our third-party distributors in the respective markets.

Manufacturing and Quality Assurance

We currently outsource the manufacturing of all components of the Eversense system to contract manufacturers across North America and Europe. We plan to continue with an outsourced manufacturing arrangement for the foreseeable future. Our contract manufacturers are all recognized in their field for their competency to manufacture the respective portions of our system and have quality systems established that meet FDA and, to the extent required, international regulatory requirements. We believe the manufacturers we currently utilize have sufficient capacity to meet our requirements. We believe that, as we increase our demand in the future, our per unit costs will decrease materially.

We have received certification from BSI, our Notified Body to the International Standards Organization ("ISO") for our quality system. This ISO 13485:2016 certification includes design control requirements. As a medical device manufacturer, the facilities of our sterilization and other critical suppliers are subject to periodic inspection by the FDA and corresponding state and foreign regulatory authorities and Notified Bodies. We believe that our quality systems and those of our suppliers are robust and achieve high product quality.

Typically, our outside vendors produce the components to our specifications and in many instances to our designs. Our suppliers are audited periodically by our quality department to ensure conformity with the specifications, policies and procedures for our devices. We believe that, if necessary, alternative sources of supply would be available in a relatively short period of time and on commercially reasonable terms. Most of the raw materials we use in our manufacturing operations are available from more than one source. However, we obtain certain raw material components are obtained principally from one supplier. In the event one of these suppliers was unable to provide the materials or product, we generally seek to maintain sufficient inventory to supply the market until an alternative source of supply can be implemented. However, in the event of an extended failure of a supplier, it is possible that we could experience an interruption in supply until we established new sources or, in some cases, implemented alternative processes.

Competition

The market for CGM systems is developing and competitive, subject to rapid change and significantly affected by new product introductions. We compete with well-capitalized companies, some of which are publicly traded, that manufacture CGM systems including Dexcom, Medtronic and Abbott. Each of these companies has received FDA approval, CE Certificates of Conformity and CE Marked their products, permitting them to market their respective CGM

systems across the United States and EEA. Dexcom's CGM system was the first CGM system to be approved by the FDA for marketing as a non-adjunctive device, and Abbott's Freestyle Libre was also approved for non-adjunctive use. Both Dexcom (G6 and G7) and Abbott (Freestyle Libre 2 and 3) systems have factory calibration, and do not require user calibration.

Dexcom has also received the first FDA iCGM indication allowing its Dexcom G6 and G7 to be interoperable with other diabetes tech devices such as insulin pumps. As the industry evolves, we anticipate encountering increasing competition from companies that integrate CGM with insulin pumps. Abbott has also received an iCGM indication for its Freestyle Libre 2 and 3 products and we expect all other CGM companies to pursue an iCGM indication including Medtronic.

In addition to CGM providers, we also compete with providers of SMBG systems. Three companies currently account for a substantial share of the worldwide sales of SMBG systems: Roche Diabetes Care, a division of Roche Diagnostics; Abbott; and Ascensia.

We may also compete with companies who are developing real-time intermittent sensing devices, low cost transcutaneous CGM systems, fully implantable CGM devices and non-invasive CGM system to measure a user's glucose level. There are also a number of academic and other institutions involved in various phases of our industry's technology development.

Although we face potential competition from many different sources, we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages. The key competitive factors affecting the success of Eversense are accuracy, duration, convenience, alert functionality, and customer support.

Many of the companies which we compete with have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, certifications and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or earlier stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development.

Seasonality

We anticipate that the revenue generated from our product sales will vary from quarter to quarter as we continue to commercialize Eversense. This variation is influenced by annual insurance deductible limits and out-of-pocket costs associated with some health insurance plans and government insurance programs providing coverage to Eversense and the utilization of patient assistance programs to offset those costs. This variation is also influenced by our distributor's reductions of inventory of our products in the first quarter and the timing of Ascensia's purchases in accordance with minimum purchase requirements under our distribution agreement. Specifically, our revenues are generally lower in the first quarter of the year as compared to the fourth quarter of the preceding year.

For additional information, refer to "Part I. Item 1A. Risk Factors" in this Annual Report on Form 10-K, including the risk factor entitled "Our product revenue is subject to seasonal variation".

Intellectual Property

Protection of our intellectual property is a strategic priority for our business. We rely on a combination of patents, trademarks, copyrights, trade secrets as well as nondisclosure and assignment of invention agreements, material transfer agreements, confidentiality agreements and other measures to protect our intellectual property and other proprietary rights.

Patents

As of December 31, 2024, we held a total of approximately 482 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 111 issued United States patents, 194 patents issued in countries outside the United States and 177 pending patent applications worldwide. Our patents expire between 2025 and 2043, subject to any patent term extensions or adjustments that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2044, subject to any patent term extensions or adjustments that may be available for such patents.

Our patents and patent applications cover certain aspects of our core sensor technologies and our product concepts for CGM systems. However, our patent applications may not result in issued patents, and any patents that have been issued or may be issued in the future may not protect the commercially important aspects of our technology. Furthermore, the validity and enforceability of our issued patents may be challenged by third parties and our patents could be invalidated or modified by the issuing governmental authority. Third parties may independently develop technology that is not covered by our patents that is similar to or competes with our technology. In addition, our intellectual property may be infringed or misappropriated by third parties, particularly in foreign countries where the laws and governmental authorities may not protect our proprietary rights as effectively as those in the United States.

The medical device industry in general, and the glucose testing sector of this industry in particular, are characterized by the existence of a large number of patents and frequent litigation based on assertions of patent infringement. We are aware of numerous patents issued to third parties that may relate to the technology used in our business, including the design and manufacture of CGM sensors and CGM systems, as well as methods for continuous glucose monitoring. Each of these patents contains multiple claims, any one of which may be independently asserted against us. The owners of these patents may assert that the manufacture, use, sale or offer for sale of our CGM sensors or CGM systems infringes one or more claims of their patents. Furthermore, there may be additional patents issued to third parties of which we are presently unaware that may relate to aspects of our technology that such third parties could assert against us and materially and adversely affect our business. In addition, because patent applications can take many years to issue, there may be patent applications that are currently pending and unknown to us, which may later result in issued patents that third parties could assert against us and materially and adversely affect our business.

Any adverse determination in litigations, post grant trial proceedings, including interference proceedings, at the Patent Office relating to intellectual property to which we are or may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties, and result in the cancellation and/or invalidation of our intellectual property. Furthermore, if a court finds that we have willfully infringed a third party's intellectual property, we could be required to pay treble damages and/or attorney fees for the prevailing party, in addition to other penalties. Although intellectual property disputes in the medical device area are often settled through licensing or similar arrangements, costs associated with such arrangements can be substantial and often require ongoing royalty payments. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement; if we are able to redesign our products to avoid infringement, we may not receive FDA approval in a timely manner. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which could have a significant adverse impact on our business.

Trademarks

We have 14 U.S. trademark registrations and 133 foreign trademark registrations, as well as one pending foreign trademark application.

Trade Secrets

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect such intellectual property and proprietary information by generally requiring our employees, consultants, contractors, scientific collaborators and other advisors to execute non-disclosure and

assignment of invention agreements upon the commencement of their employment or engagement as the case may be. Our agreements with our employees prohibit them from providing us with any intellectual property or proprietary information of third parties. We also generally require confidentiality agreements or material transfer agreements with third parties that receive or have access to our confidential information, data or other materials. Notwithstanding the foregoing, there can be no assurance that our employees and third parties that have access to our confidential proprietary information will abide by the terms of their agreements. Despite the measures that we take to protect our intellectual property and confidential information, unauthorized third parties may copy aspects of our products or obtain and use our proprietary information.

Government Regulation

The Eversense system is a medical device subject to extensive and ongoing regulation by the FDA, CMS, the European Union, competent authorities of the EEA countries, Notified Bodies and regulatory bodies in other countries. Regulations cover virtually every critical aspect of a medical device company's business operation, including research activities, product development, contracting, reimbursement, medical communications, and sales and marketing. In the United States, the Federal Food, Drug and Cosmetic Act ("FDCA"), and the implementing regulations of the FDA govern product design and development, preclinical and clinical testing, premarket clearance or approval, product manufacturing, import and export, product labeling, product storage, recalls and field safety corrective actions, advertising and promotion, product sales and distribution, and post-market clinical surveillance. Our business is subject to federal, state, local, and foreign regulations and standards, such as ISO 13485, ISO 14971, FDA's Quality System Regulation ("QSR") contained in 21 CFR Part 820, Directive 90/385/EEC concerning active implantable medical devices and, Regulation 2017/745 on Medical Devices, as amended.

Regulation by the FDA

The FDA classifies medical devices into one of three classes according to the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device's safety and effectiveness. The Eversense System is a Class III device and subject to pre-market approval ("PMA") application under section 515 of the FDCA in order to obtain a marketing approval. A PMA application must be supported by valid scientific evidence that typically includes extensive technical, preclinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device. A PMA application also must include a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, 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.

Any devices we manufacture and distribute pursuant to clearance or approval by the FDA are subject to pervasive and continuing regulation by the FDA and certain state agencies. These include product listing and establishment registration requirements, which help facilitate FDA inspections and other regulatory actions. As a medical device manufacturer, all of our manufacturing facilities are subject to inspection on a routine basis by the FDA. We are required to adhere to applicable regulations setting forth detailed Current Good Manufacturing Practice ("cGMP") requirements, as set forth in the Quality System Regulation, or QSR, which require, manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all phases of the design and manufacturing process. Noncompliance with these standards can result in, among other things, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to grant 510(k) clearance or PMA approval of devices, withdrawal of marketing approvals and criminal prosecutions. We believe that our design, manufacturing and quality control procedures are in compliance with the FDA's regulatory requirements.

We must also comply with post-market surveillance regulations, including medical device reporting ("MDR") requirements which require that we review and report to the FDA any incident in which our products may have caused or contributed to a death or serious injury. We must also report any incident in which our product has malfunctioned if that malfunction would likely cause or contribute to a death or serious injury if it were to recur.

Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Medical devices approved or cleared by the FDA may not be promoted for unapproved or uncleared uses, otherwise known as "off-label" promotion. 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 substantial monetary penalties and criminal prosecution.

International Regulation

International sales of medical devices are subject to national, supra-national, and local government regulations, which may vary substantially from country to country. The time required to obtain approval or certification in another country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

On May 26, 2021, Regulation (EU) 2017/745 on Medical Devices, or the Medical Device Regulation, entered into application, repealing and replacing both Directive 93/42/EEC concerning medical devices, or MDD, and Directive 90/385/EEC concerning active implantable medical devices, or AIMD. The Medical Device Regulation and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. Medical devices must comply with the General Safety and Performance Requirements, ("GSPRs") set out in Annex I of the Medical Device Regulation. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPRs provided in the Medical Device Regulation and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a

competent Ethics Committee. This process can be expensive and time-consuming. After a device is placed on the market, it remains subject to significant regulatory requirements.

The Medical Device Regulation provides a transitional provision. Accordingly, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD from May 25, 2017, and which remained valid on May 26, 2021 and have not since been withdrawn will, with certain exceptions, remain valid until December 31, 2027 for Class III and Class IIb implantable medical devices and until December 31, 2028 for other Class IIb, Class IIa and Class I devices with a measuring function or which are sterile. Class I medical devices, for which the conformity assessment procedure in accordance with the MDD or the AIMD did not require the involvement of a Notified Body but will require the involvement of a Notified Body in accordance with the Medical Device Regulation and for which an EU Declaration of Conformity was issued in accordance with the MDD or the AIMD prior to May 26, 2021, can continue to be placed on the EEA market until December 31, 2028. Manufacturers of medical devices may only benefit from the above extended transitional provisions deadlines if the following conditions are fulfilled: (i) the devices continue to comply with the requirements of the MDD or AIMD, (ii) there are no significant changes in the design and intended purpose, (iii) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, (iv) the manufacturer implements a quality management system by May 26, 2024 which complies with the requirements of the Medical Devices Regulation, (v) by May 26, 2024 an application is lodged with a Notified Body for conduct of the conformity assessment of the devices covered by the CE Certificate of Conformity, or the devices intended to substitute for such devices, in accordance with the Medical Device Regulation and a related written agreement is signed with the Notified Body by September 26, 2024, and (vi) from May 26, 2021, compliance with the Medical Device Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices is ensured in place of the corresponding requirements in the MDD or AIMD.

In addition, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD from May 25, 2017, which were valid on May 26, 2021 and have not been withdrawn since but which expired before March 20, 2023, will only continue to be valid in accordance with the extended transitional deadlines above if either (i) the manufacturer signed a written agreement with a Notified Body for the conformity assessment of the device covered by the expired CE Certificate of Conformity, or the device intended to substitute that device, in accordance with the Medical Device Regulation before the date of expiry of the CE Certificate of Conformity, or (ii) a competent authority of an EU Member State has granted a derogation from the application conformity assessment procedure in accordance with Article 59(1) or Article 97(1) of the Medical Device Regulation.

Class III custom-made implantable medical devices may be placed on the market until May 26, 2026 without a CE Certificate of Conformity issued by Notified Body, provided that (i) by May 26, 2024, an application is lodged with a Notified Body for the conformity assessment of the devices, in accordance with the Medical Device Regulation and a related written agreement is signed with the Notified Body by September 26, 2024.

The advertising and promotion of medical devices in the EU is subject to the national laws of the individual EU Member States that implemented the MDD, the AIMD and that apply the Medical Device Regulation, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EU Member States governing the advertising and promotion of medical devices. EU Member States' national legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Accordingly, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD from May 25, 2017, and which remained valid on May 26, 2021 and have not since been withdrawn will, with certain exceptions, remain valid until December 31, 2027 for Class III and Class IIb implantable medical devices and until 31 December 2028 for other Class IIb, Class IIa and Class I devices with a measuring function or which are sterile. Class I medical devices, for which the conformity assessment procedure in accordance with the MDD or the AIMD did not require the involvement of a Notified Body but will require the involvement of a Notified Body in accordance with the Medical Device Regulation and for which an EU Declaration of Conformity was issued in accordance with the MDD or the AIMD prior to May 26, 2021, can continue to be placed on the EEA market until December 31, 2028. Manufacturers of medical devices may only benefit from the above extended

transitional provisions deadlines if the following conditions are fulfilled: (i) the devices continue to comply with the requirements of the MDD or AIMD, (ii) there are no significant changes in the design and intended purpose, (iii) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, (iv) the manufacturer implements a quality management system by May 26, 2024 which complies with the requirements of the Medical Devices Regulation, (v) by May 26, 2024 an application is lodged with a Notified Body for conduct of the conformity assessment of the devices covered by the CE Certificate of Conformity, or the devices intended to substitute for such devices, in accordance with the Medical Device Regulation and a related written agreement is signed with the Notified Body by September 26, 2024, and (vi) from May 26, 2021, compliance with the Medical Device Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices is ensured in place of the corresponding requirements in the MDD or AIMD.

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Other Regulatory Requirements

Even after a device receives clearance, certification or approval and is placed in commercial distribution, numerous regulatory requirements apply. These include, but are not limited to:

- establishment registration and device listing;
- QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- MDR regulations, which require that manufacturers report to the FDA, competent authorities of the EEA countries and Notified Bodies, and foreign regulatory authorities, when applicable, if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- voluntary and mandatory device recalls addressing problems when a device is defective and could be a risk to health; and
- corrections and removals reporting regulations, which require that manufacturers report to the FDA, competent authorities of the EEA countries and Notified Bodies, and foreign regulatory authorities, when applicable, 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.

Also, the FDA requires us to conduct Post Approval Studies (post-market surveillance studies) and establish and maintain a system for tracking our products through the chain of distribution to the patient level. The FDA and applicable regulatory authorities enforce regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

Moreover, the FDA, competent authorities of the EEA countries and Notified Bodies, and foreign regulatory authorities, when applicable, strictly regulates marketing, labeling, advertising and promotion of medical products. Medical products may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved medical products for unapproved indications. Companies may also share truthful and not misleading information that is otherwise consistent with the labeling. The FDA, competent authorities of the EEA countries and Notified Bodies, and foreign regulatory authorities, when applicable, 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.

In the United States, failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies. These may include, among other things, any of the following sanctions or consequences:

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve future products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearance or approval;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

In the EEA, similar regulatory requirements apply once a device has been CE marked and placed on the EEA Market. EEA countries are responsible for enforcing the EU's medical device rules and for ensuring that only compliant medical devices are placed on the market or put into service in their jurisdictions. In addition, similar actions and obligations may be imposed by the competent authorities of an EEA country, or a foreign regulatory authority. If a Notified Body suspects or discovers any non-compliance, this may also result in Notified Bodies revoking, suspending or varying a CE Certificate of Conformity that they have issued for a device or the manufacturer's quality system.

Our contract manufacturers, specification developers and some suppliers of components or device accessories, also are required to manufacture our products in compliance with current good manufacturing practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes that any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down such manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

Health Insurance Portability and Accountability Act of 1996 and Other Foreign and State Laws and Regulations Affecting the Transmission, Security and Privacy of Personal Information

We are subject to certain data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as service providers of covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, and their covered subcontractors. HITECH also created four new tiers of civil monetary penalties 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. Accordingly, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from HIPAA and each other in significant ways and may not have the same effect.

In the EEA, the General Data Protection Regulation (2016/679) ("EU GDPR") and in the United Kingdom ("UK"), the United Kingdom's GDPR ("UK GDPR") (together the "GDPR"), applies to personal data about identified or identifiable data subjects processed by automated means and data contained in, or intended to be part of, non-automated filing systems (traditional paper files) as well as transfer of such data to a country outside of the EEA or UK. Under the EU GDPR companies may face temporary of definitive bans on data processing and other corrective actions, fines of up to €20 million or up to 4% of the annual global turnover, whichever is greater; or private litigation related to processing of personal data brought by classes of data subject or consumer protection organizations authorized at law to represent their interests. The GDPR includes more stringent operational requirements for data processors and data controllers and creates additional rights for data subjects.

Fraud and Abuse Laws

In addition to FDA restrictions, there are numerous U.S. federal and state laws and equivalent third country laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of these laws are punishable by significant criminal, civil, and administrative sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs, or similar comparable foreign programs.

Federal Anti-Kickback and Self-Referral Laws

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. 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 and require strict compliance to provide protection. 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 federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a review of all its relevant 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 (or purchases, or recommendations related to) federal healthcare covered business, the federal Anti-Kickback Statute has been implicated and potentially violated.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to ten years, criminal fines of up to $100,000 per violation, possible exclusion from federal healthcare programs such as Medicare and Medicaid and other penalties, including significant civil monetary penalties and integrity oversight and reporting obligations to resolve allegations of non-compliance. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which do not have the same exceptions or safe harbors and apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs. Further, the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively “PPACA”). Specifically, as noted above, under the federal Anti-Kickback Statute, the government must prove the defendant acted "knowingly" to prove a violation occurred. The PPACA added a provision to clarify that with respect to violations of the federal Anti-Kickback Statute, "a person need not have actual knowledge" of the statute or specific intent to commit a violation of the statute. This change effectively overturns case law interpretations that set a higher standard under which prosecutors had to prove the specific intent to violate the law. In addition, the PPACA codified case law 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 federal civil False Claims Act.

Federal law also includes a provision commonly known as the "Stark Law," which prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. We believe that we have structured our provider arrangements to comply with current fraud and abuse law requirements.

Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. As a result, our provider and training arrangements may ultimately be found to be not in compliance with applicable federal law.

Federal False Claims Act & HIPAA

The federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the federal False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits against companies under the federal False Claims Act. Penalties include significant civil monetary penalties for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines, be excluded from Medicare, Medicaid or other federal or state healthcare programs, or be subject to integrity oversight and reporting obligations to resolve allegations of non-compliance, as a result of an investigation arising out of such action.

There are other federal anti-fraud laws that 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, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, 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.

Additionally, HIPAA established two federal crimes for healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits 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. A violation of either of these statutes is a felony and may result in fines, imprisonment, exclusion from Medicare, Medicaid or other federal or state healthcare programs, or integrity oversight and reporting obligations to resolve allegations of non-compliance.

Civil Monetary Penalties Law

In addition to the federal Anti-Kickback Statute and the civil and criminal false claims laws, including the federal False Claims Act, the federal government has the authority to seek civil monetary penalties ("CMPs") assessments, and exclusion against an individual or entity based on a wide variety of prohibited conduct. For example, the Civil Monetary Penalties Law authorizes the imposition of substantial CMPs against an entity that engages in activities including, but not limited to: (1) knowingly presenting or causing to be presented, a claim for services not provided as claimed or which is otherwise false or fraudulent in any way; (2) knowingly giving or causing to be given false or misleading information reasonably expected to influence the decision to discharge a patient; (3) offering or giving remuneration to any beneficiary of a federal health care program likely to influence the receipt of reimbursable items or services; (4) arranging for reimbursable services with an entity which is excluded from participation from a federal health care program; (5) knowingly or willfully soliciting or receiving remuneration for a referral of a federal health care program beneficiary; or (6) using a payment intended for a federal health care program beneficiary for another use. Noncompliance can result in significant civil money penalties for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

Physician Payments Sunshine Act

Transparency laws regarding payments or other items of value provided to healthcare providers and teaching hospitals may also impact our business practices. The federal Physician Payment Sunshine Act requires most medical device manufacturers to report annually to CMS financial arrangements, payments, or other transfers of value made by that entity to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), 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. The payment information is made publicly available in a searchable format on a CMS website. Failure to comply with the reporting requirements can result in significant civil monetary penalties. Similar laws have been enacted or are under consideration in many states and foreign jurisdictions.

State Fraud and Abuse Provisions

Many states have also adopted some form of anti-kickback and anti-referral laws, false claims laws, some of which apply regardless of source of payment and do not have the same exceptions as the federal laws, as well as professional fee-splitting laws. We believe that we are in conformance with such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

State Corporate Practice of Medicine Restrictions

Our consolidated financial statements include our subsidiaries and VIEs. Through the administrative agreements with the Eon Care PCs, our medical affiliates, we have exclusive authority over all non-medical decisions related to their ongoing business operations. Some states have laws that prohibit business entities from practicing medicine, employing physicians to practice medicine, or exercising control over medical decisions of physicians. These laws are generally referred to as corporate practice of medicine laws. These state laws and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced

by both the courts and regulatory authorities, each with broad discretion. In these states, a violation of the corporate practice of medicine prohibition constitutes the unlawful practice of medicine. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to pay significant fines and restructure our contractual and other arrangements. In addition, any physician who participates in an arrangement that violates a state's corporate practice of medicine prohibition may be punished for aiding and abetting a lay entity in the unlawful practice of medicine.

Outside the United States, interactions between medical device companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct.

Healthcare and Regulatory Reform

Federal and state governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such new laws may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. For example, in March 2010, the PPACA, was enacted, which substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industry. In the years since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of the PPACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the second Trump administration will impact the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional congressional action is taken. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

It is uncertain whether and how future legislation could affect prospects for our product candidates or what actions federal, state, or private payors for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation.

Brexit and the Regulatory Framework in the United Kingdom

Following the result of a referendum in 2016, the UK left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the European Union, the UK was subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules continued to apply. The UK and the European Union have signed an EU-UK Trade and Cooperation Agreement ("TCA"), which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and European Union's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the European Union and the UK in relation to goods. The TCA does not, however, specifically address medical devices. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a "third country," a country that is not a member of the European Union and whose citizens do not enjoy the European Union right to free movement. Northern Ireland will continue to follow many aspects of the European Union regulatory rules, particularly in relation to trade in goods, including the Medical Device Regulation.

On May 26, 2021, the Medical Device Regulation entered into application in the EU. However, the Medical Device Regulation is not applicable in the UK. In the UK, medical devices are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which retains a regulatory framework similar to the framework set out by the MDD. In light of the fact that the CE Marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UKCA Mark to replace the CE Mark. Northern Ireland will, however, continue to be covered by the regulations governing CE Marks. The UK Government has established transitional provision to recognize the acceptance of CE marked medical devices on the Great Britain market. Accordingly, Class III and Class IIb implantable medical devices which have been CE marked in accordance with the MDD or AIMD and for which a CE Certificate of Conformity has been delivered by a Notified Body in accordance with the MDD or AIMD, can be placed on the Great Britain market until the sooner of the expiry of the related CE Certificate of Conformity or June 30, 2028. However, in light of the extended transitional provisions of the Medical Device Regulation, related CE Certificates of Conformity will expire, at the latest, on December 31, 2027. Other Class IIb, Class IIa and Class I devices with a measuring function which have been CE marked in accordance with the MDD or AIMD and for which a CE Certificate of Conformity has been delivered by a Notified Body in accordance with the MDD or AIMD, can be placed on the Great Britain market until the sooner of the expiry of the related CE Certificate of Conformity or June 30, 2028. Class I medical devices, for which the conformity assessment procedure in accordance with the MDD or the AIMD did not require the involvement of a Notified Body but will require the involvement of a Notified Body in accordance with the Medical Device Regulation and for which an EU Declaration of Conformity was issued in accordance with the MDD or the AIMD prior to May 26, 2021, can continue to be placed on the Great Britain market until June 30, 2028. Medical devices which have been CE marked in accordance with the Medical Device Regulation may be placed on the Great Britain market until June 30, 2030.

The UK government plans on introducing new legislation governing medical devices with an aim for core aspects of the future regime for medical devices to apply from July 1, 2025. New legislation is also anticipated to bring into force strengthened post-market surveillance requirements ahead of the wider future regulatory regime. These post-market surveillance requirements are expected to apply from mid-2025, following a six-month implementation period.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

UK Bribery Act and other anti-corruption laws

The UK Bribery Act 2010 and other applicable foreign anti-corruption laws that apply in countries where we do business, generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the UK's Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the UK and authorities in the EU, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as trade control laws. Failure to comply with the UK's Bribery Act, and other anti-corruption laws and trade control laws could subject us to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses.

Environmental Health and Safety Regulations

We are also subject to various environmental health and safety rules and regulations both within the U.S. and internationally relating to pollution or protection of human health and the environment. Our research and development, manufacturing, and clinical processes involve handling potentially harmful or hazardous materials regulated under environmental laws. We may be held liable for damages, penalties and other remedial actions and legal costs if we fail to comply with these laws. These expenses or this liability could have a significant negative impact on our financial condition and reputation.

Employees and Human Capital Resources

We believe that our future success depends upon our continued ability to attract and retain highly skilled and qualified employees who share in our mission to transform lives in the global diabetes community with differentiated, long-term implantable glucose monitoring technology. As of December 31, 2024, we had 117 full-time employees, of whom over half hold Ph.D., M.D., master's degree, or other post-graduate degrees, and all of whom are in the United States. Most employees are in Operations and Research and Development positions aligned with our corporate focus of designing, developing and manufacturing glucose monitoring products. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Culture

Employee engagement is always important to us, and improving our employee engagement with a remote, in-person and hybrid workforce remained a strategic imperative for us in 2024. We are committed to maintaining a flexible working environment for our employees, however, this requires an intentional focus to build communications and connections in the workplace. Throughout the year, we employed initiatives and communications to attach our employees to our company mission, vision, and values. Our values define the behaviors of our existing employees, and the new hires that we welcomed to our organization during 2024:

- *Customer Inspired* emphasizes how we put the customer first while we use our talents, passion, empathy, and hard work to build technology solutions for the unmet needs of our customers.

- *Game-Changing* Innovation affects everything we do from how we think, design, and manufacture advanced technology that makes a difference.

- *Learn Fast* highlights our respect for the process of discovery and supports intelligent risk-taking knowing that all outcomes are learning opportunities to iterate and improve.

- *Thrive Together* reflects the deep respect and trust in the diversity of our backgrounds, knowledge, skills, ideas and capabilities and our belief in each other and our partners to drive success.

- *Get It Done* represents working with a sense of urgency to go above and beyond to get the job done right through quality, compliance, and timeliness.

We utilize a human resource software which collects weekly employee feedback on work experience, culture, communications, interaction with their managers and other topics enabling us to react and address real time feedback. This software is an excellent tool to help monitor our culture at the organizational level, as well as the individual manager level. This feedback allows us to evaluate our initiatives and the reactions of our employees to successes and challenges in the organization. We leverage this platform to distribute surveys on specific topics, which demonstrates our commitment to hearing the voice of our employees and creating an inclusive environment. This software also provides opportunities for peer-to-peer recognition and valuable insights for managers to better lead their teams. We also conduct

company calls at least once month to update all employees on progress towards our company objectives, initiatives, what is happening in various departments, customer feedback and to celebrate employee achievements and company milestones. In addition, we conduct regular employee engagement events to recognize the value of our employees and their contributions.

Employee Health & Wellbeing

We are committed to the health and safety of our employees and have safety training programs that ensure our workforce knows how to do their jobs safely and in compliance with laws and regulations. We operate in modern, efficient, and safe facilities, and have minimal accident and injury rates. In 2022, we launched a platform to improve harassment training efforts, and we continued this training in 2024. We also expanded our wellness program "A Healthier You" in 2024. This program focuses on three pillars: financial, physical, and workplace wellness. Each pillar is supported by specific tools and resources to educate and reinforce the importance of wellness. This program includes a stipend to further support healthy behaviors and to demonstrate our commitment to employee well-being. In 2024, we created a Wellness Committee to engage interested employees and help deliver the initiatives. We created special interest groups, such as healthy eating and fitness activities, plus we delivered a weekly newsletter to emphasize the importance of regular healthy habits and to increase mental health awareness.

Organizational Development

We are committed to attracting, developing, and retaining employees by promoting an environment to continuously develop and learn. As part of our performance management process, all levels of employees are formally required to meet with their managers at least quarterly to receive feedback on their established objectives, identify opportunities for skill development, discuss opportunities to support their career goals, and reflect on how their behaviors demonstrate our corporate values. The executive team meets routinely to discuss key initiatives for strategic, operational, and organizational planning. Many of these meetings were focused on organizational development including reviewing demographic data and employment engagement data to better understand our employee profiles and address their specific needs. We continued to celebrate our revised technical leadership pathway with an awards program to recognize and reward our 2024 patent inventors. We continue to encourage professional certification and continuing education by reimbursement for professional certification classes, testing, maintenance, and tuition reimbursement of up to $5,250 annually. During 2024, we enhanced our focus on the development of and investment in our key leaders within the organization by offering a Manager Training Program for our managers and director level employees. We regularly engage in development conversations with our managers and directors regularly to reinforce best practices and ensure effective performance management.

Inclusion in the Workplace

As stated in our company values, our success thrives on the diversity of backgrounds, knowledge, skills, ideas, and capabilities within our workforce. We deeply respect each other and trust the diversity we have. With over half of our employees representing diverse ethnicities, we aspire to promote a diverse and inclusive culture that reflects the diversity of the customers we serve and fosters an environment where all employees feel welcomed, respected, and valued.

Total Rewards

We provide competitive compensation and benefits to attract and retain the best people. We engage nationally recognized compensation and benefits consulting firms to evaluate our total rewards programs and to provide benchmarking against our peers within the industry. We provide our employees with market competitive pay and bonuses. In 2021, we implemented a year-end market adjustment review process to ensure we maintain our competitive pay and pay equity between active employees and new hires and to align to the highly competitive labor market. As a result of this review process, we evaluate any market adjustments required to stay on track with the everchanging labor market and align with individual employee performance. Annual increases and incentive compensation are based on merit and documented through our performance management process as part of our annual review procedures. All employees are issued stock options and/or restricted stock units under our broad-based stock incentive programs. We

offer an employee stock purchase program to all employees. Finally, we offer comprehensive benefits to all eligible employees, including health insurance, paid time off, a retirement plan with company match, health savings accounts, flexible spending accounts, life and disability coverage, voluntary accident, and critical illness.

Corporate Information

We were originally incorporated as ASN Technologies, Inc. in Nevada on June 26, 2014. In 2015, we acquired Senseonics, Incorporated, a medical technology company focused on the design, development and commercialization of glucose monitoring systems to improve the lives of people with diabetes by enhancing their ability to manage their disease with relative ease and accuracy. From its inception in 1996 until 2010, Senseonics, Incorporated devoted substantially all of its resources to researching various sensor technologies and platforms. Beginning in 2010, the company narrowed its focus to designing, developing and refining a commercially viable glucose monitoring system.

In connection with the acquisition of Senseonics, Incorporated, we reincorporated in Delaware and changed our name to Senseonics Holdings, Inc. in 1996. Upon the closing of the acquisition, Senseonics, Incorporated merged with a wholly owned subsidiary of ours formed solely for that purpose and became our wholly owned subsidiary. Eon Care Services, LLC and Eon Management Services, LLC are wholly owned subsidiaries of Senseonics, Incorporated formed in April 2024 and July 2024, respectively.

Our principal executive offices are located at 20451 Seneca Meadows Parkway, Germantown, Maryland 20876-7005 and our telephone number is (301) 515-7260. Our common stock is listed on the NYSE American under the symbol “SENS.”

Available Information

Our website address is www.senseonics.com. In addition to the information contained in this Annual Report, information about us can be found on our website. Information contained in, or accessible through, our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC’s website is www.sec.gov.

Item 1A. Risk Factors

Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in this Annual Report, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.

Summary of Risks Affecting Our Business

Our business is subject to numerous risks. The following summary highlights some of the risks you should consider with respect to our business and prospects. This summary is not complete, and the risks summarized below are not the only risks we face. You should review and consider carefully the risks and uncertainties described in the “Risk Factors” section of this Annual Report on Form 10-K, which includes a more complete discussion of the risks

summarized below as well as a discussion of other risks related to our business and an investment in our common stock, as well as our other public filings with the Securities and Exchange Commission, or SEC.

Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects and cause the trading price of our common stock to decline:

- We have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability. Our results of operations may fluctuate significantly from quarter to quarter or year to year.
- We expect that a substantial majority of our future revenue will result from our Commercialization Agreement with Ascensia. If Ascensia fails to perform satisfactorily under this agreement, including among other things if they are delayed or unsuccessful in growing the adoption of our product, our commercialization efforts and financial results would be directly and adversely affected.
- The markets in which we participate are highly competitive, and our primary competitors, as well as a number of other companies, medical researchers and existing medical device companies, are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for Eversense or render Eversense less competitive or obsolete, which would significantly reduce our potential sales.
- We have limited operating history as a commercial-stage company and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.
- Our actual operating results may differ significantly from any guidance provided. If our actual results of operations fall below the expectations of investors or securities analysts, the price of our common stock could decline significantly.
- Medical device development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, ongoing development for lifecycle management of our products.
- Our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer. In particular, the FDA and other foreign regulatory clearance, certification, or approval processes are expensive, time-consuming and uncertain, and the failure to maintain required regulatory clearances, certifications and approvals could prevent us from commercializing Eversense and future versions of Eversense.
- Failure to secure or retain coverage or adequate reimbursement for Eversense or future versions of Eversense systems, including the related insertion and removal procedures, by third-party payors could adversely affect our business, financial condition and operating results.
- We have partnerships with companies such as NPG and directly contract with healthcare professionals to establish broad inserter networks and as the number of insertions increase so does our reliance on these partners. If NPG or other partners fail to perform satisfactorily under these agreements our commercialization efforts and financial results would be directly and adversely affected.
- Our stock price has been highly volatile and may continue to be highly volatile. The stock market in general and the market for innovative, emerging medtech and biotechnology companies in particular, has experienced volatility that has often been unrelated to the operating performance of particular companies. We cannot predict the action of market participants and, therefore, can offer no assurances that the market for our common stock will be stable or appreciate over time.
- Our operating results are subject to significant fluctuations.
- Due to our recurring losses and uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, there is substantial doubt about our ability to continue as a going concern.
- We contract with third parties for the manufacture of Eversense. Risks associated with the manufacturing of our products, loss of key suppliers or disruption to their facilities could reduce our gross margins and negatively affect our operating results.
- We operate in a regulated industry and our business, operations and the business and operations of our third-party manufacturers are subject to various foreign, U.S. federal, state and local laws and regulations, including those promulgated by the FDA and equivalent foreign regulatory authorities, among others. Failure to comply

with applicable laws and regulations should harm our business and we may incur significant expenditures related to compliance efforts.

- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs to our products, limit their use or adoption, and otherwise negatively affect our operating results and business.
- Holders of debt instruments may exert substantial influence over us and may exercise their control in a manner adverse to the interests of our common stockholders.

Risks Relating to our Business and our Industry

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

Since our inception, we have incurred significant net losses and expect to incur additional losses in the near future. We incurred total net loss of $(78.6) million and $(60.4) million for the years ended December 31, 2024, and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $947.9 million. To date, we have financed our operations primarily through sales of our equity securities and debt financings. We have devoted substantially all of our resources to the research and development of our products, including conducting clinical trials, and the commercial launch of Eversense in the United States, select markets in Europe, the Middle East, and Africa (EMEA).

To implement our business strategy we need to, among other things, gain regulatory approval or certification in other regions where we intend to sell our products, expand our commercial launch in the United States and Europe, and develop future generations of Eversense. We have never been profitable from operations and do not expect to be profitable for at least the next several years. We expect to make significant investments in product development as we pursue these objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, and we expect to continue incurring expenses and operating losses over the next several years. Any additional operating losses may have an adverse effect on our stockholders' equity, and we cannot assure you that we will ever be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain regulatory approvals or certificates, diversify our product offerings or continue our operations.

Our Commercialization Agreement with Ascensia to market Eversense may not be successful.

We have a Commercialization Agreement with Ascensia, pursuant to which we have granted Ascensia the exclusive right to distribute Eversense worldwide, subject to certain exceptions. Pursuant to this agreement, our future success will be dependent on Ascensia effectively marketing and selling Eversense. We expect that the substantial majority of our future revenue will come pursuant to this agreement. Prior to our Commercialization Agreement with Ascensia, Ascensia had limited experience with marketing durable medical equipment and no experience marketing CGM systems. In order to strengthen commercial execution, Ascensia has recently established an independent dedicated business unit responsible for commercializing Eversense, which reports directly to Ascensia’s parent company, PHC Holdings Corporation (“PHC”), and Ascensia has engaged a new president of CGM to lead that business unit. However, there can be no assurance that these efforts will be successful. If Ascensia fails to perform satisfactorily under this agreement, including among other things if they are delayed or unsuccessful in growing the adoption of our product, our commercialization efforts and financial results would be directly and adversely affected.

The Commercialization Agreement is terminable by Ascensia under a number of circumstances, including if we undergo a change of control. The agreement is terminable by either party if the other party materially breaches its obligations under the agreement; provided, however, that if Ascensia is unable to achieve the specified minimum spending or revenue targets described above, then we will only have the right to convert Ascensia’s exclusive rights to

nonexclusive rights, which may make it difficult for us to successfully engage with another commercial partner. The agreement is also terminable by either party if the other party undergoes bankruptcy, dissolution or winding up.

We cannot guarantee this agreement with Ascensia will be successful, that it will continue, or that we will be able to achieve or maintain any particular volume of sales under the agreement or increase the volume of sales at a satisfactory pace or at all from this relationship in the future.

Our Commercialization Agreement with Ascensia and the terms of our debt may discourage a change of control of our company.

The terms of our agreements with Ascensia and PHC may discourage a third party from acquiring, or attempting to acquire, control of our company, even if a change of control was considered favorable by some or all of our stockholders. For example, because of the exclusivity of the distribution arrangements with Ascensia and the minimum five-year term of that exclusivity (which may be extended under certain circumstances), prospective strategic acquirors may be unwilling to undertake an acquisition of our company.

We have limited operating history as a commercial-stage company and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

Our experience as a commercial-stage company upon which to evaluate our business, future sales expectations and operating results is limited. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive and rapidly evolving markets, particularly companies that develop and sell medical devices. These risks include our ability to:

- obtain regulatory clearance, certification or approval to commercialize our products;
- perform clinical trials with respect to current Eversense or future versions of Eversense;
- implement and execute our business strategy;
- expand and improve the productivity of our sales and marketing infrastructure to grow sales of Eversense or future versions of Eversense;
- increase awareness of our brand and Eversense and build loyalty among people with diabetes, their caregivers and healthcare providers;
- manage expanding operations;
- manage and secure effective sales of our product through our new collaboration with Ascensia, including its establishment of required commercial infrastructure in the U.S. and elsewhere, and its adapting to a new product category in which it has limited experience;
- expand the capabilities and capacities of our third-party manufacturers, including increasing production of current products efficiently and having our vendors adapt their manufacturing facilities to the production of new products;
- respond effectively to competitive pressures and developments;
- enhance Eversense and develop future versions of Eversense; and
- attract, retain and motivate qualified personnel in various areas of our business.

Due to our limited operating history as a commercial-stage company, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

If we are unable to successfully expand our commercialization of Eversense in the United States and Europe through our Commercialization Agreement with Ascensia, our business will be harmed.

We have limited commercialization experience in both the United States and Europe. We have invested substantially all of our efforts and financial resources to the development and commercialization of Eversense. Our ability to generate revenue from our products will depend heavily on successful commercialization of products in the

United States and Europe, which is entirely dependent on our collaboration with Ascensia, and on continuing development of future generations of our Eversense system. The success of any products that we develop will depend on several factors, including:

- receipt of timely marketing approvals from applicable regulatory authorities or CE Certificates Conformity from Notified Bodies in the EEA;
- our ability to procure and maintain suppliers and manufacturers of the components of Eversense and future versions of Eversense;
- market acceptance of Eversense by people with diabetes, the medical community and third-party payors;
- our ability to obtain and maintain coverage and adequate reimbursement for Eversense and the related insertion and removal procedures from third-party payors;
- our success in educating healthcare providers and people with diabetes about the benefits, administration and use of Eversense and future versions of Eversense;
- the prevalence and severity of adverse events experienced with Eversense and future versions of Eversense;
- the perceived advantages, cost, safety, convenience and accuracy of alternative diabetes management therapies;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for Eversense and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices; and
- maintaining a continued acceptable accuracy, safety, duration and convenience profile of Eversense.

Our revenue is dependent, in part, upon the size of the markets in the territories for which we have regulatory approval or certification, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of people with diabetes we target is not as significant as we estimate or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products.

Our revenue is dependent on the success of Ascensia in commercializing our product and its future versions. Our product is a new product for Ascensia globally and they must continue to establish certain functions of their U.S. commercial organization to successfully market and sell our CGM system. Ascensia's continued organizational development of its sales and marketing capabilities will be critical to successful commercialization of our Eversense systems. If Ascensia is unable to maintain effective sales, marketing and other functions that are required to support the product, it will have a materially negative impact on our net revenues from Eversense.

Approval in the United States by the FDA or approval, or certification by a regulatory agency or Notified Body in another country does not guarantee approval, or certification by the regulatory authorities or Notified Bodies in other countries or jurisdictions or ensure approval, or certification for the same conditions of use. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval or certification processes vary among countries and can involve additional product testing and validation and additional administrative review periods. If we do not achieve one or more of these approvals, or certifications in a timely manner or at all, we could experience significant delays or an inability to fully commercialize Eversense and achieve profitability.

Both before and after a product is commercially released, we will have ongoing responsibilities under U.S. and EU regulations. We will also be subject to periodic inspections by the FDA, the Notified Bodies in the EEA and comparable foreign authorities to determine compliance with regulatory requirements, such as the QSR, of the FDA, medical device reporting regulations, vigilance in reporting of adverse events and regulations regarding notification, corrections, and recalls. These inspections can result in observations or reports, warning letters or other similar notices or forms of enforcement action. If the FDA, or any comparable foreign regulatory authority concludes that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable health risk, such authority could ban these products, suspend, vary or cancel our marketing authorizations or CE Certificates of Conformity, impose "stop-sale" and "stop-import" orders, refuse to issue export certificates, detain or seize adulterated or misbranded products, order a recall, repair, replacement, correction or refund of such products, or require us to notify health providers and others that the products present unreasonable risks of substantial harm to the public health. Discovery of previously unknown problems with our product's design or manufacture may result in restrictions on the use of Eversense, restrictions placed on us or our suppliers, or withdrawal or variation of an existing regulatory clearance

or CE Certificate of Conformity for Eversense. The FDA, competent authorities of EEA countries and comparable foreign regulatory authorities may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, assess civil or criminal penalties against our officers, employees or us, or recommend criminal prosecution of our company. Adverse regulatory action may restrict us from effectively marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our business, financial condition, and operating results.

Foreign governmental regulations have become increasingly stringent and more extensive, and we may become subject to even more rigorous regulation by foreign governmental authorities in the future. Penalties for a company's noncompliance with foreign governmental regulation could be severe, including revocation or suspension of a company's business license and civil or criminal sanctions. In some jurisdictions, such as Germany, any violation of a law related to medical devices is also considered to be a violation of the unfair competition law. In such cases, governmental authorities, our competitors and business or consumer associations may then file lawsuits to prohibit us from commercializing Eversense in such jurisdictions. Our competitors may also sue us for damages. Any domestic or foreign governmental law or regulation imposed in the future may have a material adverse effect on our business, financial condition and operating results.

We are dependent on one product, Eversense. Our success depends on our ability to continue to develop, commercialize and gain market acceptance for our products.

Our current business strategy is highly dependent on the successful commercialization of Eversense by Ascensia and achieving and maintaining market acceptance. In order to sell Eversense to people with diabetes, we and Ascensia must educate them, their caregivers and healthcare providers that Eversense is an attractive alternative to competitive products for the monitoring of glucose levels, including SMBG, as well as other competitive CGM systems and alternatives to CGM methodologies. Market acceptance and adoption of Eversense depends on educating people with diabetes, as well as their caregivers and healthcare providers, as to the distinct features, ease-of-use, positive lifestyle impact, and other perceived benefits of Eversense as compared to competitive products.

Achieving and maintaining market acceptance of Eversense could be negatively impacted by many factors, including:

- the failure of Eversense to achieve wide acceptance among people with diabetes, their caregivers, healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;
- lack of evidence supporting the accuracy, duration, safety, ease-of-use or other perceived benefits of Eversense over competitive products or other currently available diabetes management therapies;
- perceived risks associated with the use of Eversense or similar products or technologies generally;
- the introduction of competitive products and the rate of acceptance of those products as compared to Eversense;
- adverse results of clinical trials relating to Eversense or similar competitive products;
- loss of regulatory approval or CE Certificates of Conformity for Eversense, adverse publicity or other adverse events including any product liability lawsuits; and
- any limitations in the ability of Ascensia to effectively communicate and promote product benefits.

In addition, Eversense may be perceived by people with diabetes, their caregivers or healthcare providers to be more complicated or less effective than traditional monitoring methodologies, including SMBG or CGM systems which may require less calibration, and people may be unwilling to change their current regimens.

Moreover, healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party payor reimbursement. Accordingly, healthcare providers may not recommend Eversense unless and until there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as receiving recommendations from prominent healthcare providers or other key opinion leaders in the diabetes treatment community.

If we are not successful in educating people with diabetes of the benefits of Eversense, or if we are unable to achieve the support of caregivers and healthcare providers or widespread market acceptance for Eversense, then our sales

potential, strategic objectives and profitability could be negatively impacted, which would adversely affect our business, financial condition and operating results.

We contract with third parties for the manufacture of Eversense. Risks associated with the manufacturing of our products could reduce our gross margins and negatively affect our operating results.

We do not have any manufacturing facilities or direct manufacturing personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of Eversense for commercial sale and development of future CGM products. Our business strategy depends on our third-party manufacturers' ability to manufacture Eversense in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our reliance on the manufacturing capabilities of our third-party manufacturers, including:

- quality or reliability defects in Eversense;
- inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- failure to increase production of Eversense to meet demand;
- inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- difficulty identifying and qualifying alternative manufacturers in a timely manner;
- inability to establish agreements with current or future third-party manufacturers or to do so on acceptable terms; or
- potential damage to, disruption of or destruction of our manufacturers' equipment or facilities, including their information technology systems.

These risks are likely to be exacerbated by our limited experience with Eversense and its manufacturing process. As demand for our products increases, our third-party suppliers will need to invest additional resources to purchase components, hire and train employees, and enhance their manufacturing processes. If our manufacturers fail to increase production capacity efficiently, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. Further, we may be required to fund capital investments at our third-party suppliers to support increased production capacity. In addition, although we expect some of our future versions of Eversense to share product features and components with our current Eversense versions, manufacturing future versions of Eversense may require the modification of production lines, the identification of new manufacturers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these future versions of Eversense commercially viable.

We depend on a limited number of third-party suppliers for the components of Eversense and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials, could harm our business.

We rely on third-party suppliers to supply and manufacture the components of our Eversense system. For our business strategy to be successful, our suppliers must be able to provide us with components and Eversense systems in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Future increases in sales of Eversense, whether expected or unanticipated, could strain the ability of our suppliers to deliver an increasingly large supply of components and Eversense systems in a manner that meets these various requirements.

We generally use a small number of suppliers of components for our products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Generally, we do not have long-term supply agreements with our suppliers, and, in many cases, we make our purchases on a purchase order basis. Under most of our supply and manufacturing agreements, we have no obligation to buy any given quantity of products, and our suppliers have no obligation to sell us or to manufacture for us any given quantity of components or products. As a result, our ability to purchase adequate quantities of components or our products may be limited, and we may not be able to convince suppliers to make components and products available to us. Additionally, our suppliers may encounter problems that limit their ability to supply components or manufacture products for us,

including financial difficulties, damage to their manufacturing equipment or facilities, or product discontinuations. As a result, there is a risk that certain components could be discontinued and no longer available to us. We may be required to make significant "last time" purchases of component inventory that is being discontinued by the supplier to ensure supply continuity. If we fail to obtain sufficient quantities of high-quality components to meet demand for our products in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and regulatory requirements, we may not be able to quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver components at the level our business requires could disrupt the manufacturing of our products and limit our ability to meet our sales commitments, which could harm our reputation and adversely affect our business.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other foreign regulatory authorities, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, and termination of distribution, product seizures or civil penalties. It 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 result in a requirement to seek additional regulatory approvals or certifications. Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results.

Our third-party suppliers operate primarily at facilities in a single location, and any disruption to these facilities could adversely affect our business and operating results.

Each of our third-party suppliers operates at a facility in a single location and substantially all of our inventory of component supplies and finished goods is held at these locations. We, and our suppliers, take precautions to safeguard facilities, including acquiring insurance, employing back-up generators, adopting health and safety protocols and utilizing off-site storage of computer data. However, vandalism, terrorism or a natural or other disaster, such as an earthquake, health epidemic, such as the coronavirus, fire or flood, could damage or destroy equipment or our inventory of component supplies or finished products, cause substantial delays in our operations, result in the loss of key information, or cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our suppliers' facilities could harm our business, financial condition and operating results.

If we do not enhance our product offerings through our research and development efforts, we may fail to effectively compete or become profitable.

In order to capture and grow market share in the intensively managed diabetes market, we will need to enhance and broaden our product offerings in response to the evolving demands of people with diabetes and healthcare providers, as well as competitive pressures and technologies. These development needs include additional features, extended product life and other attributes we believe may be desired by patients. We may not be successful in developing, obtaining regulatory approval or certification for, or marketing future versions of Eversense. In addition, notwithstanding our market research efforts, our future products may not be accepted by people with diabetes, their caregivers, healthcare providers or third-party payors who reimburse people with diabetes for Eversense and healthcare providers for their services. The success of Eversense or future versions of Eversense will depend on numerous factors, including our ability, and the ability of our commercial partners, to:

- identify the product features that people with diabetes, their caregivers and healthcare providers are seeking in a CGM system and successfully incorporate those features into our products;
- develop and introduce future generations of Eversense in a timely manner;
- offer products at a price that is competitive with other products then available;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the accuracy and safety of Eversense or future versions of Eversense;
- obtain coverage and adequate reimbursement for Eversense or future versions of Eversense and the related insertion and removal procedures; and

- obtain the necessary regulatory approvals or certifications for Eversense and future versions of Eversense. However, if regulatory authorities or Notified Bodies were to disagree, this would adversely impact our ability to commercialize that product enhancement.

If we fail to generate demand by developing products that incorporate features requested by people with diabetes, their caregivers or healthcare providers, or if we do not obtain regulatory clearance, certification or approval for future versions of Eversense in time to meet market demand, we may fail to generate sales sufficient to achieve or maintain profitability. We have in the past experienced, and we may in the future experience, delays in various phases of product development, approval, certification and commercial launch, including during research and development, regulatory submission and approval or certification, manufacturing, limited release testing, marketing and customer education efforts. Any delays in our anticipated product launches may significantly impede our ability to successfully compete in our markets. In particular, such delays could cause customers to delay or forego purchases of our products, or to purchase our competitors' products. Even if we are able to successfully develop future versions of Eversense when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by the changing preferences of people with diabetes or the introduction by our competitors of products embodying new technologies or features.

Failure to secure or retain coverage or adequate reimbursement for Eversense or future versions of Eversense systems, including the related insertion and removal procedures, by third-party payors, and an inability of patients to be able to access the product, could adversely affect our business, financial condition and operating results.

We plan to derive nearly all of our revenue from sales of Eversense in the United States and Europe and expect to do so for the next several years. Patients who receive treatment for their medical conditions and their healthcare providers generally rely on third party payors to reimburse all or part of the costs associated with their medical treatment, including healthcare providers' services. As a result, access to coverage and adequate reimbursement for Eversense by third-party payors is essential to the acceptance of our products by people with diabetes. Similarly, healthcare providers may choose not to order a product unless third-party payors cover and reimburse a substantial portion of the product. Coverage determinations and reimbursement levels of both our products and the healthcare provider's performance of the insertion and removal procedures are critical to the commercial success of our product, and if we or our commercial partners are not able to secure positive coverage determinations and reimbursement levels for our products or the insertion and removal procedures, our business would be materially adversely affected.

Within and outside the United States, reimbursement is obtained from a variety of sources, including government sponsored and private health insurance plans. These third-party payors determine whether to provide reimbursement for specific products and procedures. A third-party payor's decision to provide coverage for our products does not imply that an adequate reimbursement rate will be obtained. Further, one third-party payor's decision to cover our products does not assure that other payors will also provide coverage for the products or will provide coverage at an adequate reimbursement rate. In addition, there may be significant delays in obtaining a reimbursement determination, and coverage, if granted, may be more limited than the purposes for which the product is cleared or certified by the FDA, a Notified Body in the EEA or other foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers its associated costs, including research, development, manufacture, sale and distribution. For example, payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices.

Private insurance companies and other private third-party payors set payor-specific reimbursement policies. The extent of coverage and the rate of reimbursement vary on a payor-by-payor basis. Most of the largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of CGM devices. These policies include varied coverage requirements regarding patient condition and characteristics. Many of these coverage policies reimburse for CGM systems under durable medical equipment benefits, which are restrictive in nature and require the healthcare provider or supplier to comply with extensive documentation and other requirements. In addition,

those third-party payors that cover CGM products may and have included limitations as to the patient conditions and characteristics eligible for coverage and may adopt different coverage and reimbursement policies for our products, which could also diminish payments for Eversense. It is possible that some third-party payors will not offer any coverage for our products. Even if favorable coverage and reimbursement status is attained for Eversense, less favorable coverage policies and reimbursement rates may be implemented in the future.

Eversense is an implantable medical device in the clinic setting and thus follows a different reimbursement path when compared to the current CGM class. Some payors will adopt a payment methodology that will bundle payment of device and procedure back to the implanting clinic. Other payors may choose to reimburse device and procedure separately. Without a Category 1 code to define the payment process, there will be some heterogeneity in this process. Given this heterogeneity, we will have to work closely with certified clinics to keep abreast of which process to follow and what to expect. This will be disruptive to some clinics and could delay product uptake until the process of payment becomes more homogenous and well defined for clinics to follow. Until a steady state is reached, delays in processing and clinic operating coordination could result in the loss of sales, which could negatively affect our business, financial condition and operating results.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs by imposing lower payment rates and negotiating reduced contract rates, among others. As such, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional preauthorization requirements, both in the United States and in international markets. Our dependence on the commercial success of our Eversense products makes us particularly susceptible to any cost containment or reduction efforts. If third-party coverage and reimbursement of products for which we may receive regulatory approval or certification is not available or adequate in either the United States or international markets, or if our production costs increase faster than increases in reimbursement levels, we or our commercial partners may be unable to sell Eversense or future versions of Eversense profitably and our business would be adversely impacted.

Moreover, in the EU some countries may require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medical devices, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It is now in effect as of January 12, 2025, although its implementation is phased.

In April 2022, as a part of commercialization efforts, our partner Ascensia implemented the PASS program designed to enhance affordability and access to Eversense for patients who do not have insurance coverage for Eversense, or whose insurance is denied or is insufficient. The program's design being ineffective, or a lack of a patient assistance program could adversely impact the sales of Eversense and, consequently, our net revenues. In addition, we may not be able to recognize a substantial portion of the revenue related to Eversense insertions for the patients participating in these access programs. The amount of time required to obtain favorable coverage and reimbursement decisions, including navigating the appeals process with third-party payors, is uncertain, and we may see increased product utilization without corresponding recognized revenue. Our operating results may be adversely impacted if we are unable to obtain successful appeals or favorable coverage decisions by insurance providers, or if there are not effective patient access programs in place.

If important assumptions we have made about what people with intensively managed diabetes are seeking in a CGM system are inaccurate, our business and operating results may be adversely affected.

Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the diabetes market for CGM in particular, any one or more of which may prove to be inaccurate. For example, we believe that the benefits of CGM will continue to drive increased rates of market acceptance for products in this space. However, this trend is uncertain and limited sources exist to obtain reliable market data.

Another key element of our business strategy is utilizing market research to understand how people with diabetes are seeking to improve their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed Eversense. However, our market research is based on interviews, focus groups and online surveys involving people with diabetes on insulin, their caregivers and healthcare providers that represent only a small percentage of the overall diabetes market. As a result, the attributes we incorporated into the Eversense system may not be reflective of what is desired by the various constituents in the diabetes market. Consequently, our estimates of our future market share and penetration may not be accurate and our sales may be less than estimated.

We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, many of whom have greater resources than we have, our sales and operating results may be negatively affected.

The market for CGM systems is developing and competitive, subject to rapid change and significantly affected by new product introductions. We compete with well-capitalized companies, some of which are publicly traded, that manufacture CGM systems including Dexcom, Medtronic and Abbott. Each of these companies has received approval from the FDA to market their respective CGM system. Dexcom's CGM system was the first CGM system to be approved by the FDA for marketing as a non-adjunctive device, and Abbott's Freestyle Libre was also approved for non-adjunctive use. Both Dexcom (G6 and G7) and Abbott (Freestyle Libre) systems have factory calibration, and do not require user calibration.

Dexcom has also received the first FDA iCGM indication allowing its Dexcom G6 and G7 to be interoperable with other diabetes tech devices such as insulin pumps. As the industry evolves, we anticipate encountering increasing competition from companies that integrate CGM with insulin pumps. Abbott also received an iCGM indication for their Freestyle Libre 2 and 3 products and we expect all other CGM companies to pursue an iCGM indication including Medtronic.

In addition to CGM providers, we also compete with providers of SMBG systems. Three companies currently account for a substantial share of the worldwide sales of SMBG systems: Roche Diabetes Care, a division of Roche Diagnostics; Abbott; and Ascensia Diabetes Care Holdings AG. There are also a number of academic and other institutions involved in various phases of our industry's technology development.

Many of these competitors enjoy several advantages over us, including:

- greater financial and human resources for sales and marketing, and product development;
- established relationships with healthcare providers and third-party payors;
- established reputation and name recognition among healthcare providers and other key opinion leaders in the diabetes industry;
- in some cases, an established base of long-time customers;
- products supported by long-term clinical data;
- larger and more established sales, marketing and distribution networks;
- greater ability to cross-sell products or provide incentives to healthcare providers to use their products; and
- more experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval or clearance and certification.

In addition, mergers and acquisitions in the diabetes industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

If we are unable to effectively compete with our competitors, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed.

Competitive products or other technological innovations for the monitoring, treatment or prevention of diabetes may render our products less competitive or obsolete.

Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the monitoring and management of diabetes that offer distinct features, have a longer duration than available alternatives, are easy-to-use, receive adequate coverage and reimbursement from third-party payors, include essential safety features and are more appealing than available alternatives. Our primary competitors, as well as a number of other companies, medical researchers and existing medical device companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. For example, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve treatment of diabetes, which, if successful, could render glucose monitoring devices, like Eversense, obsolete. Any technological breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for Eversense or render Eversense less competitive or obsolete altogether, which would significantly reduce our potential sales.

Because of the size of the diabetes market, we anticipate that companies will continue to dedicate significant resources to developing competitive products. The frequent introduction by competitors of products 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 competitive products. In addition, the entry of multiple new products may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products. If a competitor develops a product that competes with or is perceived to be superior to Eversense, or if a competitor employs strategies that place downward pressure on pricing within our industry, our sales may decline significantly or may not increase in line with our expectations, either of which would harm our business, financial condition and operating results.

The size and future growth in the market for CGM systems and CGM-related products has not been established with precision and may be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market, our sales growth may be adversely affected.

Our estimates of the size and future growth in the market for CGM systems and CGM-related products, including the number of people currently managing their diabetes with insulin who may benefit from and be amenable to using Eversense, are based on a number of internal and third-party studies, reports and estimates. In addition, our internal estimates are based in large part on current treatment patterns by healthcare providers using CGM systems and our belief that the incidence of diabetes in the United States and worldwide is increasing. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for CGM systems and CGM related products and our products, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The actual incidence of diabetes, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. As a result, our estimates of the size and future growth in the market for our CGM systems may prove to be incorrect. If the actual number of people with diabetes who would benefit from Eversense and the size and future growth in the market for Eversense is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business.

Our ability to maintain and grow our revenue will depend on establishing a customer base and retaining a high percentage of our customer base.

A key to maintaining and growing our revenue will be establishing a customer base and retaining a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of disposable sensors. Ascensia intends to continue developing customer loyalty programs to help with retention aimed at patients, their caregivers and healthcare providers, which include patient ambassadors, training specific to Eversense, ongoing support by sales and clinical employees and 24/7 technical support and customer service. If demand for our products fluctuates as a result of the introduction of competitive products, changes in reimbursement policies, manufacturing problems, perceived safety issues with our or our competitors' products, the failure to secure regulatory clearance or approvals, certifications or for other reasons, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our business, financial condition and operating results.

Various factors outside our direct control may adversely affect manufacturing, sterilization and distribution of our products.

The manufacture, sterilization and distribution of our products is challenging. Changes that our suppliers may make outside the purview of our direct control can have an impact on our processes, quality of our products and the successful delivery of products to our customers. Mistakes and mishandling are not uncommon and can affect supply and delivery. Some of these risks include:

- failure to complete sterilization on time or in compliance with the required regulatory standards;
- transportation and import and export risk, particularly given the international nature of our supply and distribution chains;
- delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment (including through cyberattacks or other security incidents) or other forms of disruption to business operations affecting our manufacturers or suppliers; and
- latent defects that may become apparent after products have been released and that may result in a recall of such products.

If any of these risks were to materialize, our ability to provide our products to customers on a timely basis would be adversely impacted.

Potential complications from Eversense or future versions of Eversense may not be revealed by our clinical experience.

Based on our experience, complications from the use of Eversense may include sensor errors, sensor failures or skin irritation under the adhesive dressing of the transmitter. Inflammation or redness, swelling, minor infection, and minor bleeding at the sensor insertion site are also possible risks with an individual's use of the device. However, if unanticipated side-effects result from the use of Eversense or future versions of Eversense, we could be subject to liability and our systems would not be widely adopted. Additionally, we have limited clinical experience with repeated use of our CGM system in the same patient or the same insertion site. We cannot assure you that long-term use would not result in unanticipated complications, even after the device is removed.

Undetected errors or defects in Eversense or future versions of Eversense could harm our reputation, decrease the market acceptance of Eversense or expose us to product liability claims.

Eversense or future versions of Eversense may contain undetected errors or defects. Disruptions or other performance problems with Eversense or future versions of Eversense, including our sensors not lasting for the full approved or certified duration of use, may harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may

also be subject to increased warranty and liability claims for damages related to errors or defects in Eversense or future versions of Eversense. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of Eversense could harm our business and operating results. This risk exists even if a device is cleared, certified or approved for commercial sale and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Any side effects, manufacturing defects, misuse or abuse associated with Eversense or future versions of Eversense systems could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability lawsuits.

The sale and use of Eversense or future versions of Eversense could lead to the filing of product liability claims if someone were to allege that Eversense or one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. Product liability claims may be brought against us by people with diabetes, healthcare providers or others selling or otherwise coming into contact with our products, among others. 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:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize Eversense or future versions of Eversense;
- decreased demand for Eversense;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

While we currently maintain product liability insurance covering claims up to $10.0 million per occurrence, we cannot assure you that such insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing such insurance coverage in the future.

We may enter into collaborations, in-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, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop products and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators 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, 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 or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any 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. For example, one of our vendors who provides a component to the Eversense sensor has communicated to us its belief that one of its employees should be named as a co-inventor on a related patent application. We have communicated to the third party that its employee should not be named as a co-inventor and its employee has not been named as a co-inventor to date. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable 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 we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could harm our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience;
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters; and
- unanticipated or undisclosed liabilities of any target.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability, due to reasons including, among other things, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures.

A widespread public health crisis such as a pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the effects of public health crises could materially affect our business and the value of our common stock. It may have further negative impacts, such as (a) a global or U.S. recession or other economic crisis; (b) credit and capital markets volatility (and access to these markets, including by our suppliers and customers); (c) manufacturing supply disruption due to travel restrictions or other government actions; (d) disruptions in raw material supply, our manufacturing operations, or in our distribution and supply chain; and (e) our ability to conduct planned clinical trials and commercialization activities. The ultimate impact of a public health crisis is highly uncertain.

The Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Risks Related to our Financial Results and Need for Financing

We will need to generate significant sales to achieve profitable operations.

We intend to continue to increase our operating expenses in connection with the commercialization of Eversense with our collaboration partner Ascensia, our ongoing research and development activities including the development of next generation products and the clinical trials for those products, and the commensurate development of our management and administrative functions. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we expect, or if our operating expenses exceed our expectations, our financial performance and operating results will be adversely affected.

Our operating results may fluctuate from quarter to quarter or year to year.

We have limited operating history as a commercial-stage company and we anticipate that there will be meaningful variability in our operating results among years and quarters, as well as within each year and quarter. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

- regulatory clearance, certification or approvals affecting our products or those of our competitors;
- Ascensia's ability to increase sales of Eversense and to commercialize and sell our future products, and the number of our products sold in each quarter;
- Ascensia's ability to establish and grow an effective sales and marketing infrastructure and third-party distribution network;
- acceptance of our products by people with diabetes, their caregivers, healthcare providers and third-party payors;
- the pricing of our products and competitive products, and the effect of third-party coverage and reimbursement policies;
- the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;
- interruption in the manufacturing or distribution of our products;
- seasonality and other factors affecting the timing of purchases of Eversense;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- results of clinical research and trials on our products in development;
- the ability of our suppliers to timely provide us with an adequate supply of components and CGM systems that meet our requirements;
- changes in the fair value of embedded derivative instruments in the terms of some of our financings, which are subject to potentially wide fluctuations from period to period as a result of changes in our stock price; and
- the timing of revenue recognition associated with our product sales pursuant to applicable accounting standards.

As a result of our lack of operating history as a commercial-stage company and Ascensia's lack of experience selling CGM systems, and Eversense in particular, and due to the complexities of the industry and regulatory framework in which we operate, it will be difficult for us to forecast demand for our future products and to forecast our sales with any degree of certainty. For example, many of the products we will seek to develop and introduce in the future will require regulatory approval, certification or clearance and import licenses before we can sell such products and given that the timing of such approvals, certification, clearances or licenses may be uncertain, it will be difficult for us to predict sales projections for these products with any degree of certainty before such approvals, certifications, clearances or licenses are obtained. In addition, we will be increasing our operating expenses as we expand our business. Accordingly, we may experience substantial variability in our operating results from year to year and quarter to quarter. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our product revenue is subject to seasonal variation

Our product revenues have historically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year. We believe this arises primarily due to the annual reset of health insurance plan deductibles that occur at the beginning of the insurance plan year and the utilization of patient assistance programs to offset those costs and our distributors reductions of inventory of our products in the first quarter. The seasonal variance is has also been impacted by the timing of Ascensia's purchases in accordance with minimum purchase requirements under our distribution agreement. As a result, our distributors typically end the calendar year with higher levels of inventory than at the end of the first quarter of the following year. As a result, our net sales are typically lower in the first quarter of the year than would otherwise have been the case as a result of the reduction of product inventory at our distributors. Many health insurance plans and government insurance programs reset annual limits on deductibles and out-of-pocket costs at the beginning of each calendar year and require participants to pay for a large portion of medical products and services until such deductibles and annual out-of-pocket cost limits are met. As a result of these factors, patients may delay medical expenses or find cheaper alternatives until such deductibles and annual out-of-pocket cost limits are met. Any reduction in the demand for Eversense as a result of the foregoing factors or otherwise, can adversely affect our business, operating results and financial condition.

Covenants under the Loan and Security Agreement may result in the acceleration of outstanding indebtedness and limit the manner in which we operate.

In September 2023, we entered into a loan agreement (the "Loan and Security Agreement") with several institutions (collectively, the "Lenders") and Hercules Capital, Inc. ("Hercules"), as administrative agent. The Loan and Security Agreement contains customary terms and covenants, including financial covenants, such as operating within an approved budget and achieving minimum revenue and liquidity targets, and negative covenants, such as limitations on indebtedness, liens, mergers, asset transfers, certain investing activities and other matters customarily restricted in such agreements. Most of these restrictions are subject to certain minimum thresholds and exceptions. The Loan and Security Agreement also contains customary events of default, after which borrowings under the Loan and Security Agreement will be due and payable immediately, including defaults related to payment compliance, material inaccuracy of representations and warranties, covenant compliance, material adverse changes, bankruptcy and insolvency proceedings, cross defaults to certain other agreements, judgments against the Company, change of control or delisting events, termination of any guaranty, governmental approvals, and lien priority.

As a result, we are limited in the manner in which we conduct our business and we may be unable to engage in favorable business activities, repurchase shares of our common stock or finance future operations or capital needs.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Despite our current debt levels, subject to certain conditions and limitations, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.

Despite our current consolidated debt levels, subject to certain conditions and limitations in the indentures related to the 2025 Notes and the Loan and Security Agreement, we may be able to incur substantial additional debt in the future, some of which may be secured debt. We may not be subject to any restrictions on incurrence of additional indebtedness under the terms of any future indebtedness. If new debt is added to our current debt levels, the related risks that we and they now face could intensify.

Our business may be exposed to foreign exchange risks.

We incur some of our expenses and derive revenues from the Eversense system in currencies other than the U.S. dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. Therefore, for example, an increase in the value of the U.S. dollar against the euro or the British pound could have a negative impact on our revenue and earnings growth as euro and British pound revenue and earnings, if any, are translated into U.S. dollars at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

There is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our management concluded that our recurring losses from operations, existing unrestricted cash, cash equivalents and marketable securities, anticipated debt repayments, and minimum cash and satisfaction of performance milestones to comply with debt covenants under its Loan and Security Agreement raise substantial doubt about our ability to continue as a going concern for the next twelve months after issuance of our financial statements. As of December 31, 2024, the Company had unrestricted cash, cash equivalents and marketable securities of $74.6 million consisting of cash and investments in highly liquid U.S. money market funds. On October 28, 2024, we raised additional proceeds of approximately $14.8 million before expenses incurred by the Company in a registered direct offering of the Company's common stock and concurrent private placement of warrants to purchase shares of the Company's common stock. We do not expect our existing cash and cash equivalents will be sufficient to fund our operations through the next twelve months and we will need to seek additional capital to fund our operations, working capital needs, capital expenditures and other strategic initiatives beyond that time. There can be no assurance that we will be successful in raising additional capital or that any needed financing will be available in the future at terms acceptable to us. As such, we cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements are issued and there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, and substantial doubt exists about our ability to continue as a going concern. If we are unable to generate to secure additional capital on acceptable terms or at all, we may be required to significantly reduce or cease our operations, which could result in the loss to investors of their investment in our securities.

Risks Related to Development of our Products

If we modify our approved product or CE marked, we may need to seek additional approvals or CE Certificates of Conformity, which, if not granted, would prevent us from selling our modified products.

A component of our strategy is to continue to modify and upgrade our Eversense system, which requires approval or certification by the FDA and analogous regulatory bodies in other jurisdictions. We may not be able to obtain additional regulatory approvals or certifications for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future approvals or certification, including potential delays in obtaining approval of our currently pending applications, would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability.

Any modifications to the Eversense that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires approval of a new PMA, or PMA supplement or similar modifications in other jurisdictions. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement, or appropriate modifications in other jurisdictions, and may only require notice to FDA in a PMA Annual Report, or similar notifications in other jurisdictions. In the U.S., the FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any such decision. The FDA may not agree with our decisions regarding whether new approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Similar regulatory considerations apply outside the U.S. If new regulatory approvals or certifications are required, this could delay or preclude our ability to market the modified system.

For those medical devices sold in the EEA, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining variation of existing CE Certificates of Conformity or a new Certificate can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Medical device development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, ongoing development for lifecycle management of our products.

While we have completed pivotal trials in Europe and the United States, we are and may need to conduct future clinical trials in order to develop new versions of our system or to comply with requirements for post-approval studies. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further, the outcomes of our earlier clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their products performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval or certification.

If we are unable to successfully complete clinical trials of Eversense or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- not obtain marketing approval or certification for such modifications;
- be delayed in obtaining marketing approval or certification for such modifications;
- be subject to additional post-marketing testing requirements; or
- have Eversense removed from the market after obtaining marketing approval.

Our development costs will also increase if we experience delays in testing, marketing approvals, or certification. Significant clinical trial delays also could allow our competitors to bring innovative products to market before we do and impair our ability to successfully commercialize our products.

Risks Related to Employee Matters and Managing our Growth

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Tim Goodnow, our Chief Executive Officer, Rick Sullivan, our Chief Financial Officer, Mukul Jain, our Chief Operating Officer, and Ken Horton, our General Counsel and Corporate Development Advisor, as well as the other members of our scientific and clinical teams. Although we have employment agreements with our executive officers, each of them may terminate their employment with us at any time and will continue to be able to do so. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, as we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous medical device companies for similar personnel, many of which have greater financial and other resources dedicated to attracting and retaining personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Although it will be subject to restrictions on trading, a portion of the equity of our management team will not contain other contractual transfer restrictions. This liquidity may represent material wealth to such individuals and impact retention and focus of existing key members of management.

We may need to expand our development and regulatory capabilities and our marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2024, we had 117 full-time employees. As our commercialization progresses, we may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, product development, clinical sciences, regulatory affairs, supply chain, and marketing. To manage our future growth, 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. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Additionally, we have and may undertake cost reduction plans, which may include reorganization of our workforce. These actions could disrupt the employee base, our ability to attract and retain qualified personnel, or cause other operational and administrative inefficiencies.

Our employees, independent contractors, consultants, manufacturers and distributors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, manufacturers and distributors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity 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. 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 civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement of profits, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the design, manufacture, testing and sale of medical devices. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition, injury or death to customers. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain customers, any of which could harm our business, financial condition and operating results.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial deductibles for which we are responsible. Product liability claims in excess of applicable insurance coverage would negatively impact our business, financial condition and operating results. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance premiums. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

Risks Related to our Intellectual Property

Our ability to protect our intellectual property and proprietary technology is uncertain.

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of December 31, 2024, we held a total of approximately 482 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 111 issued United States patents, 194 patents issued in countries outside the United States, and 177 pending patent applications worldwide. Our patents expire between 2025 and 2043, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to

expire on dates ranging from 2033 to 2044, subject to any patent term extensions or adjustments that may be available for such patents. We are also seeking patent protection for our proprietary technology in Europe, Japan, China, Canada, India, Australia and other countries and regions throughout the world. We have 14 U.S. trademark registrations and 133 foreign trademark registrations, as well as one pending foreign trademark application.

We have applied for patent protection relating to certain existing and proposed products and processes. Currently, several of our issued U.S. and foreign patents as well as various pending U.S. and foreign patent applications relate to the structure and operation of our CGM sensor and CGM systems, which are important to the functionality of our products. If we fail to timely file a patent application in any jurisdiction, we may be precluded from doing so at a later date. Furthermore, we cannot assure you that any of our patent applications will be approved in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not provide us with any meaningful commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Even if we are successful in receiving patent protection for certain products and processes, our competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors and have registered or applied to register many of these trademarks. For example, we have one pending foreign application for the "Eversense Now" trademark relating to our mobile application. We cannot assure you that our trademark applications will be approved in a timely manner or at all. Third parties also may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We also rely on trade secrets, know-how and technology, which are not protectable by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not have an adequate remedy to compensate us for our trade secrets or other proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in the related or resulting know-how and inventions. If any of our trade secrets, know-how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business, financial condition and results of operations could be materially adversely affected.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may 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 material. The occurrence of any of these events may harm our business, financial condition and operating results.

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 applications will be due to be paid to the United States Patent and Trademark Office ("USPTO") the European Patent Office ("EPO"), and other foreign patent agencies over the lifetime of our owned patents and applications. The USPTO, the EPO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaboration partners fail to maintain the patents and patent applications covering our proprietary technologies, our competitors might be able to enter the market earlier with similar products or technology, which would have an adverse effect on our business.

The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, stop our development and commercialization measures, harm our reputation or require us to pay damages.

Our success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

The medical device industry in general, and the glucose testing sector of this industry in particular, are characterized by the existence of a large number of patents and frequent litigation based on assertions of patent infringement. We are aware of numerous patents issued to third parties that may relate to the technology used in our business, including the design and manufacture of CGM sensors and CGM systems, as well as methods for continuous glucose monitoring. Each of these patents contains multiple claims, any one of which may be independently asserted against us. The owners of these patents may assert that the manufacture, use, sale or offer for sale of our CGM sensors or CGM systems infringes one or more claims of their patents. For example, as noted in Item 3: Legal Proceedings, in May 2024, we were served with a complaint by Cellspin Soft, Inc., a non-practicing entity, filed against us in the United States District Court for the Eastern District of Texas, alleging that we infringe on certain patents owned by it and seeking unspecified damages. We note that the validity of all three patents-in-suit is currently being challenged in Inter Partes Review proceedings at the U.S. Patent and Trademark Office, where the Patent Trial and Appeal Board instituted a review which the Company has joined. On February 5, 2025, the court issued an order staying the complaint pending resolution of the Inter Partes Review. We are further reviewing the allegations, and intend to vigorously defend this matter, however, the outcome of any litigation, such as this, is inherently unpredictable.

Furthermore, there may be additional patents issued to third parties of which we are presently unaware that may relate to aspects of our technology that such third parties could assert against us and materially and adversely affect our business. In addition, because patent applications can take many years to issue, there may be patent applications that are currently pending and unknown to us, which may later result in issued patents that third parties could assert against us and harm our business.

In preparation for commercializing our Eversense products, we are performing an analysis, the purpose of which is to review and assess publicly available information to determine whether third parties hold any valid patent rights that a well-informed court would more likely than not find that we would infringe by commercializing our products, understanding that there are risks and uncertainties associated with any litigation and no predictions or

assurances can be made regarding the outcome of any such litigation. Although our review and analysis are not complete and subject to the express limitations in the preceding sentence, we are not aware of any such valid patent rights. Moreover, we have not previously performed an exhaustive review of this type, and we cannot be certain that it will not result in our locating patent rights relating to our products of which we were not previously aware.

In the future, we could receive communications from various industry participants alleging our infringement of their intellectual property rights. Any potential intellectual property litigation could force us to do one or more of the following:

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;
- redesign those products that contain the allegedly infringing intellectual property; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, and if available, may be non-exclusive, thereby giving our competitors access to the same technology.

Patent litigation can involve complex factual and legal questions, and its outcome is uncertain. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, stop our development and commercialization measures and harm our reputation. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us increases.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including those that are our direct competitors or could potentially be our direct competitors. In some cases, those employees joined our company recently. We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we successfully defend against these claims, litigation could cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There can be no assurance that this type of litigation will not occur, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize Eversense or future versions of Eversense, which could have an adverse effect on our business, financial condition and operating results.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, inventorship disputes may arise from conflicting obligations of employees, consultants or others who are involved in developing our medical devices or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. 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, intellectual property that is important to our medical devices and other technologies. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to the patent laws of countries other than the United States, which may not offer the same level of patent protection and whose rules could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.

Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection which makes it difficult to stop infringement.

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent protection. For example, we may elect not to seek patent protection in some jurisdictions in order to save costs. We may be forced to abandon specific patents due to a lack of financial resources.

Our intellectual property rights do not necessarily address all potential competitive threats or confer meaningful competitive benefits.

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 any competitive advantage. The following examples are illustrative:

- others may be able to make devices that are the same as or similar to Eversense but that are not covered by the claims of the patents that we own;
- we or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own and, therefore, we may be unable to enforce them;
- we 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 may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as 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; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to our Legal and Regulatory Environment

Our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies in the United States, foreign regulatory authorities and the Notified Bodies in the EEA. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. These governmental authorities enforce laws and regulations that are meant to assure product safety and effectiveness, including the regulation of, among other things:

- product design and development;

- preclinical studies and clinical trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance, certification or approval;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated revenues. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the regulatory agency or other regulators or Notified Bodies to grant future clearances, CE Certificates of Conformity or approvals, and the suspension, variation or withdrawal of existing approvals or CE Certificates of Conformity by such regulatory bodies. For example, in September 2019 we voluntarily initiated a recall of Eversense sensors that had not yet been implanted, due to premature loss of function due to inadequate hydration of the sensor's glucose-sensing surface. This recall, as well as any of the above sanctions, could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and operating results.

The FDA regulatory clearance process and regulatory processes in other countries are expensive, time-consuming and uncertain, and the failure to obtain and maintain required regulatory clearances, certification and approvals could prevent us from commercializing Eversense and future versions of Eversense.

Products that are approved through a PMA application generally need FDA approval before they can be modified, and similar approval or certification processes are required in other jurisdictions where we may want to market our products. The process of obtaining regulatory approvals or certifications to market a medical device can be costly and time-consuming, and we may not be able to obtain these approvals or certifications on a timely basis, or at all for our products.

If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our expectations.

The FDA or comparable foreign regulatory authorities and Notified Bodies can delay, limit or deny approval or certification of a device for many reasons, including:

- we may not be able to demonstrate that our products are safe and effective for their intended users;
- the data from our clinical trials may be insufficient to support approval or certification; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA or comparable foreign regulatory authorities may change approval or certification policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or certification of our product modifications under development.

Any delay in, or failure to receive or maintain, approval or certifications for our products could prevent us from generating revenue from these products or achieving profitability.

If we or our third-party suppliers fail to comply with the FDA's or other foreign regulatory authorities' good manufacturing practice regulations, this could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party suppliers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. We are subject to equivalent limitations and penalties in foreign countries. Any of the foregoing actions could impair our reputation, business, financial condition and operating results.

A recall of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Our third-party suppliers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our third-party distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. For example, in September 2019 we voluntarily initiated a recall of Eversense sensors that had not yet been implanted, due to premature loss of function due to inadequate hydration of the sensor’s glucose-sensing surface. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner.

Further, 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, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EEA. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements 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, variation or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption and anti-money-laundering laws in foreign jurisdictions, as well as export control laws, customs laws, sanctions laws and other laws governing our future global operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our current and future global operations will expose us to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and

criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the Foreign Corrupt Practices Act ("FCPA") and other federal statutes and regulations, including those established by the Office of Foreign Assets Control ("OFAC"). In addition, the U.K. Bribery Act of 2010 ("Bribery Act") prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money-laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations could adversely impact our business, results of operations and financial condition.

We will implement and maintain policies and procedures designed to ensure compliance by us, and our directors, officers, employees, representatives, third-party distributors, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anticorruption, anti-money-laundering and anti-terrorism laws and regulations, including in foreign jurisdictions. We cannot assure you, however, that our policies and procedures will be sufficient or that directors, officers, employees, representatives, third-party distributors, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money-laundering and anti-terrorism laws or regulations, including in foreign jurisdictions, may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

We are subject to additional federal, state and foreign laws and regulations relating to our healthcare business; our failure to comply with those laws could have an adverse impact on our business.

We are subject to broadly applicable federal, state, and foreign healthcare laws, including health care fraud and abuse and health information privacy and security laws, which could adversely impact our business. Such healthcare laws applicable to our operations include:

- the federal Anti-Kickback Statute, which will apply to our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs. 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;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which is enforceable through civil whistleblower or qui tam actions, prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. 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 false claims statutes;
- HIPAA, and its implementing regulations, which created federal criminal and civil statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their implementing regulations, which also imposes obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health

information for or on behalf of a covered entity and their subcontractors, regarding the privacy, security and transmission of such individually identifiable health information;

- federal "sunshine" requirements imposed by the PPACA, on device manufacturers regarding the annual reporting to CMS, of any "transfer of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners, and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Failure to timely submit required information may result in significant civil monetary penalties;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state fee-splitting laws, and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA;
- state corporate practice of medicine laws, which prohibit business entities from practicing medicine, employing physicians to practice medicine, or exercising control over medical decisions of physicians. In addition, any physician who participates in an arrangement that violates a state's corporate practice of medicine prohibition may be punished for aiding and abetting a lay entity in the unlawful practice of medicine; and
- equivalent foreign legislation and requirements including in relation to interactions between medical devices companies and healthcare professionals, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment

The risk of our being found in violation of these laws and regulations is increased by the fact that the scope and enforcement of these laws is uncertain, many of them have not been fully interpreted by the regulatory authorities or the courts, their provisions are open to a variety of interpretations, or they vary country by country. We are unable to predict what additional federal, state or foreign legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal, state or foreign governments may (i) impose additional restrictions or adopt interpretations of existing laws that could have a material adverse effect on us or (ii) challenge our current or future activities under these laws. Any of these challenges could impact our reputation, business, financial condition and operating results.

Our activities, including our research, sales and marketing, and patient reimbursement support activities, and relationships with Eon Care PCs, may be subject to scrutiny under these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including significant civil, criminal, and administrative penalties, damages, fines, disgorgement of profits, imprisonment, exclusion from governmental health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any federal, state or foreign regulatory review to which we may become subject, regardless of the outcome, would be costly and time-consuming. In addition, if our affiliated physicians are found to have violated these laws, they could also be subject to significant fines and other sanctions through professional licensure proceedings.

For example, to enforce compliance with the federal laws, the U.S. Department of Justice has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management's attention from our core business. Additionally, if we settle an investigation with law enforcement or other regulatory agencies, we may be forced to agree to additional onerous

compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

We 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 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, and sensitive third-party data. 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).

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.

The collection and use of personal health data in the EEA and the UK is governed by the EU and UK GDPR (collectively, GDPR). The GDPR applies to the processing of personal data by any company established in the EEA or UK and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA or UK. 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 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. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as processors. The Swiss Federal Act on Data Protection, or the FADP, also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA and UK to countries that do not ensure an adequate level of protection, like the United States. In the ordinary course of business, we transfer personal data from the EEA and UK or 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 EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK or other jurisdictions to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer

personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA or 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 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. Other jurisdictions have adopted and may adopt stringent data localization and cross-border data transfer laws.

In addition to data privacy and security laws, we are contractually subject to certain industry standards adopted by industry groups and, we are, and may become subject in the future, to additional such obligations. 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. 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 publish privacy policies, whitepapers and other statements concerning data privacy and security. Regulations in the United States are increasingly scrutinizing these statements, and if these policies 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.

Our employees and personnel use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot providers. These practices are subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

Obligations related to data privacy and security (and consumers' 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 has in the past and may in the future necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

If we or our parties on which we rely fail to comply or are alleged to have failed to comply with applicable data privacy 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 on processing personal data; orders to destroy or not use personal data 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 associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance

costs, delays or impediments in the development of new products, inability to process personal data or to operate in certain jurisdictions; negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

Moreover, governments and regulators in certain jurisdictions, including Europe, are increasingly seeking to regulate the use, transfer and other processing of non-personal information (for example, under the European Union's Data Act). This means that, if and to the extent such regulations are relevant to our operations or those of our customers, certain of the above risks and considerations may apply equally to our processing of both personal and non-personal information.

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 proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property and trade secrets (collectively, 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 upon which we rely. 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. We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, 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, 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.

Because of our hybrid work policies, sensitive information that is normally protected may be less secure 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 and technologies to operate critical business systems to process sensitive information in a variety of contexts. 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 upon whom we rely on experience a security incident or other interruption, as they have in the past, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers 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 our third-party partners' supply chains 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. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of phishing attempts in the past, and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products and services.

We may expend significant resources or modify our business activities to try to protect against security incidents, and have in the past. Certain data privacy and security obligations have required us to implement and maintain specific security measures to protect our information technology systems and sensitive information.

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

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

We may be liable if the FDA, competent authorities of the EEA countries, or another regulatory agency concludes that we have engaged in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Healthcare providers may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA, competent authorities of the EEA countries, or other foreign regulatory authorities determine that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or competent authorities of the EEA countries, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although we intend to train our marketing and direct sales force to not promote our

products for uses outside of their cleared uses and our policy will be to refrain from statements that could be considered off-label promotion of our products, the FDA competent authorities of the EEA countries, or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals or certifications and comply with extensive safety and quality regulations in other countries.

The advertising and promotion of our products in the EEA is subject to EEA countries' national laws implementing the AIMD and applying the Medical Device Regulation, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EEA countries governing the advertising and promotion of medical devices. EEA countries' legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals, which could negatively impact our business, operating results and financial condition.

Off-label use of our product by patients could lead to product liability claims and regulatory action.

Eversense is currently labeled as non-adjunctive; however, once weekly fingerstick calibrations are still required. We have no control over whether patients adhere to labeling instructions and confirm blood glucose levels to ensure calibration with Eversense. If a patient fails to do so and has an adverse reaction to self-medication, the patient might make a claim against us. While we do not believe that, as a general matter, such a claim would have merit, the possibility of an adverse result to the manufacturer cannot be dismissed, and in any event, we could incur significant defense costs. Also, if there should be widespread off-label use of our system by patients, and resulting adverse medical events, the FDA, competent authorities of the EEA countries or other foreign regulatory bodies might require us to implement additional measures to reduce off-label use, which could be costly or reduce adoption of Eversense.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance, certification or approval of our products.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

On a global level, the regulatory environment is increasingly stringent and unpredictable. Many countries have introduced or expanded their existing regulation of medical devices or are planning to expand their existing regulation in the future. Regulatory requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact the cost, the time needed to approve, and ultimately, our ability to maintain existing approvals or certifications or obtain future approvals or certifications for our products. For example, in the EU, on May 26, 2021, the EU Medical Device Regulation entered into application repealing and replacing both Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC concerning active implantable medical devices. We affixed the CE mark to the original 90-day Eversense CGM system in June 2016, which marked the first certification for the product to be sold within the European Economic Area (EEA). Subsequently, we affixed the CE mark to the extended life Eversense XL CGM system in September 2017 which was sold in select markets in Europe and the Middle East. The changes to the regulatory system implemented in the EU by the Medical Device Regulation include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to

indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well as a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the Medical Device Regulation may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the Medical Device Regulation.

In addition, the exit of the UK from the EU, commonly referred to as "Brexit" could lead to regulatory divergence between the EU and the UK. On May 26, 2021, the MDR entered into application in the EU. However, the MDR is not applicable in Great Britain (i.e. England, Wales and Scotland) but does apply in Northern Ireland. In Great Britain, medical devices are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, for the time being, retains a regulatory framework similar to the framework set out by the MDD. The UK's regulator, the Medicines & Healthcare products Regulatory Agency plans on introducing new legislation governing medical devices with an aim to bring the new regulations into force during 2025 ("MHRA") has published a road-map to new regulations for medical devices. The first of the regulations, which strengthen post-market surveillance requirements, is scheduled to come into force on June 17, 2025. Further updated regulations are scheduled to follow in 2025 and 2026. Should the UK or Great Britain further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the UK.

Regulations of the FDA and other regulatory agencies, including third country authorities and Notified Bodies, in and outside the U.S. impose extensive compliance and monitoring obligations on our business. These agencies review our design and manufacturing practices, labeling, record keeping, manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We are subject to unannounced device inspections by Notified Bodies, as well as other regulatory authorities overseeing the implementation and adherence of applicable regulations. These inspections may include our suppliers' facilities. In addition, the competent authorities of individual EEA countries have powers to suspend the marketing and use, or demand the recall, of unsafe or non-compliant devices. They also have the power to bring enforcement action against companies or individuals for breaches of the device rules. Non-compliance may also result in Notified Bodies revoking, suspending or varying any CE Certificate of Conformity that they have issued for a device or the manufacturer's quality system.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our products would harm our business, financial condition and operating results.

While a goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. For example, the PPACA was enacted in March 2010. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industries.

There have been executive, judicial and Congressional challenges and amendments to certain aspects of the PPACA. For example, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the

PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the second Trump administration will impact the PPACA and our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they, or the PPACA, may have on our business and operations, and any of these impacts may be adverse on our operating results and financial condition.

Risks Related to our Common Stock

Because our stock price has and will likely continue to be highly volatile, the market price of our common stock may be lower or more volatile than expected.

Our stock price has been highly volatile. The stock market in general and the market for innovative, emerging medtech and biotechnology companies in particular have experienced volatility that has often been unrelated to the operating performance of particular companies. From January 1, 2023 through February 14, 2025, the trading price of our common stock has been as low as $0.25 per share and as high as $1.31 per share. This stock price volatility has been accompanied by significant variability in trading volume of our common stock in comparison to historical experience.

The volatility in our trading volumes has not necessarily correlated to the company's announcement of material developments and often appears unrelated to changes in actual or expected operating performance. Purchases or sales of large quantities of our stock, including the establishment and/or closing of significant short positions in our stock could have an unusual or adverse effect on our market price. Market fluctuations may also cause short sellers to periodically enter the market in the belief that we will have poor results in the future. Abnormal trading activity, including activity that is considered market manipulation, can lead to irrational and/or temporary movements in the price of our common stock, which, in turn, may increase its risk and volatility. We cannot predict the actions of market participants and, therefore, can offer no assurances that the market for our common stock will be stable or appreciate over time.

The market price of our common stock may also be influenced by many additional factors, including:

- analyst coverage, recommendations or changes in their estimates of our financial performance;
- future announcements about us or our competitors, including the results of technological innovations or new commercial products;
- announcement of operating results and other factors relating to the commercialization of our products;
- clinical trial and topline data results;
- depletion of our cash reserves;
- sale of equity securities or issuance of additional debt;
- announcement by us of significant strategic partnerships, capital commitments or acquisitions;
- changes in government regulations;
- impact of competitor successes;
- developments in our relationships with our collaboration partners;
- global market or financial developments;
- announcements relating to health care reform, legislation and reimbursement levels, including third-party payor coverage decisions;
- sales of substantial amounts of our stock by existing stockholders (including stock by insiders or 5% stockholders);

- regulatory approvals, certifications, timelines or other actions;
- litigation;
- public concern as to the safety of our products or recalls;
- the make-up of our shareholder base; and
- the other factors described in this Risk Factors section.

The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plans, or otherwise will dilute our existing stockholders.

Our certificate of incorporation authorizes us to issue up to 1,400,000,000 shares of common stock and up to 5,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock, including securities convertible into common stock, in connection with a financing, acquisition, investment, our equity incentive plans or otherwise. This includes the issuance, from time to time, of non-statutory stock options exercisable for shares of our common stock and/or restricted stock units that may be settled in shares of our common stock pursuant to the Senseonics Holdings, Inc. 2023 Commercial Equity Plan. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

PHC may have the ability exert substantial influence over us in a manner adverse to your interests.

Subject to maintaining specified ownership thresholds, PHC continues to hold the right to designate up to two individuals to serve on our board of directors as outlined in their Investor Rights Agreement.

As a result, PHC may be able to significantly influence our decisions, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. PHC may have interests different from the interests of the other holders of our common stock.

If our estimates relating to our critical accounting policies are based on assumptions or judgments that change or prove to be incorrect, our operating results could fall below expectations of financial analysts and investors, resulting in a decline in our stock price.

The preparation of financial statements in conformity with U.S. GAAP requires our management to make estimates, assumptions and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of financial analysts and investors, resulting in a decline in our stock price. Significant assumptions and estimates used in preparing our consolidated financial statements include those related to revenue recognition and variable consideration, reserves for inventory obsolescence and warranties, stock-based compensation, embedded features of our senior convertible notes and income taxes.

We do not intend to pay cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to our debt agreements, we are precluded from paying any cash dividends. Accordingly, you may have to sell some or all of your shares of our common stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by some or all of our stockholders. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors is elected each year;
- stockholders are not entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders are not permitted to call a special meeting of stockholders; and
- stockholders are required to give advance notice of their intention to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

(1) any derivative action or proceeding brought on our behalf;
(2) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;
(3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or
(4) any action asserting a claim governed by the internal affairs doctrine. However, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act.

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive 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, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other

companies' charter documents has been challenged in legal proceedings. 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, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially adversely affect our business.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations of the NYSE American. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting and perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting that exists at the reporting date, we will be unable to assert that our internal control over financial reporting is effective. We have no material weaknesses in our internal control over financial reporting at December 31, 2024. While we have established certain procedures and controls over our financial reporting processes, we cannot assure you that these efforts will prevent future material weaknesses or restatements of our financial statements. For future reporting periods, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. We may not be able to remediate any future material weaknesses, or to complete our evaluation, testing and any required remediation in a timely fashion.

Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NYSE American, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation for U.S. Federal and numerous U.S. states. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such jurisdictions. Nevertheless, our effective income tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal or state income tax laws, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

We may be unable to utilize our tax attribute carryforwards to reduce our income taxes.

At December 31, 2024, we had gross federal and state net operating loss ("NOL") carryforwards of $703.3 million and $89.7 million, respectively and research and experimental credit carryforwards of $17.1 million. Federal NOL carryforwards in the amount of $193.3 million will expire in varying amounts between 2025 and 2037 and tax credits of $17.1 million will expire in varying amounts between 2025 and 2044. These net operating loss carryforwards and credits could expire unused and be unavailable to offset future income tax liabilities. Federal NOL carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but limited to offset 80% of our taxable income annually. State NOLs have various expiration dates beginning in 2032. Under Section 382/383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which generally occurs if the percentage of the corporation's stock owned by 5% stockholders increases by more than 50% over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382/383 ownership changes and if a portion of our NOL and tax credit carryforwards are subject to an annual limitation under Section 382/383. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOL and tax credit carryforwards is significantly limited, it would harm our future operating results by effectively increasing our future tax obligations.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. For instance, the Inflation Reduction Act ("IRA") imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. The Tax Cuts and Jobs Act of 2017 ("TCJA"), as modified by the Coronavirus Aid, Relief, and Economic Security ("CARES") Act significantly reformed existing tax laws. The IRA, TCJA, or any future tax reform legislation could have a material impact on the value of our deferred tax assets, result in significant one-time charges, and increase our future tax expenses.

Our bank deposits in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance limits could be impacted if the underlying financial institutions fail.

Our cash and cash equivalents are held in accounts at US Bank Corp, JPMorgan Chase Bank, Truist Bank, and Silicon Valley Bank and consist of cash in our operating accounts and cash invested in money market funds. At any point in time, the funds in our operating accounts may exceed the FDIC insurance limits. While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail. To date, we have not experienced significant losses or lack of access to cash in our operating accounts or our invested cash or cash equivalents; however, we can provide no assurances that access to our operating cash or invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets.

Item 1B. Unresolved Staff Comments

None.

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, and confidential information that is proprietary, strategic or competitive in nature (collectively, "Information Systems and Data").

Our information security function is led by our head of IT and supported by our executive team (specifically, our CEO, COO, and CFO), our engineering department, and third-party service providers, and helps identify, assess and manage the Company's cybersecurity threats and risks. This group identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example: manual and automated tools, conducting scans of the threat environment, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors and evaluating threats reported to us, external audits, third party testing and vulnerability assessments, and tabletop incident response exercises.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response processes; disaster recovery plan; encryption of certain data; network security controls; segregation of certain data; access and physical security controls; asset management; tracking and disposal; systems monitoring; a vendor risk management program; employee training; penetration testing by third parties; and maintaining cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our executive team evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, 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 for example professional services firms, managed cybersecurity services providers, penetration testing firms, dark web monitoring services and cybersecurity software providers.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract manufacturers and distributors. We have vendor management processes designed to manage cybersecurity risks associated with our use of certain of these providers. The processes in place include a risk assessment for certain vendors and the imposition of certain contractual obligations related to cybersecurity on certain providers. 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 processes involve different levels of assessment designed to help identify cybersecurity risks associated with these providers.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including the risk factor entitled "If our information technology systems or those third parties with whom we work, for 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."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing the Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our executive team and head of IT who has over twenty-five years of IT management experience.

Management is responsible for hiring appropriate personnel and the head of IT is responsible for communicating key priorities to relevant personnel. The executive team works with the head of IT to help prepare for

cybersecurity incidents, approve cybersecurity processes, and review security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the executive team, legal and others. The executive team works with the head of IT and the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives regular reports from the IT function concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties

Our principal offices occupy approximately 33,000 square feet of research and office space for our corporate headquarters in Germantown, Maryland pursuant to a lease that expires in 2033. We believe that our current facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

From time to time, we are subject to litigation and claims arising in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties.

In February 2021, the Company received notice and accepted service of a civil complaint that had been filed in the Western District of Texas and styled Carew ex rel. United States v. Senseonics, Inc., No. SA20CA0657DAE. The complaint was filed by a relator under seal in May 2020 pursuant to the qui tam provisions in the federal False Claims Act. Prior to the unsealing of the complaint, the government declined to intervene in the case. The case, therefore, is being pursued only by the relator and his counsel. The complaint alleges the Company's marketing practices with physicians for its product, Eversense CGM system, violated the False Claims Act, 31 U.S.C. § 3729 and the Texas Medicaid Fraud Prevention Law, Tex. Hum Res. Code § 36.002. The court granted the Company's motion to dismiss the complaint on March 31, 2022 but permitted the plaintiff to file an amended complaint. The court dismissed the amended complaint and entered judgment in favor of Senseonics Holdings, Inc. on March 30, 2023. The relator filed a notice of appeal to the United States Court of Appeals for the Fifth Circuit on April 28, 2023. The appeal was fully briefed and the case was argued before the Fifth Circuit on February 6, 2024. On February 28, 2024 the Fifth Circuit issued a Per Curiam order affirming the District Court's decision that Carew failed to state a claim. This order affirms the District Court's dismissal of plaintiff's lawsuit.

In May 2024, the Company received notice and accepted service of a civil complaint that had been filed in the Eastern District of Texas and styled Cellspin Soft, Inc. vs. Senseonics Holdings, Inc., and Ascensia Diabetes Care Holdings AG Case No. 2:24-cv 263. The case was filed by a non-practicing entity alleging patent infringement of three patents. The validity of all three of these patents currently is being challenged in Inter Partes Review proceedings at the U.S. Patent and Trademark Office by another party, and on September 30, 2024, the Patent Trial and Appeal Board instituted a review with respect to each of the asserted claims in these three patents. Together with LifeScan and Ascensia, on October 30, 2024, we filed a joint motion to join the Inter Partes Review as well as similar Inter Partes Review challenges to these patents. On February 5, 2025, the court issued an order staying the proceedings in the Eastern District of Texas pending resolution of the Inter Partes Review. Should any asserted claim in the three patents survive the invalidity challenge in the Inter Partes Review proceedings, the Company intends to vigorously defend the lawsuit.

Except as described above, we are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

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 for Common Stock

Our common stock is listed on the NYSE American under the symbol "SENS."

Dividend Policy

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our ability to pay dividends on shares of our common stock is further limited by restrictions on our ability to pay dividends or make distributions under the terms of the agreements governing our indebtedness and may be limited by future similar agreements.

Stockholders

As of February 24, 2025, we had approximately 156 active holders of record of our common stock. The number of beneficial owners of our Common Stock is substantially greater than the number of record holders because a large portion of our Common Stock is held of record in broker "street names" for the benefit of individual investors.

Recent Sales of Unregistered Securities

None.

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 consolidated financial statements and related notes in Part II, Item 8 of this 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 plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a medical technology company focused on the development and manufacturing of glucose monitoring products designed to transform lives in the global diabetes community with differentiated, long-term implantable glucose

management technology. Our implantable CGM ("Eversense"), including Eversense E3 and Eversense 365 CGM systems are designed to continually and accurately measure glucose levels in people with diabetes via an under-the-skin sensor, a removable and rechargeable smart transmitter, and a convenient app for real-time diabetes monitoring and management for a period of up to six months in the case of Eversense E3 and up to twelve months in the case of Eversense 365, as compared to seven to 14 days for non-implantable CGM systems. In February 2022, the 180-day Eversense E3 CGM system was approved by the FDA and Ascensia began commercializing Eversense E3 in the United States in the second quarter of 2022. In June 2022, we affixed the CE mark to the Eversense E3 CGM system and Ascensia began commercialization in select markets in Europe during the third quarter of 2022. In September 2024, the 365-day extended life Eversense E3 CGM system was approved by the FDA and Ascensia began commercializing Eversense 365 in the United States in the fourth quarter of 2024.

Our net revenues are derived from sales of the Eversense CGM system which includes the Eversense Sensor Pack containing the sensor, insertion tool, and adhesive patches, the Eversense Smart Transmitter Pack containing the transmitter and charger and in some cases the procedure revenue associated with insertions and removals.

We primarily sell directly to our network of distributors, strategic fulfillment partners, who provide the Eversense system to healthcare providers and patients through a prescribed request and invoice insurance payors for reimbursement. In addition, we sell our product through a consignment model through arrangements with our network of healthcare professionals. Sales of the Eversense system are widely dependent on the ability of patients to obtain coverage and adequate reimbursement from third-party payors or government agencies. We leverage and target regions where we have coverage decisions for patient device use and provider insertion and removal procedure payment. We have reached approximately 300 million covered lives in the United States through positive insurance payor coverage decisions. In June 2023, we received positive payor coverage decision from UnitedHealthcare, the largest healthcare insurance company in the United States that effective July 1, 2023, Eversense E3 CGM system would be covered. On August 3, 2020, the Center for Medicare and Medicaid Services ("CMS") released its Calendar Year 2021 Medicare Physician Fee Schedule Proposed Rule that announces proposed policy changes for Medicare payments, including the proposed establishment of national payment amounts for the three CPT© Category III codes describing the insertion (CPT 0446T), removal (0447T), and removal and insertion (0048T) of an implantable interstitial glucose sensor, which describes our Eversense CGM systems, as a medical benefit, rather than as part of the Durable Medical Equipment channel that includes other CGMs. In December 2021, CMS released its Calendar Year 2022 Medicare Physician Fee Schedule that updated global payments for the device cost and procedure fees. In November 2022, CMS released its Calendar Year 2023 Medicare Physician Fee Schedule Proposed Rule that updates the payment amounts for the three CPT© III codes to account for the longer 6-month sensor. In February 2024, we announced that Medicare coverage was expanded for Eversense E3 to include all people with diabetes using insulin and non-insulin users who have a history of problematic hypoglycemia providing access to millions of Medicare patients. All of the Medicare administrative contractors ("MAC") expansions became effective in 2024. CMS provided G-codes to enable immediate access to Eversense 365 for all eligible Medicare beneficiaries. We have been working with payors to transition their policies to Eversense 365 and have confirmed immediate coverage policy transition from select payors.

We are in the early commercialization stages of the Eversense brand and are focused on driving awareness of our CGM system amongst people with diabetes and their healthcare providers. In both the United States and our overseas markets, we have entered into strategic partnerships and distribution agreements that allow third party collaborators with direct sales forces and established distribution systems to market and promote Senseonics CGM systems, including 90-day Eversense, Eversense XL, Eversense E3, Eversense 365 and future generation products. Our future generation products in development are our "Gemini" product variation to allow for a 2-in-1 glucose monitoring system combining the functionality of CGM and Flash Glucose Monitoring, in an implantable sensor with battery that may be utilized with a smart transmitter to get continuous glucose readings and alerts, or be utilized through a swipe over the sensor with a smart phone to get on-demand glucose reading without a smart transmitter and our "Freedom" product variation which would include Bluetooth in the sensor eliminating the on-body component.

United States Development and Commercialization of Eversense

In 2016, we completed our PRECISE II pivotal clinical trial in the United States. This trial, which was fully enrolled with 90 subjects, was conducted at eight sites in the United States. In the trial, we measured the accuracy of Eversense measurements through 90 days after insertion. We also assessed safety through 90 days after insertion or through sensor removal. In the trial, we observed a mean absolute relative difference ("MARD") of 8.5% utilizing two calibration points for Eversense across the 40-400 mg/dL range when compared to YSI blood reference values during the 90-day continuous wear period. Based on the data from this trial, in October 2016 we submitted a pre-market approval ("PMA") application to the FDA to market Eversense in the United States for 90-day use. On June 21, 2018, we received PMA approval from the FDA for the Eversense system. In July 2018, we began distributing the 90-day Eversense system directly in the United States through our own direct sales and marketing organization. We have received Category III CPT codes for the insertion and removal of the Eversense sensor.

In December 2018, we initiated the PROMISE pivotal clinical trial to evaluate the safety and accuracy of Eversense for a period of up to six months in the United States and in September 30, 2019, we completed enrollment of the PROMISE trial. In the trial, we observed performance matching that of the then current Eversense 90-day product available in the United States, with a MARD of 8.5%. This result was achieved with reduced calibration, down to one per day, while also doubling the sensor life to six months. Following the results of the PROMISE trial, on September 30, 2020, a PMA supplement application to extend the wearable life of the Eversense CGM System to six months was submitted to the FDA. In February 2022, the Eversense E3 CGM system was approved by the FDA.

In June 2019, we received FDA approval for the non-adjunctive indication (dosing claim) for the Eversense system and launched with an updated app in December 2019. With this approval, the Eversense system can be used as a therapeutic CGM to replace fingerstick blood glucose measurement for treatment decisions, including insulin dosing.

On February 26, 2020, we announced that the FDA approved a subgroup of PROMISE trial participants to continue for a total of 365 days to gather feasibility data on the safety and accuracy of a 365-day sensor. This sub-set of 30 participants were left undisturbed for 365 days with the goal of measuring accuracy and longevity over the full 365 days. Information gathered from this sub-set and additional development efforts provided us the confidence to start the Pivotal study for the Eversense 365 System.

In April 2020, we announced that we received an extension to our CE Certificate of Conformity in the EEA such that the Eversense XL is no longer contraindicated for MRI, which means the sensor does not need to be removed from under the skin during MRI scanning. We had previously obtained this indication for Eversense in the United States in 2019. This MRI approval is a first for the CGM category, as all other sensors are required to be removed during an MRI scan.

On August 9, 2020, we entered into a collaboration and commercialization agreement with Ascensia (the "Commercialization Agreement") pursuant to which we granted Ascensia the exclusive right to distribute our 90-day Eversense CGM system and our 180-day Eversense E3 CGM system worldwide, with the following initial exceptions: (i) until January 31, 2021, the territory did not include territories covered by our then existing distribution agreement with Roche Diagnostics International AG and Roche Diabetes Care GmbH, which are the Europe, Middle East and Asia, excluding Scandinavia and Israel, and 17 additional countries, including Brazil, Russia, India and China, as well as select markets in the Asia Pacific and Latin American regions; (ii) until September 13, 2021, the territory did not include countries covered by our current distribution agreement with Rubin Medical, which are Sweden, Norway and Denmark; and (iii) until May 31, 2022, the territory did not include Israel. Pursuant to the Commercialization Agreement, in the United States, Ascensia began providing sales support for the 90-day Eversense product on October 1, 2020 and Ascensia ramped up sales activities and assumed commercial responsibilities for the 90-day Eversense product during the second quarter of 2021.

In February 2022, we received approval from the FDA for the Eversense E3 CGM System. The approval for our third-generation sensor, with proprietary sacrificial boronic acid ("SBA") technology doubles the sensor life to six months with MARD of 8.5%. Ascensia began commercializing Eversense E3 in the United States during the second quarter of 2022.

The ENHANCE clinical study was initiated as a pivotal study with the purpose of gathering additional clinical data to support an integrated continuous glucose monitoring (iCGM) submission for the Eversense E3 system using the SBA technology. In March 2022, we extended the ongoing ENHANCE clinical study to evaluate the safety and accuracy of the Eversense 365 System for a period of up to one year in the United States. In September 2022, we completed enrollment of the ENHANCE study and the last patient of the adult cohort completed the study in the third quarter of 2023. In November 2022, we submitted and in the first quarter of 2023 we received approval of an investigational device enrollment ("IDE") for the enrollment of a pediatric cohort in the ENHANCE study. In 2023 the data gathered in the ENHANCE study supported the iCGM submission and in April 2024 Eversense was authorized to be marketed as an iCGM through the FDA's De Novo pathway, by establishing the special controls that will serve as a predicate device for 510(k) submissions in the future. Based on the analysis of the ENHANCE Pivotal study data, the decision was made to advance to the next generation sensor platform as the underlying technology used in the 365-day and future products. In May 2024, this data supported an FDA 510(k) submission for a new product with a 365-day duration and once per week calibration. The 510(k) submission was approved by the FDA on September 17, 2024 and our 365-day product was cleared for sale in the United States. Ascensia began commercializing Eversense 365 in the United States during the fourth quarter of 2024.

In April 2024 and July 2024, Eon Care Services, LLC and Eon Management Services, LLC were formed as wholly owned subsidiaries of Senseonics, Incorporated. In November 2024, Eon Management Services, LLC entered into the Administrative Agreement with the Eon Care PCs, which are consolidated as VIEs. The wholly owned entities and Eon Care PCs (collectively, "Eon Care") were established to support patient access to the Eversense system by providing convenient Eversense insertion and training services. The Company expects established CPT codes associated with Eversense insertions to enable a self-sustaining economic model for this initiative in the future.

In November 2022, we announced a collaboration with the Nurse Practitioner Group ("NPG") designed to expand U.S. patient access to Eversense by providing additional convenient in-office and at-home sensor insertion options utilizing NPG's broad network in approximately 30 states. Under the agreement between Senseonics and NPG, NPG providers will be certified to perform Eversense procedures in the specified geographies and will offer its services for patients who have been prescribed Eversense. During 2023, we expanded the inserter network by setting up Eversense procedure capabilities in additional select geographic areas. In October 2024, we acquired the sensor insertion network assets of NPG to begin transitioning nurse practitioners to our Eon Care subsidiaries in order to further expand patient access and convenience.

In July 2024, we began first-in-human testing for the Gemini system. The next-generation Gemini product utilizes a fully implantable self-powering system that includes a flash glucose monitor with no on-body component for people with type 2 diabetes and traditional CGM with an on-body component for people with type 1 diabetes. The Gemini product is built on the 365-day sensor platform and the clinical and regulatory work will be focused on demonstrating the battery integration and functionality rather than the sensor life. Data gathered from this first-in-human testing will be utilized for an IDE submission anticipated in the second half of 2025.

European Commercialization of Eversense

In September 2017, we affixed the CE mark for Eversense XL, which permits the product to be sold freely in any part of the European Economic Area ("EEA"). The Eversense XL is indicated for a sensor life of up to 180 days. Eversense XL began commercialization in the EEA in the fourth quarter of 2017. All such commercialization and marketing activities remain subject to applicable government approvals.

We previously held a distribution agreement with Roche and granted Roche the exclusive right to market, sell and distribute Eversense in certain territories within EMEA and other countries outside of the United States. The distribution rights under the agreement expired January 31, 2021.

In June 2022, we affixed the CE mark for the Eversense E3 CGM system, and Ascensia began commercialization in certain European markets during the second half of 2022.

In February 2025, we submitted the Eversense 365 CGM system to our notified body for CE Mark approval. The submission was prepared in compliance with the EU medical device regulation ("MDR") and, upon approval, would enable the commercialization of Eversense 365 in European Union member countries. Following CE Mark approval, we plan to launch Eversense 365 with our global commercial partner, Ascensia, in the second half of 2025.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States.

The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities and equity and 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. These estimates, particularly estimates relating to accounting for variable consideration related to revenue, inventory obsolescence and embedded derivatives, have a material impact on our financial statements and are discussed in detail throughout our analysis of the results of operations discussed below. We did not make any material changes to these assumptions for the year ended December 31, 2024. We do not expect any material changes to the underlying assumptions during the year ending December 31, 2025.

We base our estimates on historical experience and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets, liabilities and equity that are not readily apparent from other sources. Actual results and outcomes could differ from these estimates and assumptions.

Revenue

We generate a significant portion of product revenue from sales of the Eversense system and related components and supplies to Ascensia, through the Commercialization Agreement, who then resells the products to health care providers and patients.

Revenue from product sales to Ascensia is recognized at a point in time when the Ascensia obtains control of our product based upon the delivery terms as defined in the contract at an amount that reflects the consideration which we expect to receive in exchange for the product. Our contract with Ascensia contains performance obligations, mostly for the supply of goods, and are typically satisfied upon transfer of control of the product and does not include the right to return unless there is a product issue, in which case we may provide replacement product. Product conformity guarantees do not create additional performance obligations and are accounted for as warranty obligations in accordance with guarantee and loss contingency accounting guidance.

The consideration we expect to receive includes estimates of variable consideration for which reserves are established that is primarily the result of variable consideration such as patient assistance program rebates, prompt-pay discounts, tier-volume price discounts and for the Commercialization Agreement, revenue share. Variable consideration, such as rebates and prompt-pay incentives, are treated as a reduction in revenue and variable considerations, such as revenue share, is treated as an addition in revenue when the product sale is recognized. The amount of variable consideration that is included in the transaction price may be constrained 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, when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint requires the use of significant management judgment. Depending on the variable consideration, we develop estimates for the expected value based on the terms of the agreements, historical data, geographic mix, reimbursement rates, and market conditions. Variances in the consideration recognized is partially mitigated by minimum price provisions for certain purchases under the contract.

Inventory Obsolescence

Inventory is valued at the lower of cost or net realizable value. Cost is determined using the standard cost method that approximates first in, first out. We record an adjustment to reduce the value of inventory for items that are potentially obsolete, where the standard costs require adjustment to the net realizable value, and are in excess of future demand taking into consideration current sales orders, timing of new product launches, market conditions, and remaining shelf life. Our sensor manufacturing process can span several months, involves various contract manufacturers and includes raw components with long lead times, often resulting in significant work-in-progress inventory. However, expiry does not commence until the chemistry is applied to the sensor. We are able to isolate pre-chemistry sensor inventory in progress from post-chemistry sensor inventory and finished goods to assess against demand forecasts and customer dating requirements for potential excess or obsolete inventory. Our estimates are based on information known at the time and include factors such as anticipated future usage and sales, potential for external unfavorable conditions such as import holds or quality issues, and planned product upgrades.

However, if actual product conditions differ from our assumptions, additional inventory adjustments that would increase cost of sales could be required.

Derivative Financial Instruments

In connection with our issuance of the convertible senior subordinated notes due 2023, or the 2023 Notes in January 2018, we bifurcated the embedded conversion option, along with the interest make-whole provision and make-whole fundamental change provision, and recorded the embedded conversion option as a derivative liability in our consolidated balance sheets in accordance with ASC Topic 815, Derivatives and Hedging. The 2023 Notes were paid in full in January 2023 and the derivative liability was derecognized.

In connection with our issuance of the convertible senior subordinated notes due 2025, or the 2025 Notes in July 2019, we bifurcated the embedded conversion option along with the fundamental change make-whole provision and the cash settled fundamental make-whole shares provision, and recorded the fair value of these embedded features as a derivative liability in our consolidated balance sheets in accordance with Accounting Standards Codification, or ASC, Topic 815, Derivatives and Hedging. The 2025 Notes were paid in full in January 2025 and the derivative liability was derecognized.

In August 2020, we issued convertible senior secured notes due 2024, or the PHC Notes. The Note Purchase Agreement also contained several provisions requiring bifurcation as a separate derivative liability including an embedded conversion feature, mandatory prepayment upon event of default that constitutes a breach of the minimum revenue financial covenant, optional redemption upon an event of default, change in interest rate after PMA approval and default interest upon an event of default. We recorded the fair value of the embedded features as a derivative liability in our consolidated balance sheets in accordance with ASC Topic 815, Derivatives and Hedging. The PHC notes were cancelled in full on March 31, 2023 in exchange for a pre-funded warrant to acquire shares of our common stock (“the PHC Exchange Warrant”) and the derivative liability was derecognized.

The derivative instruments are remeasured at the end of each reporting period with changes in fair value recorded in the consolidated statements of operations and comprehensive loss in other income (expense) as a change in fair value of the derivative liability. The fair value assessment incorporates management’s assumptions for probabilities of conversion occurrence through maturity, stock price, volatility, risky bond rate, and trade data when available. We engage a third-party valuation specialist to perform the valuation using the binomial option pricing model.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table sets forth our results of operations for the years ended December 31, 2024 and 2023.

	2024	2023	Period Change
	(in thousands)		(in thousands)
Revenue, net	$ 3,973	$ 1,655	$ 2,318
Revenue, net - related parties	18,499	20,735	(2,236)
Total revenue	22,472	22,390	82
Cost of sales	21,939	19,299	2,640
Gross profit	533	3,091	(2,558)
Expenses:			
Research and development expenses	41,144	48,752	(7,608)
Selling, general and administrative expenses	34,231	29,942	4,289
Operating loss	(74,842)	(75,603)	761
Other income (expense), net:			
Interest income	4,502	5,362	(860)
Exchange related gain, net	—	14,109	(14,109)
Interest expense	(8,437)	(11,110)	2,673
Gain on change in fair value of derivatives	102	6,648	(6,546)
Other income	59	202	(143)
Total other (expense) income, net	(3,774)	15,211	(18,985)
Net Loss	$ (78,616)	$ (60,392)	$ (18,224)

Components of Results of Operations

Total revenue

Our total net revenue increased to $22.5 million for the twelve months ended December 31, 2024, compared to $22.4 million for the year ended December 31, 2023, an increase of $0.1 million. This increase was primarily driven by sales growth in the US largely due to growth in the consignment program and 365-day product demand. In the fourth quarter, we had higher shipments to Ascensia for sales of the 365-day product in the US after obtaining FDA approval in September 2024. Higher sales within the United States of $1.2 million was largely offset by $1.1 million in lower sales outside of the United States primarily due to reduced inventory levels.

Cost of sales and gross profit

Our cost of sales were $21.9 million for the twelve months ended December 31, 2024 compared to $19.3 million for the twelve months ended December 31, 2023, an increase of $2.6 million. Our gross profit decreased to $0.5 million for the twelve months ended December 31, 2024, compared to $3.1 million for the twelve months ended December 31, 2023. Gross profit as a percentage of revenue, or gross margin, was 2.4% and 13.8% for the twelve months ended December 31, 2024 and December 31, 2023, respectively. The reduction in gross margin was primarily driven by $4.8 million in one-time charges as the result of the transition from Eversense E3 to Eversense 365, partially offset by manufacturing costs previously expensed to research and development expenses. Prior to receiving FDA approval for the 365-day product in September 2024, costs associated with manufacturing 365-day inventory in the aggregate amount of $2.1 million were expensed as research and development expense. If we were to have included these costs previously expensed as a component of costs of sales, our costs of sales would have been $23.5 million, resulting in a gross loss of $1.1 million. We expect cost of sales related to the Eversense 365 will continue to reflect a lower average cost per unit over approximately the next quarter as the previous expensed inventory is fully exhausted.

Research and development expenses

Research and development expenses were $41.1 million for the twelve months ended December 31, 2024, compared to $48.8 million for the twelve months ended December 31, 2023, a decrease of $7.7 million. The decrease was primarily due to a $13.2 million reduction of clinical studies spend including consulting support services and a $0.4 million decrease in other research costs due to the completion of 365-day product trials. These decreases were partially offset by a $3.2 million increase in personnel costs to support our development projects, $1.8 million in 365-day product manufacturing costs incurred prior to FDA approval, a $0.8 million increase in contract fabrication costs and a $0.2 million increase in facilities costs.

Selling, general and administrative expenses

Selling, general and administrative expenses were $34.2 million for the twelve months ended December 31, 2024, compared to $29.9 million for the twelve months ended December 31, 2023, an increase of $4.3 million. The increase was primarily due to a $2.4 million increase in personnel costs, a $1.4 million increase in legal expenses, and a $0.7 million increase in third-party consulting fees. These increases were partially offset by a $0.4 million reduction in insurance costs and other sales and marketing expenses.

Total other (expense) income, net

Total other expense, net was $(3.8) million for the twelve months ended December 31, 2024, compared to other income, net of $15.2 million for the twelve months ended December 31, 2023, a decrease in other income of $19.0 million. The decrease in other income was primarily due to a $14.1 million reduction in exchange related gains, net, a $6.5 million reduction in gain on the change in the fair value of derivatives driven by the decrease in our stock price, and $1.0 million reduction in interest and other income. These decreases were partially offset by a $2.7 million reduction in interest expense primarily driven by the exchanges of the PHC Notes for a pre-funded warrant and the exchange of a portion of the 2025 Notes for cash and equity in 2023.

Liquidity and Capital Resources

Since our inception, we have incurred significant net losses and expect to incur additional losses in the near future. We incurred total net loss of $(78.6) million and $(60.4) million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $947.9 million. To date, we have financed our operations primarily through sales of our equity securities and debt financings. As of December 31, 2024, the Company had unrestricted cash and cash equivalents of $74.6 million.

In the past two years, we have taken a number of measures to strengthen our financial position, including the repayment of our 2023 Notes, the sale of common stock in a registered direct offering and related issuance of warrants, the issuance of a pre-funded warrant to PHC for cash in a private placement, the exchange of our PHC Notes for a newly issued pre-funded warrant, the exchange of a portion of our 2025 Notes for cash and common stock in a series of private exchanges and the repayment of the remaining 2025 Notes, the entry into a term loan facility and the issuance of shares of common stock pursuant to an at the market offering program. These transactions are described in greater detail below. We have also taken measures to manage our operating expenses, including through a company restructuring in 2024.

On October 24, 2024, the Company completed a registered direct securities offering to certain institutional investors in which we issued and sold 45,714,286 shares of common stock at $0.35 per share and simultaneously issued warrants (“PP Warrants”) to these investors in a private placement to purchase an aggregate of 45,714,286 shares of common stock at an exercise price of $0.35 per share. The PP Warrants are non-exercisable for the first six months after issuance and expire on April 29, 2030. The offering closed on October 28, 2024, and the Company received proceeds of approximately $14.8 million after payment of fees to the placement agent, but before payment of any additional expenses incurred by the Company in connection with the transaction.

On September 8, 2023, we entered into a loan agreement (the “Loan and Security Agreement”) with several institutions (collectively, the “Lenders") and Hercules Capital, Inc. (“Hercules”) in its capacity as administrative agent

and collateral agent for itself and the Lenders, pursuant to which the Lenders agreed to make available up to $50.0 million in senior secured term loans (the "Term Loan Facility"), consisting of (i) an initial term loan of $25.0 million (the "Tranche 1 Loan"), which was funded on September 8, 2023 and (ii) two additional tranches of term loans in the amounts of up to $10.0 million (the "Tranche 2 Loan") and $15.0 million (the "Tranche 3 Loan"), respectively, which will become available to us upon our satisfaction of certain terms and conditions set forth in the Loan and Security Agreement. In December 2023, we met the terms and conditions to draw on Tranche 2 Loan and the loan was funded on January 2, 2024 in an amount of $10.0 million. The loans under the Loan and Security Agreement mature on September 1, 2027.

On August 10, 2023, we entered into separate, privately negotiated exchange agreements (the "Exchange Agreements") with a limited number of holders (the "Noteholders") of our outstanding 5.25% Convertible Senior Notes due 2025 (the "2025 Notes"). Under the terms of the Exchange Agreements, the holders of the 2025 Notes agreed to exchange up to $30.8 million in aggregate principal amount of the 2025 Notes (the "Exchanged Notes") for a combination of $7.5 million of cash and newly issued shares of common stock. The number of shares issued was determined based upon the volume-weighted average price per share of the common stock during a 15-day averaging period. Based on the volume-weighted average price per share of the common stock during the averaging period, we issued a total of 35.1 million shares of common stock in the exchanges. Following the exchange, the remaining balance of the 2025 Notes was $20.4 million. On January 15, 2025, the Company repaid the outstanding principal and accrued interest in full.

In August 2023, we entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Goldman Sachs & Co. LLC ("GS"), under which we could offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $106.6 million through GS as our sales agent in an "at the market" offering, which represented the remaining capacity under our then-existing at the market program with Jefferies LLC, as described below. GS will receive a commission up to 3.0% of the gross proceeds of any common stock sold through GS under the Equity Distribution Agreement. The shares will be offered and sold pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the Securities and Exchange Commission on August 10, 2023. On October 24, 2024, the Company amended the Equity Distribution Agreement with GS to reduce the maximum amount of shares issuable thereunder to $55.0 million. For the year ended December 31, 2024, the Company received approximately $4.3 million in net proceeds from the sale of 11,918,121 shares under the Equity Distribution Agreement.

In November 2021, we entered into an Open Market Sale Agreement (the "2021 Sales Agreement") with Jefferies LLC ("Jefferies") under which we could offer and sell, from time to time, at our sole discretion, shares of our common stock having an aggregate offering price of up to $150.0 million through Jefferies as our sales agent in an "at the market" offering. Jefferies received commissions up to 3.0% of the gross proceeds of any common stock sold through Jefferies under the 2021 Sales Agreement. For the twelve months ending December 31, 2023 and 2022, we received $7.4 million and $34.2 million in net proceeds from the sale of 9,944,663 shares and 15,160,899 shares, respectively, of our common stock under the 2021 Sales Agreement. Effective August 7, 2023, in connection with the transactions described above, we and Jefferies mutually agreed to terminate the 2021 Sales Agreement. At the time of termination, approximately $106.6 million remained available for issuance pursuant to the 2021 Sales Agreement.

On March 13, 2023, we issued and sold to PHC in a private placement a warrant (the "Purchase Warrant") to purchase an aggregate of 15,425,750 shares of common stock (the "Purchase Warrant Shares"). The purchase price of the Purchase Warrant was approximately $0.97 per Purchase Warrant Share. The Purchase Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per Purchase Warrant Share. We received aggregate gross proceeds of $15.0 million in the transaction, before deducting private placement expenses payable by us.

On August 9, 2020, we entered into a financing agreement with Ascensia's parent company, PHC Holdings Corporation ("PHC"), pursuant to which we issued $35.0 million in aggregate principal amount of Senior Secured Convertible Notes due on October 31, 2024 (the "PHC Notes"), to PHC on the Closing Date. We also issued PHC 2,941,176 shares of common stock to PHC as a financing fee. We also had the option to sell and issue PHC up to $15.0 million of convertible preferred stock on or before December 31, 2022, contingent upon obtaining approval for the 180-day Eversense E3 product for marketing in the United States before such date. Upon the closing of the PHC Notes, we

prepaid in full the First Lien Notes, issued and sold pursuant to a loan agreement with Highbridge Capital Management, LLC ("Highbridge") (the "Highbridge Loan Agreement"), in the amount of approximately $17.6 million. As described in Note 2, on March 13, 2023, we entered into an agreement with PHC, whereby PHC has agreed to exchange the PHC Notes for a warrant (the "PHC Exchange Warrant") to purchase up to 68,525,311 shares of common stock. The Exchange Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per share. On March 31, 2023 (6:00 am Japan Standard Time on April 1, 2023), the PHC Exchange was consummated, and the Company issued the PHC Exchange Warrant in consideration for the cancellation of the PHC Notes.

On November 9, 2020, we entered into the Equity Line Agreement with Energy Capital, pursuant to which Energy Capital committed to purchase up to an aggregate of $12.0 million of shares of our newly designated Series B convertible Preferred Stock ("Series B Preferred Stock"), at our request from time to time during the 24-month term of the Equity Line Agreement. Beginning on January 1, 2022, since there had been no sales of the Series B Preferred Stock pursuant to the Equity Line Agreement, Energy Capital had the right, at its sole discretion to purchase up to $12.0 million of Series B Preferred Stock under the Equity Line Agreement at a purchase price of $1,000 per share of Series B Preferred Stock initially convertible into common stock, beginning six months after the date of its issuance, at a conversion price of $0.3951 per share. On November 7, 2022, Energy Capital exercised in full its right to purchase $12.0 million of Series B Preferred Stock. In the first quarter of 2025, Energy Capital converted its Series B Preferred Stock in full into 30,372,058 shares of common stock.

Warrants

In connection with certain of our historical financing transactions, we have issued warrants to investors and providers of debt financing, as described below.

On June 30, 2016, we entered into a loan agreement with Oxford Finance and Silicon Valley Bank (collectively, the "Lenders") and issued to the Lenders 10-year stock purchase warrants to purchase an aggregate of 116,581, 63,025 and 80,645 shares of common stock at an exercise price of $3.86, $2.38 and $1.86 per share, respectively ("Oxford/SVB Warrants"). The Oxford/SVB warrants expire on June 30, 2026, November 22, 2026 and March 29, 2027, respectively.

On April 24, 2020, we entered into a loan agreement with Highbridge and issued the lender warrants to purchase an aggregate of 4,500,000 shares of the Company's common stock with an exercise price of $0.66 per share ("Highbridge Warrants"). The Highbridge Warrants are exercisable until April 24, 2030. During the year ended December 31, 2021, the warrant holders exercised 1,750,000 warrants.

On March 13, 2023, we issued and sold to PHC a Purchase Warrant to purchase 15,425,750 shares of common stock for $15.0 million. The Purchase Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per Purchase Warrant Share. All or any part of the Purchase Warrant is exercisable by PHC at any time and from time to time.

In March 2023, we entered into an exchange agreement with PHC, pursuant to which PHC exchanged $35.0 million aggregate principal amount of the PHC Notes, including all accrued and unpaid interest thereon, for a warrant (the "PHC Exchange Warrant") to purchase up to 68,525,311 shares of common stock. The PHC Exchange Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per PHC Exchange Warrant Share. All or any part of the Exchange Warrant is exercisable by PHC at any time and from time to time.

On September 8, 2023, we entered into the Loan and Security Agreement with several lenders and issued the Tranche 1 Warrants to acquire an aggregate of 832,362 shares of common stock at an exercise price of $0.6007 per share. The Tranche 1 Warrants may be exercised through the earlier of (i) September 8, 2030 and (ii) the consummation of certain acquisition transactions involving the company, as set forth in the warrant agreement.

On January 2, 2024, we issued the Tranche 2 Warrants to acquire an aggregate of 347,887 shares at an exercise price of $0.5749 per share. The Tranche 2 Warrants may be exercised through the earlier of (i) January 2, 2031 and (ii) the consummation of certain acquisition transactions involving the company, as set forth in the warrant agreement.

On October 24, 2024, in connection with the registered direct offering described above, the Company issued to the investors in the offering the PP Warrants to purchase an aggregate of 45,714,286 shares of common stock at an exercise price of $0.35 per share. The PP Warrants are non-exercisable for the first six months after issuance and expire on April 29, 2030.

Indebtedness

Loan and Security Agreement

On September 8, 2023, we entered into the Loan and Security Agreement with the Lenders and Hercules, pursuant to which the Lenders agreed to make available to us the Term Loan Facility, consisting of (i) an initial Tranche 1 Loan, which was funded in the amount of $25.0 million on the Effective Date and (ii) the Tranche 2 Loan and Tranche 3 Loan, respectively, which would become available to the Company upon our satisfaction of certain terms and conditions set forth in the Loan and Security Agreement. The loans under the Loan and Security Agreement mature on September 1, 2027. In December 2023, we met the terms and conditions to draw on Tranche 2 Loan and the loan was funded on January 2, 2024 in an amount of $10.0 million.

Convertible Notes

The following table summarizes our outstanding senior convertible note obligations at December 31, 2024:

Convertible Note	Issuance Date	Coupon	Aggregate Principal (in millions)	Maturity Date	Initial Conversion Rate per $1,000 Principal Amount	Conversion Price per Share of Common Stock
2025 Notes	July 1, 2019	5.25%	$ 20.4	January 15, 2025	757.5758	$ 1.32

The 2025 Notes were repaid in full on January 15, 2025. See Note 13 in the accompanying notes to our consolidated financial statements included elsewhere in this Annual Report for further discussion of the 2025 Notes.

Funding Requirements and Outlook

Our ability to generate revenue and achieve profitability depends on the successful commercialization and adoption of our Eversense CGM systems by diabetes patients and healthcare providers, along with future product development, regulatory approvals, certifications and post-approval requirements. These activities, including our ongoing focus to grow covered lives through positive insurance payor policy decisions and continued development of Eversense 365-day product in the United States, will require significant uses of working capital through 2025 and beyond. As of December 31, 2024, the Company had unrestricted cash and cash equivalents of $74.6 million.

In accordance with the FASB Accounting Standards Codification Topic 205-40, Presentation of Financial Statements - Going Concern, management is required to assess the Company’s ability to continue as a going concern through twelve months after issuance of the financial statements. Based on the Company's current operating plan, existing unrestricted cash, cash equivalents and marketable securities, anticipated debt repayments, minimum cash requirements and satisfaction of performance milestones to comply with debt covenants under its Loan and Security Agreement, the Company has determined that substantial doubt exists regarding its ability to continue as a going concern for the one-year period following the date these condensed consolidated financial statements are issued. To sustain its future operations beyond such one-year period, the Company will require additional funding. As part of our liquidity strategy, the Company will continue to monitor our capital structure and market conditions, and the Company may finance our cash needs through public or private debt and equity financings and other sources which may include collaborations, strategic alliances, and licensing arrangements with third parties. There is no assurance that the Company will be successful in obtaining sufficient funding on acceptable terms, if at all, and could be forced to delay, reduce, or eliminate some or all of its research, clinical trials, product development or future commercialization efforts, which could materially adversely affect its business prospects or its ability to continue as a going concern.

Cash Flows

The following is a summary of cash flows for each of the periods set forth below (in thousands):

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (60,465)	$ (70,163)
Net cash provided by investing activities	32,838	89,713
Net cash provided by financing activities	26,830	20,366
Net (decrease) increase in cash and cash equivalents	$ (797)	$ 39,916

Net cash used in operating activities

Net cash used in operating activities was $60.5 million for the year ended December 31, 2024, and consisted of a net loss of $78.6 million, partially offset by a $0.9 million net change in operating assets and liabilities, $9.2 million of stock-based compensation, $3.9 million in non-cash inventory costs primarily due to transition to the 365-day product, and $4.1 million related to depreciation/amortization and other non-cash items.

Net cash used in operating activities was $70.2 million for the year ended December 31, 2023, and consisted of a net loss of $60.4 million, a $14.1 million exchange-related gain, a $6.6 million gain in the fair value of derivatives on convertible notes, and a $4.0 million net change in operating assets and liabilities, partially offset by $8.7 million of stock-based compensation, and $6.3 million related to depreciation/amortization and other non-cash items.

Net cash provided by investing activities

Net cash provided by investing activities was $32.8 million for the year ended December 31, 2024, and consisted of $93.1 million from the sale and maturity of marketable securities, partially offset by $58.1 million from the purchase of marketable securities and $2.2 million of capital expenditures for laboratory equipment and leasehold improvements.

Net cash provided by investing activities was $89.7 million for the year ended December 31, 2023, and consisted of $158.6 million from the sale and maturity of marketable securities, partially offset by $68.5 million from the purchase of marketable securities and $0.4 million of capital expenditures for laboratory equipment and leasehold improvements.

Net cash provided by financing activities

Net cash provided by financing activities was $26.8 million for the year ended December 31, 2024, and primarily consisted of an aggregate of $4.0 million in proceeds related to the issuance of common stock pursuant to our at the market offering and the exercise of stock options, $14.5 million in proceeds from a registered direct offering, and $10.0 million in net proceeds from borrowings pursuant to the Loan and Security Agreement, partially offset by $1.7 million taxes paid related to net share settlement of equity awards.

Net cash provided by financing activities was $20.4 million for the year ended December 31, 2023, and primarily consisted of an aggregate of $7.4 million in proceeds related to the issuance of common stock pursuant to our at the market offering and the exercise of stock options, $14.7 million in proceeds from the issuance of the PHC Purchase Warrant, and $24.4 million in net proceeds from borrowings pursuant to the Loan and Security Agreement, partially offset by $15.7 million and $7.5 million in repayment and exchange of the 2023 Notes and 2025 Notes, respectively, $2.7 million taxes paid related to net share settlement of equity awards, and $0.4 million in debt issuance costs.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2024, we had cash and cash equivalents of $74.9 million and at December 31, 2023 we had cash, cash equivalents and marketable securities of $109.5 million. We generally hold our cash in interest-bearing money market accounts or short-term investments that meet our policy for cash equivalents. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents. The Company's Loan and Security Agreement is affected by variations in the U.S. prime rate of interest. As of December 31, 2024, we had $35.0 million outstanding under the agreement. A 2% change in the prime rate would result in additional annual interest of approximately $0.4 million based on the outstanding balance at December 31, 2024. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Foreign Currency Risk

The majority of our international sales are denominated in Euros. Therefore, our U.S. dollar value of sales is impacted by exchange rates versus the Euro. Currency fluctuations or a strengthening U.S. dollar can decrease our revenue from these Euro-denominated international sales. To date, foreign currency transaction gains and losses and exchange rate fluctuations have not been material to our consolidated financial statements, and we do not believe that the effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would have had a material impact on our operating results or financial condition. We do not currently engage in any hedging transactions to manage our exposure to foreign currency exchange rate risk.

Item 8. Financial Statements and Supplementary Data

SENSEONICS HOLDINGS, INC. AND SUBSIDIARIES
Consolidated Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
Senseonics Holdings, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Senseonics Holdings, Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statement of operations and comprehensive loss, stockholders' (deficit) equity, and cash flows for each of the years in the two-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's current operating plan, existing unrestricted cash and cash equivalents, and minimum cash and satisfaction of performance milestones to comply with debt covenants under its Loan and Security Agreement raise substantial doubt about its ability to continue as a going concern for the one-year period following the date the consolidated financial statements are issued. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ KPMG LLP

We have served as the Company's auditor since 2022.

McLean, Virginia
March 3, 2025

Senseonics Holdings, Inc.
Consolidated Balance Sheets
(in thousands, except for share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 74,597	$ 75,709
Restricted cash	315	—
Short term investments, net	—	33,747
Accounts receivable, net	1,365	808
Accounts receivable, net - related parties	4,921	3,724
Inventory, net	4,421	8,776
Prepaid expenses and other current assets	5,819	7,266
Total current assets	91,438	130,030
Deposits and other assets	4,926	7,006
Property, equipment and intangible assets, net	4,074	1,184
Total assets	$ 100,438	$ 138,220
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 3,205	$ 4,568
Accrued expenses and other current liabilities	13,636	11,744
Accrued expenses and other current liabilities, related parties	1,870	945
Note payable, current portion, net	20,138	—
Total current liabilities	38,849	17,257
Long-term debt and notes payables, net	34,703	41,195
Derivative liabilities	—	102
Non-current operating lease liabilities	5,785	6,214
Total liabilities	79,337	64,768
Commitments and contingencies		
Preferred stock and additional paid-in-capital, subject to possible redemption: $0.001 par value per share; 12,000 shares issued and outstanding as of each December 31, 2024 and December 31, 2023	37,656	37,656
Total temporary equity	37,656	37,656
Stockholders' (deficit) equity:		
Common stock, $0.001 par value per share; 1,400,000,000 shares and 900,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 595,351,210 shares and 530,364,237 shares issued and outstanding as of December 31, 2024 and December 31, 2023	595	530
Additional paid-in capital	930,724	904,535
Accumulated other comprehensive loss	—	(11)
Accumulated deficit	(947,874)	(869,258)
Total stockholders' (deficit) equity	(16,555)	35,796
Total liabilities, temporary equity and stockholders' (deficit) equity	$ 100,438	$ 138,220

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

Senseonics Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share data)

	Years Ended December 31,	
	2024	**2023**
Revenue, net	$ 3,973	$ 1,655
Revenue, net - related parties	18,499	20,735
Total revenue	22,472	22,390
Cost of sales	21,939	19,299
Gross profit	533	3,091
Expenses:		
Research and development expenses	41,144	48,752
Selling, general and administrative expenses	34,231	29,942
Operating loss	(74,842)	(75,603)
Other (expense) income, net:		
Interest income	4,502	5,362
Exchange related gain, net	—	14,109
Interest expense	(8,437)	(11,110)
Gain on change in fair value of derivatives	102	6,648
Other income	59	202
Total other (expense) income, net	(3,774)	15,211
Net Loss	(78,616)	(60,392)
Other comprehensive loss		
Unrealized gain on marketable securities	11	667
Total other comprehensive gain	11	667
Total comprehensive loss	$ (78,605)	$ (59,725)
Basic net loss per common share	$ (0.12)	$ (0.11)
Basic weighted-average shares outstanding	629,721,584	567,974,492
Diluted net loss per common share	$ (0.12)	$ (0.11)
Diluted weighted-average shares outstanding	629,721,584	567,974,492

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

Senseonics Holdings, Inc.
Consolidated Statements of Changes in Stockholders' (Deficit) Equity
(in thousands)

	Common Stock		Additional Paid-In	Accumulated Other	Accumulated	Total Stockholders'	Series B Convertible Preferred Stock
	Shares	Amount	Capital	Comprehensive Loss	Deficit	(Deficit) Equity	Temporary Equity
Balance, December 31, 2022	479,637	$ 480	$ 806,488	$ (678)	$ (808,866)	$ (2,576)	$ 37,656
Issuance of common stock, net of issuance costs	9,945	10	7,366	—	—	7,376	—
Issuance of common stock for vested RSUs and ESPP purchases	9,531	9	198	—	—	207	—
Issuance of warrants, net of issuance costs	—	—	63,645	—	—	63,645	—
Exercise of stock options and warrants	6	—	3	—	—	3	—
Exchange of 2025 Notes	35,139	35	20,967	—	—	21,002	—
Stock-based compensation expense	—	—	8,673	—	—	8,673	—
Shares withheld related to net share settlement of equity awards	(3,894)	(4)	(2,668)	—	—	(2,672)	—
Other	—	—	(137)	—	—	(137)	—
Net loss	—	—	—	—	(60,392)	(60,392)	—
Other comprehensive gain	—	—	—	667	—	667	—
Balance, December 31, 2023	530,364	$ 530	$ 904,535	$ (11)	$ (869,258)	$ 35,796	$ 37,656
Issuance of common stock, net of issuance costs	57,632	11	3,804	—	—	3,815	—
Issuance of the RD Shares and the PP Warrants, net of issuance costs	—	46	14,503	—	—	14,549	—
Issuance of common stock for vested RSUs and ESPP purchases	9,658	10	164	—	—	174	—
Issuance of warrants, net of issuance costs	—	—	149	—	—	149	—
Exercise of stock options and warrants	12	—	5	—	—	5	—
Stock-based compensation expense	—	—	9,225	—	—	9,225	—
Shares withheld related to net share settlement of equity awards	(2,315)	(2)	(1,661)	—	—	(1,663)	—
Net loss	—	—	—	—	(78,616)	(78,616)	—
Other comprehensive gain	—	—	—	11	—	11	—
Balance, December 31, 2024	595,351	$ 595	$ 930,724	$ —	$ (947,874)	$ (16,555)	37,656

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

Senseonics Holdings, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (78,616)	$ (60,392)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,475	1,277
Non-cash interest expense (debt discount and deferred costs)	3,845	7,402
Net amortization of premiums and accretion of discounts on marketable securities	(1,319)	(2,668)
Gain on change in fair value of derivatives	(102)	(6,648)
Exchange-related gain, net	—	(14,109)
Stock-based compensation expense	9,225	8,673
Provision for inventory obsolescence and losses	3,942	174
Loss on disposal of assets	—	5
Other	220	89
Changes in assets and liabilities:		
Accounts receivable	(2,699)	(2,191)
Prepaid expenses and other current assets	1,164	162
Inventory	696	(1,644)
Deposits and other assets	1,737	(438)
Accounts payable	(1,828)	2,297
Accrued expenses and other liabilities	2,621	(1,061)
Accrued interest	86	31
Payments on lease liabilities	(912)	(1,122)
Net cash used in operating activities	(60,465)	(70,163)
Cash flows from investing activities		
Capital expenditures	(2,239)	(350)
Purchase of marketable securities	(58,018)	(68,537)
Proceeds from sale and maturity of marketable securities	93,095	158,600
Net cash provided by investing activities	32,838	89,713
Cash flows from financing activities		
Proceeds from issuance of common stock, net	3,815	7,376
Proceeds from exercise of stock options and ESPP issuances, net	179	73
Taxes paid related to net share settlement of equity awards	(1,663)	(2,672)
Repayment of 2023 Notes	—	(15,700)
Repayment of 2025 Notes	—	(7,500)
Proceeds from issuance of Loan and Security Agreement, net	9,950	24,446
Proceeds from issuance of the RD Shares and the PP Warrants, net	14,549	—
Payment of debt issuance costs	—	(355)
Proceeds from issuance of Purchase Warrant, net	—	14,698
Net cash provided by financing activities	26,830	20,366
Net (decrease) increase in cash and cash equivalents	(797)	39,916
Cash and cash equivalents and restricted cash, at beginning of period	75,709	35,793
Cash and cash equivalents and restricted cash, at ending of period	$ 74,912	$ 75,709
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 4,506	$ 3,678
Lease liabilities arising from obtaining right-of-use assets	—	3,831
Supplemental disclosure of non-cash transactions		
Acquisition of sensor insertion network assets in exchange for accounts receivable	725	—
Liabilities for contingent consideration	50	—
Property and equipment purchases included in accounts payable and accrued expenses	418	173
Issuance of warrants in exchange for PHC Notes	—	48,564
Issuance of warrants for Loan and Security Agreement	149	364
Issuance of common stock converted from 2025 Notes	—	21,002

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

Senseonics Holdings, Inc.
Notes to Consolidated Financial Statements

1. Organization

Senseonics Holdings, Inc., a Delaware corporation, is a medical technology company focused on the development and manufacturing of long-term, implantable continuous glucose monitoring systems to improve the lives of people with diabetes by enhancing their ability to manage their disease with relative ease and accuracy.

Senseonics, Incorporated is a wholly owned subsidiary of Senseonics Holdings, Inc. and was originally incorporated on October 30, 1996 and commenced operations on January 15, 1997. Eon Care Services, LLC and Eon Management Services, LLC are wholly owned subsidiaries of Senseonics, Incorporated formed in April 2024 and July 2024, respectively. Senseonics Holdings, Inc. and its consolidated subsidiaries and affiliated entities, including its consolidated VIEs are hereinafter collectively referred to as the "Company", unless otherwise indicated or the context otherwise requires.

2. Liquidity, Capital Resources, and Going Concern

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, limited operating history as a commercial-stage company and uncertainty of future profitability. Since inception, the Company has suffered substantial operating losses, principally from expenses associated with the Company's research and development programs and commercial launch of the Eversense® 365 CGM System (for use up to one-year) in the United States, the Eversense® E3 (for use up to six months) in Europe and expenses incurred for our legacy product versions.

The Company has not generated significant profit from the sale of products and its ability to generate revenue and achieve profitability largely depends on the Company's ability to successfully expand the commercialization of Eversense, continue the development of its products and product upgrades, and to obtain necessary regulatory approvals or certifications for the sale of those products. These activities will require significant uses of working capital through 2025 and beyond. The Company generated total gross profit of $0.5 million for the twelve months ended December 31, 2024 and had an accumulated deficit of $947.9 million at December 31, 2024. To date, the Company has funded its operations principally through the issuance of preferred stock, common stock, convertible note issuance and debt. As of December 31, 2024, the Company had unrestricted cash and cash equivalents of $74.6 million.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

Based on the Company's current operating plan, existing unrestricted cash and cash equivalents, minimum cash and satisfaction of performance milestones to comply with debt covenants under its Loan and Security Agreement as discussed in Note 13, the Company has determined that substantial doubt exists regarding its ability to continue as a going concern. The Company will require additional liquidity to continue its operations over the next twelve months and we are currently evaluating strategies to obtain the required additional funding for future operations. We anticipate that our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures and other strategic initiatives. Our ability to continue to fund our operations and meet capital needs will depend on our ability to successfully obtain funding from public or private debt and equity financings and other sources of capital, as further described above under "Funding Requirements and Outlook".

Actions taken by the Company with regards to liquidity and to manage our cash flows during the years ended December 31, 2024 and 2023, included, but were not limited to the following:

On October 24, 2024, the Company entered into a securities purchase agreement with certain institutional investors to issue and sell (i) in a registered direct offering an aggregate of 45,714,286 shares of the Company's common stock, $0.001 par value per share (the "RD Shares") and (ii) in a concurrent private placement, warrants to purchase an aggregate of 45,714,286 shares of common stock (the "PP Warrants"). The combined purchase price of each RD Share and accompanying PP Warrant was $0.35 per share for total gross proceeds of $16.0 million. The RD Shares and the PP Warrants were immediately separable and were issued separately. The PP Warrants have an exercise price of $0.35 per share, are non-exercisable for the first six months after issuance and expire five years from the date of initial exercisability. The offering closed on October 28, 2024, and the Company received proceeds of approximately $14.8 million after payment of fees to the placement agent, but before payment of any additional expenses incurred by the Company in connection with the transaction. The proceeds were allocated to the RD Shares and PP Warrants based on the relative fair values of the instruments themselves at the time of issuance.

On September 8, 2023 (the "Effective Date"), the Company entered into a loan agreement (the "Loan and Security Agreement") with the several institutions or entities party thereto (collectively, the "Lenders") and Hercules Capital, Inc., a Maryland corporation ("Hercules") in its capacity as administrative agent and collateral agent for itself and the Lenders, pursuant to which the Lenders have agreed to make available to the Company up to $50.0 million in senior secured term loans (the "Term Loan Facility"), consisting of (i) an initial term loan of $25.0 million (the "Tranche 1 Loan"), which was funded on the Effective Date and (ii) two additional tranches of term loans in the amounts of up to $10.0 million (the "Tranche 2 Loan") and $15.0 million (the "Tranche 3 Loan"), respectively, which will become available to the Company upon the Company's satisfaction of certain terms and conditions set forth in the Loan and Security Agreement. In December 2023, the Company met the terms and conditions to draw on Tranche 2 Loan and the loan was funded on January 2, 2024 in an amount of $10.0 million. The loans under the Loan and Security Agreement mature on September 1, 2027 (the "Maturity Date").

On August 10, 2023, the Company entered into separate, privately negotiated exchange agreements (the "Exchange Agreements") with a limited number of holders (the "Noteholders") of the Company's currently outstanding 5.25% Convertible Senior Notes due 2025 (the "2025 Notes"). Under the terms of the Exchange Agreements, the Noteholders agreed to exchange with the Company (the "Exchanges") up to $30.8 million in aggregate principal amount of the 2025 Notes (the "Exchanged Notes") for a combination of $7.5 million of cash and newly issued shares of common stock (the "Exchange Shares"). The number of Exchange Shares was determined based upon the volume-weighted average price per share of the common stock during a 15-day averaging period commencing on August 11, 2023 and ending August 31, 2023. Based on the volume-weighted average price per share of the common stock during the averaging period, a total of 35.1 million shares of common stock were issued in the Exchanges. The Exchanges were settled on the initial share issuance date of August 14, 2023 and the final settlement date of September 5, 2023.

In August 2023, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Goldman Sachs & Co. LLC ("GS"), under which the Company could offer and sell, from time to time, at its sole discretion, shares of its common stock having an aggregate offering price of up to $106.6 million through GS as its sales agent in an "at the market" offering. GS will receive a commission up to 3.0% of the gross proceeds of any common stock sold through GS under the Equity Distribution Agreement. The shares will be offered and sold pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the Securities and Exchange Commission on August 10, 2023. On October 24, 2024, the Company amended the Equity Distribution Agreement with GS to reduce the maximum amount of shares issuable thereunder to $55.0 million. For the year ended December 31, 2024, the Company received approximately $4.3 million in net proceeds from the sale of 11,918,121 shares under the Equity Distribution Agreement.

In November 2021, the Company entered into an Open Market Sale Agreement (the "2021 Sales Agreement") with Jefferies LLC ("Jefferies"), under which the Company could offer and sell, from time to time, at its sole discretion, shares of its common stock having an aggregate offering price of up to $150.0 million through Jefferies as the sales agent in an "at the market" offering. Jefferies received commissions up to 3.0% of the gross proceeds of any common stock sold through Jefferies under the 2021 Sales Agreement. During 2023, the Company received $7.4 million in net proceeds from the sale of 9,944,663 shares of its common stock under the 2021 Sales Agreement. Effective August 7, 2023, the

Company and Jefferies mutually agreed to terminate the 2021 Sales Agreement. At the time of termination, approximately $106.6 million remained available for issuance pursuant to the 2021 Sales Agreement.

On August 9, 2020, the Company entered into a financing agreement with the parent company of Ascensia Diabetes Care Holdings AG ("Ascensia"), PHC Holdings Corporation ("PHC"), pursuant to which the Company issued $35.0 million in aggregate principal amount of Senior Secured Convertible Notes due on October 31, 2024 (the "PHC Notes"), to PHC. The Company also issued 2,941,176 shares of common stock to PHC as a financing fee. The Company also had the option to sell and issue PHC up to $15.0 million of convertible preferred stock on or before December 31, 2022, contingent upon obtaining U.S. Food and Drug Administration ("FDA") approval for the 180-day Eversense product for marketing in the United States before such date. The Company successfully obtained FDA approval in February 2022 and the option was not exercised. As described in Note 13, on March 13, 2023, the Company entered into an Exchange Agreement (the "PHC Exchange Agreement") with PHC, pursuant to which PHC agreed to exchange (the "PHC Exchange") its $35.0 million aggregate principal amount of the PHC Notes, including all accrued and unpaid interest thereon, for a warrant (the "PHC Exchange Warrant") to purchase up to 68,525,311 shares of the Company's common stock, $0.001 par value per share (the "PHC Exchange Warrant Shares"). The PHC Exchange Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per PHC Exchange Warrant Share. On March 31, 2023, the PHC Exchange was consummated, and the Company issued the PHC Exchange Warrant in consideration for the cancellation of the PHC Notes.

On March 13, 2023, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with PHC, pursuant to which the Company issued and sold to PHC in a private placement (the "Private Placement") a warrant (the "Purchase Warrant") to purchase 15,425,750 shares of the Company's common stock, $0.001 par value per share (the "Purchase Warrant Shares"). The purchase price of the Purchase Warrant was approximately $0.97 per Purchase Warrant Share, representing the undiscounted, trailing 10-day volume weighted average price of the Company's common stock through March 10, 2023. The Purchase Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per Purchase Warrant Share. The issuance of the Purchase Warrants enabled PHC to maintain, as of the closing of the transaction, a 15% beneficial ownership for purposes of the Investor Rights Agreement, dated August 9, 2020, between the Company and PHC. The Private Placement closed on March 13, 2023 (the "Private Placement Closing Date") and the Company received aggregate gross proceeds of $15.0 million, before deducting private placement expenses payable by the Company.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

The consolidated financial statements reflect the accounts of Senseonics Holdings, Inc. and its consolidated subsidiaries and affiliated entities, including its VIEs in which the Company is the primary beneficiary. All intercompany balances and transactions are eliminated upon consolidation.

In November 2024, Eon Management Services, LLC entered into management services agreements (the "Administrative Agreement") for an initial fixed term of 10 years with several professional corporations created to support patient access to the Eversense system by contracting nurse practitioners and other healthcare professionals to perform Eversense insertion procedures and other clinical activities. Eon Care Clinicians PC, Eon Care Clinicians of NJ PC, and Eon Care Clinicians of CA PC (collectively referred to as "Eon Care PCs") are the professional corporations that were established pursuant to the requirements of its respective domestic jurisdiction governing the corporate practice of medicine.

In accordance with relevant accounting guidance, the Eon Care PCs have been determined to be VIEs of the Company, as the Company is its primary beneficiary with the ability, through the Administrative Agreement to direct the activities (excluding clinical activities) that most significantly affect the Eon Care PCs financial performance and

have the obligation to absorb losses of, or the right to receive benefits from, the Eon Care PCs that could potentially be significant to it. The assets of the consolidated VIEs may only be used to settle obligations of the consolidated VIEs, if any. Our variable interest entities' assets, liabilities, and results of operations were not material to our consolidated financial results.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, recoverability of long-lived assets and definite-lived intangible assets, deferred taxes and valuation allowances, derivative assets and liabilities, obsolete inventory, warranty obligations, variable consideration related to revenue, allowance for credit losses, depreciable lives of property and equipment, and accruals for clinical study costs, which are accrued based on estimates of work performed under contract. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that it believes are reasonable, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses. Actual results could differ from those estimates; however, management does not believe that such differences would be material.

Cash and Cash Equivalents and Concentration of Credit Risk

The Company considers highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. These investments are carried at cost, which approximates fair value. Restricted cash represents cash and cash equivalents that are restricted to withdrawal or use as of the reporting date. The Company's restricted cash relates to collateral for procurement cards issued by a U.S. commercial bank. Cash, cash equivalents and restricted cash consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Cash [(1)]	$ 3,984	$ 2,756
Money market funds	70,613	72,953
Restricted cash	315	—
Cash, cash equivalents and restricted cash	$ 74,912	$ 75,709

(1) Includes overnight repurchase agreements.

Marketable Securities

Marketable securities typically consist of commercial paper, corporate debt securities, asset backed securities and government and agency securities. The Company's investments are classified as available for sale. Such securities are carried at fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, are included in consolidated results of operations. A decline in the market value of any available for sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income is recognized when earned. The cost of securities sold is calculated using the specific identification method. We classify all available-for-sale marketable securities with maturities greater than one year from the balance sheet date as non-current assets. We do not generally intend to sell these investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

Inventory and Obsolescence

Inventory is valued at the lower of cost or net realizable value. Cost is determined using the standard cost method that approximates first in, first out. The Company records an adjustment to reduce the value of inventory for items that are potentially obsolete, where standard costs require adjustment to the net realizable value, and are in excess

of future demand taking into consideration the product shelf life. The sensor manufacturing process can span several months, involves various contract manufacturers and includes raw components with long lead times, often resulting in significant work-in-progress inventory. However, expiry does not commence until the chemistry is applied to the sensor. The Company is able to isolate pre-chemistry sensor inventory in progress from post-chemistry sensor inventory in progress and finished goods to assess against demand forecasts and customer dating requirements for potential excess or obsolete inventory. The Company's estimates are based on information known as of the balance sheet date and include factors such as anticipated future usage and sales, potential for external unfavorable conditions such as import holds or quality issues, and planned product upgrades. However, if actual product quality or conditions differ from the Company's assumptions, additional inventory adjustments that would increase cost of sales could be required.

The Company capitalizes inventory costs associated with pre-launch inventory upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. The determination to capitalize inventory costs is based on the particular facts and circumstances relating to the product. Inventory costs incurred prior to regulatory approval are expensed as research and development expenses.

Accounts Receivable

The Company grants credit to various customers in the normal course of business. Accounts receivable consist of amounts due from distributors and consignment customers. These receivables are reduced by an expected credit loss at the time revenue is recognized. Uncollectible accounts are written off against the credit loss reserve after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible. At December 31, 2024 and December 31, 2023, the credit loss reserve was $0.3 million and $0.1 million, respectively.

Property and Equipment, net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which is generally between three to seven years, and is recorded within operating expenses and cost of goods sold in the consolidated statements of operations and comprehensive loss. Upon disposition of the assets, the costs and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Repairs and maintenance costs are included as expense in the accompanying statement of operations.

Intangibles

The Company amortizes intangible assets acquired using the straight-line method over the estimated economic useful life. The useful life is determined after considering the specific facts and circumstances related to the use of the intangible asset such as the contractual term of any agreement related to the asset, the historical performance of the asset, the Company's strategy for use of the asset, and any other factors which could impact the useful life of the asset.

Leases

The Company evaluates whether contractual arrangements contain leases at the inception of such arrangements. Specific considerations include whether the Company can control the underlying asset and has the right to obtain substantially all of the economic benefits or outputs from the asset. Substantially all of the Company's leases are long-term operating leases with fixed payment terms. The Company currently does not have financing leases. Right-of-use ("ROU") operating lease assets represent the Company's right-to-use an underlying asset for the lease term, and operating lease liabilities represent the Company's obligation to make lease payments. Operating lease expense is recognized on a straight-line basis over the lease term and is included in general and administrative expenses on the Company's consolidated statement of operations and comprehensive loss. Options to extend the leases or terminate the leases early are only included in the lease term when it is reasonably certain that the option will be exercised.

The Company recognizes a ROU lease asset and liability as of the lease commencement date at the present value of the lease payments over the lease term. If the discount rate in the lease agreement is not implicit, the Company estimates the incremental borrowing rate based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term. Lease and non-lease components are accounted for as a single component for facility leases. Leases with an initial term of 12 months or less are expensed over the related term.

Impairment of Long-lived Assets

Management reviews long-lived assets, including property and equipment, intangibles assets, and right-of-use assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If the undiscounted cash flows are less than the carrying amount, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. There were no impairment indicators identified in 2024 or 2023.

Derivative Financial Instruments

The Company accounts for conversion options embedded in convertible notes in accordance with ASC Topic 815, Derivatives and Hedging. ASC Topic 815 generally requires companies to bifurcate conversion options embedded in convertible notes from their host instruments and to account for them as free standing derivative financial instruments. We review the terms of convertible debt issues to determine whether there are embedded derivative instruments, including embedded conversion options, which are required to be bifurcated and accounted for separately as derivative financial instruments. In circumstances where the host instrument contains more than one embedded derivative instrument, including the conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as separate derivative instruments.

The fair value of the embedded features are accounted for as a derivative liability in the Company's consolidated balance sheets and adjusted to fair value each reporting period. The change in fair value of derivatives is recorded as a component of other (expense) income in the Company's consolidated statements of operations and comprehensive loss.

Product Warranty Obligations

The Company provides a warranty of one year on its smart transmitters. Additionally, the Company may also replace Eversense system components that do not function in accordance with the product specifications. Estimated

replacement costs are recorded at the time of shipment as a charge to cost of sales in the consolidated statement of operations and are developed by analyzing product performance data and historical replacement experience, including comparing actual return management authorizations to revenue.

The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2024 and 2023 (in thousands):

	December 31, 2024	December 31, 2023
Balance at beginning of the period	$ 514	$ 781
Provision for warranties during the period	311	242
Settlements made during the period	(419)	(509)
Balance at end of the period	$ 406	$ 514

Revenue Recognition

We generate product revenue from sales of the Eversense system and related components and supplies to Ascensia, through the Commercialization Agreement, third-party distributors outside the United States and to strategic fulfillment partners in the United States (collectively "Customers"), who then resell the products to health care providers and patients. We are paid for our sales directly to the Customers, regardless of whether or not the Customers resell the products to health care providers and patients. The Company also generates product revenue from sales of the Eversense system and related components and supplies through a consignment model with our network of healthcare professionals in the United States and revenue is recognized when the product is consumed by a patient.

Revenue from product sales is recognized at a point in time when the Customers obtain control of our product based upon the delivery terms as defined in the contract at an amount that reflects the consideration which we expect to receive in exchange for the product. Contracts with our distributors contain performance obligations, mostly for the supply of goods, and is typically satisfied upon transfer of control of the product. Customer contracts do not include the right to return unless there is a product issue, in which case we may provide replacement product. Product conformity guarantees do not create additional performance obligations and are accounted for as warranty obligations in accordance with guarantee and loss contingency accounting guidance.

Under the consignment model, small quantities of inventory are held at healthcare provider locations to ensure availability when a patient is identified. No revenue is recognized upon delivery of our products to the healthcare provider locations, as we retain the ability to control the inventory. Rather, revenue is recognized when the product is consumed by a patient. For the twelve months ended December 31, 2024 and December 31, 2023, the Company derived 15% and 5% of total revenue, respectively from consignment sales.

Our contracts may contain some form of variable consideration such as prompt-pay discounts, tier-volume price discounts and for the Commercialization Agreement, revenue share. Variable consideration, such as discounts and prompt-pay incentives, are treated as a reduction in revenue and variable considerations, such as revenue share, is treated as an addition in revenue when the product sale is recognized. The amount of variable consideration that is included in the transaction price may be constrained 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, when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint requires the use of management judgment. Depending on the variable consideration, we develop estimates for the expected value based on the terms of the agreements, historical data, geographic mix, reimbursement rates and market conditions.

Contract assets consist of unbilled receivables from customers and are recorded at net realizable value and relate to the revenue share variable consideration from the Commercialization Agreement.

Cost of Sales

The Company uses third-party contract manufacturers to manufacture Eversense and related components and supplies. Cost of sales includes raw materials, contract manufacturing service fees, expected warranty costs, recall costs, product obsolescence, scrap, third-party warehousing, shipping and handling expenses associated with product delivery, and employee-related costs of the internal supply chain and manufacturing team.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities in developing Eversense, including clinical trials and feasibility studies, and partnerships for strategic initiatives including insulin delivery and new indications. Research and development expenses include compensation and benefits for research and development employees including stock-based compensation, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, costs related to regulatory operations, fees paid to contract research organizations and other consultants, and other outside expenses. Research and development expenses are expensed as incurred.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, commissions, and other related costs, including stock-based compensation, for personnel in the Company's sales and marketing, executive, finance, accounting, business development, information technology, and human resources functions. Other significant costs include information technology, website design and advertising, educational and promotional materials, tradeshow expenses, marketing programs, facility costs, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

Stock-Based Compensation

The Company accounts for stock-based compensation related to stock option grants and restricted stock units under stock incentive plans, purchases under the employee stock purchase plan, as well as inducement stock grants based on the fair value of those awards at the date of grant. The estimated fair value of stock options on the date of grant is amortized on a straight-line basis over the requisite service period of the individual award, which typically equals the vesting period. Forfeitures are accounted for in the period in which they occur.

The Company uses the Black-Scholes-Merton option pricing model ("Black-Scholes Model") to determine the fair value of stock-option awards. Valuation of stock awards requires management to make assumptions and to apply judgment to determine the fair value of the awards. These assumptions and judgments include estimating the fair value of the Company's common stock, the risk-free interest rate, future volatility of the Company's stock price, dividend yields, and the expected life of the stock-option awards. Changes in these assumptions can affect the fair value estimate.

The risk-free interest rate assumption is based on observed interest rates for constant maturity U.S. Treasury securities consistent with the expected life of employee stock options. The expected life represents the period of time the stock options are expected to be outstanding and is based on the simplified method. Under the simplified method, the expected life of an option is presumed to be the mid-point between the vesting date and the end of the contractual term. The Company uses the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options. Expected volatility is based on the daily closing prices of the Company as well as the daily closing prices of a peer group of comparable publicly traded companies in similar stages of development. The Company has assumed no dividend yield because it does not expect to pay dividends in the future, which is consistent with its history of not paying dividends.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and

are measured using the enacted tax rates and laws that are in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

Management uses a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return, as well as guidance on derecognition, classification, interest and penalties and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. In the ordinary course of business, transactions occur for which the ultimate outcome may be uncertain. Management does not expect the outcome related to accrued uncertain tax provisions to have a material adverse effect on the Company's financial position, results of operations or cash flows. The Company recognizes interest and penalties accrued on any unrecognized tax positions as a component of income tax expense.

The Company is subject to taxation in various jurisdictions in the United States and remains subject to examination by taxing jurisdictions for the year 2004 and all subsequent periods due to the availability of NOL and tax credit carryforwards. In addition, all of the net operating losses and research and development credit carryforwards that may be used in future years are still subject to adjustment.

Fair Value of Financial Instruments

Under ASC 825, the Company is required to disclose the fair value of financial instruments that are not recognized at fair value in the statement of financial position for which it is practicable to estimate that value. The carrying amounts of cash, cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The Company's term loan under the 2025 Notes, Loan and Security Agreement and warrants are recorded at historical cost, net of discounts. The fair value for debt is estimated by a discounted cash flow model using a discount rate equal to the rate currently offered on similar borrowings. The associated embedded conversion features in the Notes are derivative instruments and along with Options are remeasured at fair value each reporting period. The valuation methodology for derivative instruments are described further within Note 18 – Fair Value Measurements.

Recent Accounting Pronouncements

Recently Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires that an entity report segment information in accordance with Topic 280, Segment Reporting. The amendment in the ASU is intended to improve reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments in this update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, on a retrospective basis, with early adoption permitted. We adopted ASU 2023-07 on December 31, 2024 on a retrospective basis and the adoption resulted in enhanced disclosures as included in Note 19, Segment Information.

Not Yet Adopted

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"), the objective of which is to enhance the transparency of income tax disclosures by requiring greater disaggregation of information presented and consistent categories in the rate reconciliation. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, or our fiscal year 2025, using either a prospective or retrospective transition method, and early adoption is permitted. The Company is currently evaluating the impact of the new standard on its financial statements and disclosures.

In November 2024, the FASB issued Accounting Standards Update ("ASU") No. 2024-03, Disaggregation of Income Statement Expenses (DISE) ("ASU 2024-03"), the objective of which is to provide greater transparency about an

entity's expenses to allow investors to better understand an entity's performance, assessing its prospects for future cash flows, and comparing its performance both over time and with that of other entities. ASC 2024-03 is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. The requirements will be applied prospectively with the option for retrospective application. Early adoption is permitted. The Company is currently evaluating the impact of the new standard on its financial statements and disclosures.

4. Revenue Recognition

Revenues by geographic region

The following table sets forth net revenues derived from the Company's two primary geographical markets, the United States and outside of the United States, based on the geographic location to which the Company delivers the product, for the years ended December 31, 2024 and 2023:

	December 31, 2024		December 31, 2023	
(Dollars in thousands)	Amount	% of Total	Amount	% of Total
Revenue, net:				
United States	$ 15,278	68.0 %	$ 14,053	62.8 %
Outside of the United States	7,194	32.0	8,337	37.2
Total	$ 22,472	100.0 %	$ 22,390	100.0 %

Contract Assets

Contract assets consist of unbilled receivables from customers and are recorded at net realizable value and relate to the revenue share variable consideration from the Ascensia Commercialization Agreement. Accounts receivable – related parties, net as of December 31, 2024 and 2023 included unbilled accounts receivable of $0.9 million and $1.5 million, respectively. The Company expects to invoice and collect all unbilled accounts receivable within 12 months.

Concentration of Revenues and Customers

Net revenue from the Company's distribution arrangement with Ascensia, a related party, accounted for 82%, and 93% of total net revenues for the years ended December 31, 2024 and 2023, respectively. Revenue earned under consignment arrangements with healthcare providers accounted for approximately 15% and 5% of total net revenues from the years ended December 31, 2024 and 2023, respectively. Ascensia earns a commission on sales made through the consignment channel. Revenues for these corresponding periods represent sales of sensors, transmitters, and miscellaneous Eversense system components.

5. Net Loss per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. An aggregate of 83,951,061 shares of common stock issuable upon the exercise of the PHC Exchange Warrant Shares and the Purchase Warrant Shares held by PHC are included in the number of outstanding shares used for the computation of basic net loss per share for both years presented. Since the shares are issuable for little or no consideration, sometimes referred to as "penny warrants", they are considered outstanding in the context of earnings per share, as discussed in ASC 260-10-45-13.

Dilutive net loss per share is computed using the weighted average number of common shares outstanding during the period and, when dilutive, potential common share equivalents. Potentially dilutive common shares consist of

shares issuable from restricted stock units, stock options, warrants and the Company's convertible instruments. Potentially dilutive common shares issuable upon vesting of restricted stock units and exercise of stock options and warrants are determined using the average share price for each period under the treasury stock method. Potentially dilutive common shares issuable upon conversion of the Company's convertible instruments are determined using the if converted method. The if-converted method assumes conversion of convertible securities at the beginning of the reporting period. Interest expense, dividends, and the changes in fair value measurement recognized during the period are added back to the numerator. The denominator includes the common shares issuable upon conversion of convertible securities.

In periods of net loss, all potentially dilutive common shares are excluded from the computation of the diluted net loss per share for those periods, as the effect would be anti-dilutive.

(Dollars, in thousands, except per share amounts)

	2024	2023
Net loss	$ (78,616)	$ (60,392)
Basic weighted average common shares outstanding	629,721,584	567,974,492
Net loss per share:		
Basic and diluted	$ (0.12)	$ (0.11)

Outstanding anti-dilutive securities not included in the diluted net loss per share calculations were as follows:

	2024	2023
Stock-based awards	36,337,178	27,609,566
2025 Notes	15,813,176	15,813,176
Series B Preferred Stock	30,372,058	30,372,058
Warrants	47,154,786	1,260,183
Total anti-dilutive shares outstanding	129,677,198	75,054,983

6. Marketable Securities

There were no marketable securities held as of December 31, 2024.

Marketable securities as of December 31, 2023, were as follows (in thousands):

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
Commercial Paper	$ 7,598	—	—	$ 7,598
Corporate debt securities	$ 7,980	1	—	$ 7,981
Asset backed securities	$ —	—	—	$ —
Government and agency securities	$ 18,180	—	(12)	$ 18,168
Total	$ 33,758	$ 1	$ (12)	$ 33,747

The Company periodically reviews its portfolio of debt securities to determine if any investment is impaired due to credit loss or other potential valuation concerns. For debt securities where the fair value of the investment is less than the amortized cost basis, the Company assesses at the individual security level, for various quantitative factors including, but not limited to, the nature of the investments, changes in credit ratings, interest rate fluctuations, industry analyst reports, and the severity of impairment. Unrealized losses on available-for-sale securities as of December 31, 2023 were

not significant and were primarily due to changes in interest rates and not due to increased credit risk associated with specific securities.

7. Inventory, net

Inventory, net consisted of the following (in thousands):

	December 31,	
	2024	2023
Work-in-process	$ 3,213	$ 5,332
Finished goods	781	2,160
Raw materials	427	1,284
Total	$ 4,421	$ 8,776

The Company recorded $4.3 million and $0.2 million in cost of sales for the years ended December 31, 2024 and 2023, respectively, to reduce the value of inventory for items that are potentially obsolete due to expiry, in excess of product demand, or to adjust costs to their net realizable value. These costs were primarily write offs of our existing Eversense E3 systems following obtaining FDA 510(k) clearance to sell Eversense 365. In addition, we incurred $0.6 million in cost of sales due to impairment losses on prepayments to suppliers as the result of the transition from Eversense E3 to Eversense 365 system.

The Company capitalizes inventory costs associated with products when future commercialization is considered probable and the future economic benefit is expected to be realized, which is typically when regulatory approval is obtained. As such, the Company began capitalizing costs related to the 365-day product inventory in September 2024 upon successfully obtaining FDA 510(k) clearance. Prior to regulatory approval, the Company expensed all inventory-related costs, including that used for clinical development, to research and development expenses. We expect this to impact the cost of sales as the pre-clearance inventory is sold to customers. The Company incurred $1.9 million and $0.3 million in product costs prior to the clearance for the years ended December 31, 2024 and 2023, which primarily consisted of work in process inventory. If we were to have included those costs previously expensed as a component of cost of sales, our cost of sales for the year ended December 31, 2024 would have been approximately $1.6 million higher, for a total cost of sales of $23.5 million. As a result, costs of sales related to sales of the 365-day product will initially reflect a lower average cost per unit over approximately the next quarter as the previous expensed inventory is fully exhausted.

8. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Contract manufacturing[1]	$ 2,720	$ 4,244
Tax credits receivable[2]	1,793	1,793
Clinical and Preclinical	689	343
IT and software	228	242
Sales and Marketing	104	20
Rent and utilities	99	122
Insurance	97	73
Accounting and Audit	71	61
Interest receivable	—	272
Research and development	—	95
Other	18	1
Total prepaid expenses and other current assets	$ 5,819	$ 7,266

(1) Includes deposits to contract manufacturers for manufacturing process
(2) Refundable employee retention credits, enacted under the CARES Act.

9. Property, Equipment and Intangible Assets, net

Property, equipment and intangible assets, net consisted of the following as of December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Property and equipment		
Machinery and laboratory equipment	$ 3,156	$ 2,783
Office furniture and equipment	606	354
Leasehold improvements	2,201	530
Intangible assets		
Sensor insertion network assets	800	—
Less: Accumulated depreciation and amortization	(2,689)	(2,483)
Property, equipment and intangible assets, net	$ 4,074	$ 1,184

Depreciation and amortization expense for the years ended December 31, 2024 and 2023 was $0.6 million and $0.4 million, respectively. During 2024, the Company disposed of fully depreciated office furniture and equipment in the amount of $0.4 million. There was no gain or loss on these disposals. There were no material disposals during 2023.

In November 2024, the Company acquired the sensor insertion network assets of NPG to directly contract with healthcare providers under our Eon Care subsidiaries. The purchase price of $0.7 million was satisfied in exchange for the settlement of a portion of NPG's outstanding accounts receivable balance. The total value of the sensor insertion network assets of $0.8 million includes the agreed-upon purchase price, the fair value of contingent consideration, and transaction costs. These intangible assets will allow us to further expand patient access to sensor insertion options and enhance convenience. The intangible assets will be amortized over a 5-year period. Over the next five years, the annual amortization expense for these finite life intangible assets will total approximately $0.8 million, as follows: less than $0.2 million in each of the years 2025-2028 and $0.1 million in 2029.

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Compensation and benefits	$ 5,311	$ 4,799
Research and development	3,416	3,846
Contract manufacturing	1,813	1,457
Professional and administration services	1,587	673
Sales and marketing services	1,287	301
Interest on notes payable	789	704
Operating lease	429	368
Product warranty and replacement obligations	406	514
Accrued construction and renovations costs	397	—
Other	71	27
Total accrued expenses and other current liabilities	$ 15,506	$ 12,689

11. Leases

The Company leases approximately 33,000 square feet of research and office space for its corporate headquarters under a non-cancelable operating lease. In May 2023, the Company amended our lease, extending the lease term through 2033, and obtained a tenant improvement allowance of $1.3 million. The Company accounted for the amendment as a lease modification and remeasured the ROU asset and lease liability as of the amendment date, which resulted in an increase of $2.5 million to the ROU asset, and an increase of $3.8 million to the lease liability. The Company has one option to extend the term for an additional period of five years beginning on June 1, 2033. The rent expense is recognized on a straight-line basis through the end of the lease term, excluding option renewals. The difference between the straight-line rent amounts and amounts payable under the lease is recorded as deferred rent.

On July 31, 2019, the Company entered into a non-cancellable operating lease agreement for approximately 30,500 square feet of office space commencing on September 2, 2019 and expiring in 2023. The Company did not have any lease related payments made to the lessor before the commitment date, lease incentives received from the lessor or initial direct cost adjustments to be added to the initial measurement of the liability. This facility was decommissioned in 2021 and an impairment charge of $0.5 million was recorded. The Company continued to make lease payments through the lease expiration date.

Operating lease expense for the years ended December 31, 2024 and 2023 was $0.9 million and 0.8 million, respectively.

The following table summarizes the lease assets and liabilities as of December 31, 2024 and 2023 (in thousands):

		December 31,	
Operating Lease Assets and Liabilities	**Balance Sheet Classification**	**2024**	**2023**
Assets			
Operating lease ROU assets	Deposits and other assets	$ 4,837	$ 5,180
Liabilities			
Current operating lease liabilities	Accrued expenses and other current liabilities	$ 429	$ 368
Non-current operating lease liabilities	Non-current operating lease liabilities	5,785	6,214
Total operating lease liabilities		$ 6,214	$ 6,582

The following table summarizes the maturity of undiscounted payments due under operating lease liabilities and the present value of those liabilities as of December 31, 2024 (in thousands):

2025	$ 939
2026	967
2026	996
2027	1,026
2028	1,057
Thereafter	3,851
Total	8,836
Present value adjustment	(2,622)
Present value of lease liabilities	$ 6,214

The following table summarizes the weighted-average lease term and weighted-average discount rate as of December 31, 2024 and 2023:

Remaining lease term (years)	2024	2023
Operating leases	8.4	9.4
Discount rate		
Operating leases	8.5 %	8.5 %

During the years ended December 31, 2024 and 2023, the Company made cash payments of $0.9 million and $1.1 million, respectively included in the measurement of its operating lease liabilities.

12. 401(k) Plan

The Company has a defined contribution 401(k) plan available to all full-time employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal income tax regulations. Participants are fully vested in their contributions. The Company has provided a discretionary match of up to 3% of the participant's contributions. Employer match expenses during the years ended December 31, 2024 and 2023 were $0.5 million and $0.5 million, respectively. Administrative expenses for the plan, which are paid by the Company, were not material in 2024 or 2023.

13. Notes Payable and Stock Purchase Warrants

Term Loans

Loan and Security Agreement

On September 8, 2023 (the "Effective Date"), the Company entered into a loan agreement (the "Loan and Security Agreement") with Hercules Capital, Inc. and its managed fund (collectively, the "Lenders"), pursuant to which the Lenders have agreed to make available to Senseonics up to $50.0 million in senior secured term loans (the "Term Loan Facility"), consisting of (i) an initial term loan of $25.0 million (the "Tranche 1 Loan"), which was funded on the Effective Date and (ii) two additional tranches of term loans in the amounts of up to $10.0 million (the "Tranche 2 Loan") and $15.0 million (the "Tranche 3 Loan"), respectively, which will become available to Senseonics upon Senseonics' satisfaction of certain terms and conditions set forth in the Loan and Security Agreement. In December 2023, the Company met the terms and conditions to draw on Tranche 2 Loan and the loan was funded on January 2, 2024 in an amount of $10.0 million. The loans under the Loan and Security Agreement mature on September 1, 2027 (the "Maturity Date").

The loans under the Loan and Security Agreement bear interest at an annual rate equal to the greater of (i) the prime rate as reported in The Wall Street Journal plus 1.40% and (ii) 9.90%. Borrowings under the Loan and Security Agreement are repayable in monthly interest-only payments through (a) initially, September 1, 2026 and (b) if the Company satisfies the Interest Only Extension Conditions (as defined in the Loan and Security Agreement), the Maturity Date. After the interest-only payment period, borrowings under the Loan and Security Agreement are repayable in equal monthly payments of principal and accrued interest until the Maturity Date.

At the Company's option, the Company may prepay all or any portion of the outstanding borrowings under the Loan and Security Agreement, subject to a prepayment fee equal to (a) 3.0% of the principal amount being prepaid if the prepayment occurs within one year of the Effective Date, 2.0% of the principal amount being prepaid if the prepayment occurs during the second year following the Effective Date, and 1.00% of the principal amount being prepaid if the prepayment occurs more than two years after the Effective Date and prior to the Maturity Date. In addition, the Company paid $425,000 in facility fees upon drawing Tranche 1 and Tranche 2 loans. The Company will pay additional facility charges in connection with any borrowing of the Tranche 3 Loan, in the amount of 0.50% of the amount. The Loan and Security Agreement also provides for an end of term fee in an amount equal to 6.95% of the aggregate principal amount of loan advances actually made under the Loan and Security Agreement, which fee is due and payable on the earliest to occur of (i) the Maturity Date, (ii) the date the Company prepays the outstanding loans in full, and (iii) the date that the secured obligations become due and payable. The end of term fee is accreted to interest expense over the term of the loans.

The Company's obligations under the Loan and Security Agreement are secured, by a first-priority security interest in substantially all of its assets. The Loan and Security Agreement contains a minimum cash covenant that requires the Company to hold unrestricted cash equal to 30% of the outstanding loan amount under the Loan and Security Agreement. The Loan and Security Agreement also contains a performance covenant, commencing on July 1, 2024, that requires the Company to generate net product revenue on a trailing six-month basis in excess of specified percentage for applicable measuring periods. The performance covenant shall be waived at any time in which either (a) the Company's market capitalization exceeds $550.0 million and the Company maintains unrestricted cash equal to at least 50% of the total amounts funded, or (b) the Company maintains unrestricted cash equal to at least 80% of the total amounts funded

In addition, the Loan and Security Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, corporate changes, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions. The Loan and Security Agreement also contains events of default including, among other things, payment defaults, breach of covenants, material adverse effect, breach of representations and warranties, cross-default to material indebtedness, bankruptcy-related defaults, judgment defaults, revocation of certain government approvals, and the occurrence of certain adverse events. Following an event of default and any applicable cure period, a default interest rate equal to the then-applicable interest rate plus 4.0% may be applied to the outstanding amount, and the Lenders will have the right to accelerate all amounts outstanding under the Loan and Security Agreement, in addition to other remedies available to them as secured creditors of the Company. The Company was in compliance with all covenants as of December 31, 2024.

In addition, in connection with the issuance of the Tranche 1 Loan the Company issued warrants to the Lenders (collectively, the "Tranche 1 Warrants") to acquire an aggregate of 832,362 shares of the Company's common stock at an exercise price of $0.6007 per share (the "Tranche 1 Warrant Shares"). The Warrants may be exercised through the earlier of (i) the seventh anniversary of the Effective Date and (ii) the consummation of certain acquisition transactions involving the Company, as set forth in the Tranche 1 Warrants. The number of Tranche 1 Warrant Shares for which the Tranche 1 Warrants are exercisable and the associated exercise price are subject to certain customary proportional adjustments for fundamental events, including stock splits and reverse stock splits, as set forth in the Tranche 1 Warrants. The proceeds from the Loan and Security Agreement were allocated between the Tranche 1 Loan and the Tranche 1 Warrants based on their respective fair value of $25.0 million and $0.4 million, and the amount allocated to the Tranche 1 Warrants was recorded in equity resulting in a debt discount to the Tranche 1 Loan that is being amortized as additional interest expense over the term of the loan agreement using the effective interest method. On January 2,

2024, in connection with the issuance of the Tranche 2 Loan the Company issued additional warrants to the Lenders (collectively, the "Tranche 2 Warrants") to acquire an aggregate of 347,887 shares at an exercise price of $0.5749 per share (the "Tranche 2 Warrant Shares"). The Company estimated the fair value of the Tranche 2 Warrants as of the grant date to be $0.1 million and classified the full amount in equity.

In connection with Loan and Security Agreement, the Company incurred $1.1 million in debt issuance costs and debt discounts which are netted against the principal balance of the initial term loan and amortized as interest expense over the term of the initial term loan using an effective interest rate of 12.92%. The fair value of the Company's Loan and Security Agreement was $37.0 million as of December 31, 2024.

Pursuant to the Loan and Security Agreement, the Company also agreed to issue additional seven year term warrants upon the funding of the Tranche 3 Loan, which warrants would be exercisable for an aggregate number of shares equal to 2.0% of the funded loan amount divided by the exercise price equal to the three-day volume-weighted average price at the time of the advance.

Stock Purchase Warrants

Securities Purchase Agreement

On March 13, 2023, pursuant to the Securities Purchase Agreement with PHC, the Company issued and sold to PHC in a private placement a warrant (the "Purchase Warrant") to purchase 15,425,750 shares of common stock (the "Purchase Warrant Shares"). The Purchase Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per Purchase Warrant Share. On the private placement closing date, the Company received aggregate gross proceeds of $15.0 million, before deducting private placement expenses payable by the Company. All or any part of the Purchase Warrant is exercisable by the holder at any time and from time to time.

The Company determined that the Purchase Warrant shall be classified as equity in accordance with ASC Topic 480, Distinguishing Liabilities from Equity and ASC Topic 815. At issuance, the Company recorded the estimated fair value of the Purchase Warrant in the amount of $14.3 million as additional paid-in-capital in the Company's consolidated balance sheets.

Because PHC was an existing stockholder of the Company at the time of the transaction, the $0.7 million excess of the purchase price over the fair value of the Purchase Warrant was recognized as an equity transaction and recorded as a capital contribution made by PHC to the Company as additional paid-in-capital in the Company's consolidated balance sheets.

Additionally, on March 13, 2023, the Company entered into the Exchange Agreement with PHC, pursuant to which PHC agreed to exchange (the "PHC Exchange") its $35.0 million aggregate principal amount of the PHC Notes, including all accrued and unpaid interest thereon, for a warrant (the "PHC Exchange Warrant") to purchase up to 68,525,311 shares of common stock (the "PHC Exchange Warrant Shares"). The PHC Exchange Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per PHC Exchange Warrant Share. All or any part of the PHC Exchange Warrant is exercisable by the holder at any time and from time to time. The number of PHC Exchange Warrant Shares represents the number of shares of common stock previously issuable upon conversion of the PHC Notes, in accordance with the original terms of the notes, including a number of shares in respect of accrued and unpaid interest through the closing date, plus additional shares with a value of $675,000 reflecting a portion of the future interest payments forgone by PHC. On March 31, 2023 (6:00 am Japan Standard Time on April 1, 2023), the PHC Exchange was consummated, and the Company issued the PHC Exchange Warrant in consideration for the cancellation of the PHC Notes.

The Company determined that the PHC Exchange Warrant shall be classified as equity in accordance with ASC 480 and ASC 815. At March 31, 2023, the Company recorded the estimated fair value of the PHC Exchange Warrant in the amount of $48.6 million as additional paid-in-capital in the Company's consolidated balance sheets.

As of December 31, 2024, the Purchase Warrant and the PHC Exchange Warrant remained unexercised and outstanding. As they are prefunded warrants, the Company included the entirety of the warrant shares as weighted average outstanding shares in the calculation of its basic earnings per share.

Convertible Notes

PHC Notes

On August 9, 2020, the Company entered into a Note Purchase Agreement (the "Note Purchase Agreement") with PHC, as the purchaser (together with the other purchasers from time to time party thereto, the "Note Purchasers") and Alter Domus (US) LLC, as collateral agent. Pursuant to the Note Purchase Agreement, the Company borrowed $35.0 million in aggregate principal through the issuance and sale of PHC Notes on August 14, 2020 (the "Closing Date"). The Company also issued 2,941,176 shares of its common stock, $0.001 par value per share to PHC as a financing fee (the "Financing Fee Shares") on the Closing Date. The Financing Fee Shares were recorded as debt discount in the amount of $1.5 million.

The PHC Notes were senior secured obligations of the Company and were guaranteed on a senior secured basis by the Company's wholly owned subsidiary, Senseonics, Incorporated. Interest at the annual rate of 9.5% was payable semi-annually in cash or, at the Company's option, payment in kind. The interest rate decreased to 8.0% in April 2022 as a result of the Company having obtained FDA approval for the 180-day E3 Eversense system for marketing in the United States. The maturity date for the PHC Notes is October 31, 2024 (the "Maturity Date"). The obligations under the PHC Notes were secured by substantially all of the Company's and its subsidiary's assets.

Each $1,000 of principal of the PHC Notes (including any interest added thereto as payment in kind) was convertible into 1,901.7956 of shares of the Company's stock, equivalent to a conversion price of approximately $0.53 per share, subject to specified anti-dilution adjustments, including adjustments for the Company's issuance of equity securities on or prior to April 30, 2022 below the conversion price. In addition, following a notice of redemption or certain corporate events that occur prior to the maturity date, the Company would have been required, in certain circumstances, to increase the conversion rate for a holder who elects to convert its PHC Notes in connection with such notice of redemption or corporate event. In certain circumstances, the Company would have been required to pay cash in lieu of delivering make whole shares unless the Company obtained stockholder approval to issue such shares.

Subject to specified conditions, on or after October 31, 2022, the PHC Notes would have become redeemable by the Company if the closing sale price of the common stock exceed 275% of the conversion price for a specified period of time and subject to certain conditions upon 10 days prior written notice at a cash redemption price equal to the then outstanding principal amount (including any payment in kind interest which has been added to such amount), plus any accrued but unpaid interest. On or after October 31, 2023, the PHC Notes would have been redeemable by the Company upon 10 days prior written notice at a cash redemption price equal to the then outstanding principal amount (including any payment in kind interest which has been added to such amount), plus any accrued but unpaid interest, plus a call premium of 130% if redeemed at least six months prior to the Maturity Date or a call premium of 125% if redeemed within six months of the Maturity Date.

The Note Purchase Agreement contained customary terms and covenants, including financial covenants, such as operating within an approved budget and achieving minimum revenue and liquidity targets, and negative covenants, such as limitations on indebtedness, liens, mergers, asset transfers, certain investing activities and other matters customarily restricted in such agreements. Most of these restrictions were subject to certain minimum thresholds and exceptions. The Note Purchase Agreement also contained customary events of default, after which the PHC Notes would be due and payable immediately, including defaults related to payment compliance, material inaccuracy of representations and warranties, covenant compliance, material adverse changes, bankruptcy and insolvency proceedings, cross defaults to certain other agreements, judgments against the Company, change of control or delisting events, termination of any guaranty, governmental approvals, and lien priority.

The Company also had the option to sell and issue PHC up to $15.0 million of convertible preferred stock on or before December 31, 2022 (the "PHC Option"), which was initially contingent upon obtaining FDA approval for the

180-day Eversense E3 product for marketing in the United States before such date, and which the Company successfully obtained in February 2022. The PHC option was not exercised and expired on December 31, 2022.

The Note Purchase Agreement also contained several provisions requiring bifurcation as a separate derivative liability including an embedded conversion feature, mandatory prepayment upon event of default that constitutes a breach of the minimum revenue financial covenant, optional redemption upon an event of default, change in interest rate after PMA approval and default interest upon an event of default. On the date of issuance, the Company recorded the fair value of the embedded features in the amount of $25.8 million as a derivative liability in the Company's consolidated balance sheets in accordance with ASC Topic 815, Derivatives and Hedging. The derivative was adjusted to fair value at each reporting period, with the change in the fair value recorded in change in fair value of derivatives that is a component of other income (expense) in the Company's consolidated statement of operations and comprehensive loss.

In connection with the issuance of the Note Purchase Agreement, the Company incurred $2.9 million in debt issuance costs and debt discounts. The associated debt issuance costs were recorded as a contra liability in the amount of $1.4 million and are deferred and amortized as additional interest expense over the term of the notes at an effective interest rate of 29.19%. There were no conversions of the PHC Notes prior to the exchange of the PHC Notes for the PHC Exchange Warrant described above.

As described above, the PHC Exchange was consummated on March 31, 2023, whereby PHC exchanged the PHC Notes in $35.0 million principal amount and all accrued and unpaid interest thereon for the PHC Exchange Warrant. On March 31, 2023, the Company was released from its obligation under the PHC Notes.

Upon execution of the PHC Exchange Agreement, the exercise of the original conversion feature of the PHC Notes became remote. Accordingly, the Company remeasured the embedded derivative to its fair value of $0. The Company recognized a change in fair value of the embedded derivative of $44.2 million in the caption "Exchange related gain (loss), net" that is a component of other income (expense) in the Company's consolidated statement of operations and comprehensive loss.

The Company accounted for the PHC Exchange as an extinguishment of the PHC Notes, and thus, it derecognized the PHC Notes in its consolidated balance sheets and recognized a loss of $25.4 million as the difference between the carrying value plus accrued interest of the PHC Notes of $23.2 million and the $48.6 million fair value of the PHC Exchange Warrant as an extinguishment loss in the caption "Exchange related gain (loss), net" that is a component of other income (expense) in the Company's consolidated statement of operations and comprehensive loss. As a result of the PHC Exchange, the Company recognized a total net gain on exchange of the PHC notes of $18.8 million representing the gain on change in the fair value of the PHC Notes conversion feature recognized as an embedded derivative and the loss on extinguishment of the PHC Notes in exchange for the PHC Exchange Warrant.

2025 Notes

In July 2019, the Company issued $82.0 million in aggregate principal amount of 2025 Notes. The 2025 Notes are general, unsecured, senior subordinated obligations of the Company and bear interest at a rate of 5.25% per year, payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2020. The 2025 Notes matured on January 15, 2025 and the Company repaid the outstanding principal and accrued interest.

The Company used $37.9 million of the net proceeds from the issuance of the 2025 Notes to repurchase $37.0 million aggregate principal amount of the Company's outstanding 2023 Notes, at a purchase price equal to the principal amount thereof, plus accrued and unpaid interest thereon.

The 2025 Notes are convertible, at the option of the holders, into shares of the Company's common stock, at an initial conversion rate of 757.5758 shares per $1,000 principal amount of the 2025 Notes (equivalent to an initial conversion price of approximately $1.32 per share).

The Company may redeem for cash all or part of the 2025 Notes, at its option, if (1) the last reported sale price of the Company's common stock has been at least 150% of the conversion price then in effect for at least 20 trading days

(whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption and (2) a registration statement covering the resale of the shares of the Company's common stock issuable upon conversion of the 2025 Notes is effective and available for use and is expected to remain effective and available for use during the redemption period as of the date of the redemption notice date. The redemption price will be equal to 100% of the principal amount of the 2025 Notes to be redeemed plus accrued and unpaid interest to, but excluding, the redemption date.

If the Company undergoes a fundamental change, such as a merger, sale, greater than 50% ownership change, liquidation, dissolution or delisting, holders may require the Company to repurchase for cash all or any portion of their 2025 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2025 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, following a notice of redemption or certain corporate events that occur prior to the maturity date, the Company will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2025 Notes in connection with such notice of redemption or corporate event. In certain circumstances, the Company will be required to pay cash in lieu of delivering make whole shares unless the Company obtains stockholder approval to issue shares.

The 2025 Notes are guaranteed on a senior unsecured basis by the Company's wholly owned subsidiary, Senseonics, Incorporated. The subsidiary guarantor is 100% owned, the guarantee is full and unconditional and joint and several and the parent company has no independent assets or operations and any subsidiaries of the parent company other than the subsidiary guarantor are minor.

In connection with the issuance of the 2025 Notes, the Company incurred $4.3 million in debt issuance costs and debt discounts. Several note holders of the 2025 Notes were also note holders of the 2023 Notes, and as a result, these transactions qualified as loan modifications. The associated debt issuance costs were allocated between the portion of 2025 Notes purchased by new note holders, and of 2025 Notes purchased by existing 2023 Note holders. Loan modifications require third-party debt related costs to be expensed immediately, whereas fees paid to lenders of the modified loans are deferred. The third-party costs associated with the new note holders were also deferred as discounts that are amortized as additional interest expense over the term of the notes.

The 2025 Notes also contained an embedded conversion option requiring bifurcation as a separate derivative liability, along with the fundamental change make-whole provision and the cash settled fundamental make-whole shares provision. The Company recorded the fair value of the embedded features in the amount of $38.3 million as a debt discount and derivative liability in the Company's consolidated balance sheets in accordance with ASC Topic 815, *Derivatives and Hedging*. The derivative was adjusted to fair value at each reporting period, with the change in the fair value recorded to other income (expense) in the Company's consolidated statement of operations and comprehensive loss.

The conversion feature does not have current observable inputs such as recent trading prices (Level 3) and are measured at fair value using the binomial option pricing model and incorporate management's assumptions for probabilities of conversion occurrence through maturity, stock price, volatility, risky (bond) rate, credit spread and recovery rates.

On April 21, 2020, $24.0 million in principal on the 2025 Notes were settled pursuant to an exchange agreement. Between September 3, 2020 and January 27, 2021, $6.8 million in aggregate principal on the 2025 Notes were converted into 5,152,259 shares of common stock.

On August 10, 2023, the Company entered into separate, privately negotiated exchange agreements (the "Exchange Agreements") with a limited number of holders (the "Noteholders") of the Company's currently outstanding 2025 Notes. Under the terms of the Exchange Agreements, the Noteholders agreed to exchange with the Company (the "Exchanges") up to $30.8 million in aggregate principal amount of the 2025 Notes (the "Exchanged Notes") for a combination of $7.5 million of cash and newly issued shares of common stock (the "Exchange Shares"). The number of Exchange Shares was determined based upon the volume-weighted average price per share of the common stock during a 15-day averaging period commencing on August 11, 2023 and ending August 31, 2023. Based on the volume-weighted average price per share of the common stock during the averaging period, a total of 35.1 million shares of

common stock were issued in the Exchanges. The Exchanges were settled on the initial share issuance date of August 14, 2023 and the final settlement date of September 5, 2023.

The Company accounted for the Exchanges as an extinguishment of the Exchanged Notes and the associated embedded derivative and recognized a loss of $4.6 million in the caption "Exchange related gain (loss), net" that is a component of other income (expense) in the Company's consolidated statement of operations and comprehensive loss. The extinguishment loss represents the difference between (i) the carrying value of the Exchanged Notes (inclusive of the fair value of the embedded derivative) and (ii) the sum of $7.5 million cash payment, the fair value of the Exchanged Shares, and transaction costs incurred in the Exchange.

Following the Exchanges, approximately $20.4 million aggregate principal amount of the 2025 Notes remained outstanding. The remaining unamortized debt discount and debt issuance costs were amortized as interest expense over the term of the loan at an effective interest rate of 15.54%. The fair value of the Company's 2025 Notes, excluding the embedded features, was $20.9 million as of December 31, 2024 and $19.1 million at December 31, 2023. The fair value of the derivative at December 31, 2024 and December 31, 2023 was $0.0 million and $0.1 million, respectively. On January 15, 2025, the Company repaid the outstanding principal and accrued interest in full and the derivative was unexercised upon maturity.

2023 Notes

In January 2018, the Company issued $50.0 million in aggregate principal amount of the 2023 Notes. In February 2018, the Company issued an additional $3.0 million in aggregate principal amount of the 2023 Notes, pursuant to the partial exercise of the overallotment option by the underwriter. The 2023 Notes were general, unsecured, senior subordinated obligations and bear interest at a rate of 5.25% per year, payable semiannually in arrears on February 1 and August 1 of each year. The net proceeds from the issuance of the 2023 Notes, after deducting transaction costs, were $50.7 million. The Company paid interest semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2018. In July 2019, the Company used the net proceeds from the issuance of the 2025 Notes to repurchase $37.0 million aggregate principal amount of the outstanding 2023 Notes.

Each $1,000 of principal of the 2023 Notes were initially convertible into 294.1176 shares of the Company's common stock, which is equivalent to an initial conversion price of approximately $3.40 per share, subject to adjustment upon the occurrence of specified events. Holders may convert at any time prior to February 1, 2023. Holders who convert on or after the date that is six months after the last date of original issuance of the 2023 Notes but prior to February 1, 2021, may also be entitled to receive, under certain circumstances, an interest make-whole payment payable in shares of common stock. If specific corporate events occur prior to the maturity date, the Company will increase the conversion rate pursuant to the make-whole fundamental change provision for a holder who elects to convert their 2023 Notes in connection with such an event in certain circumstances. Additionally, if a fundamental change occurs prior to the maturity date, holders of the 2023 Notes may require the Company to repurchase all or a portion of their 2023 Notes for cash at a repurchase price equal to 100% of the principal amount plus any accrued and unpaid interest.

The Company bifurcated the embedded conversion option, along with the interest make-whole provision and make-whole fundamental change provision, and in January 2018 recorded the embedded features as a debt discount and derivative liability in the Company's consolidated balance sheets at its initial fair value of $17.3 million. Additionally, the Company incurred transaction costs of $2.2 million. The debt discount and transaction costs were amortized to interest expense over the term of the 2023 Notes at an effective interest rate of 9.30%. The derivative was adjusted to fair value at each reporting period, with the change in the fair value recorded to other income (expense) in the Company's consolidated statement of operations and comprehensive loss. On January 31, 2023, the Company repaid the outstanding principal and accrued interest in full. The derivative was unexercised upon maturity and the fair value in the amount of $0.02 million was recognized as an extinguishment gain in the caption "Other income (expense)" in Company's consolidated statement of operations and comprehensive loss.

The following carrying amounts are outstanding under the Company's notes payable as of December 31, 2024 and December 31, 2023 (in thousands):

	December 31, 2024			
	Principal ($)	Debt (Discount) Premium ($)[1]	Issuance Costs ($)	Carrying Amount ($)
2025 Notes	20,399	(256)	(5)	20,138
Loan and Security Agreement	35,000	(49)	(248)	34,703

	December 31, 2023			
	Principal ($)	Debt (Discount) Premium ($)[1]	Issuance Costs ($)	Carrying Amount ($)
2025 Notes	20,399	(3,090)	(52)	17,257
Loan and Security Agreement	25,000	(733)	(329)	23,938

(1) Includes accretion of end of term fees payable at maturity

Interest expense related to the notes payable for the periods presented below is as follows (in thousands):

	Twelve Months Ended December 31, 2024				
	Interest Rate	Interest ($)	Debt Discount & Fees ($)[1]	Issuance Costs ($)	Total Interest Expense ($)
2025 Notes	5.25%	1,071	2,833	47	3,951
Loan and Security Agreement	9.90%	3,520	883	83	4,486
Total		4,591	3,716	130	8,437

(1) Includes accretion of end of term fees payable at maturity

	Twelve Months Ended December 31, 2023				
	Interest Rate	Interest ($)	Debt Discount & Fees ($)[1]	Issuance Costs ($)	Total Interest Expense ($)
2023 Notes	5.25%	69	121	—	190
2025 Notes	5.25%	2,149	5,451	91	7,691
PHC Convertible Notes	8.00%	700	1,442	88	2,230
Loan and Security Agreement	9.90%	791	184	24	999
Total		3,709	7,198	203	11,110

The following are the scheduled maturities of the Company's notes payable (including end of term fees) as of December 31, 2024 (in thousands):

2025	$	20,399
2026		12,996
2027		24,437
Total	$	57,832

14. Stockholders' Deficit

In connection with the Company's acquisition of Senseonics, Incorporated in December 2015 (the "Acquisition"), (1) all outstanding shares of common stock of Senseonics, $0.01 par value per share, were exchanged for 1,955,929 shares of the Company's common stock, $0.001 par value per share (reflecting an exchange ratio of 2.0975), (2) all outstanding shares of preferred stock were converted into shares of common stock of Senseonics, and exchanged into 55,301,674 shares of the Company's common stock, $0.001 par value per share, and (3) all outstanding options and warrants to purchase shares of common stock of Senseonics were exchanged for or replaced with options and warrants to acquire shares of the Company's common stock using the same exchange ratio.

Common Stock

As of December 31, 2024 and December 31, 2023, the Company's authorized capital stock included 1,400,000,000 and 900,000,000 shares of common stock, par value $0.001 per share, respectively. The Company had 595,351,210 and 530,364,237 shares of common stock issued and outstanding at December 31, 2024 and December 31, 2023, respectively.

Preferred Stock

As of December 31, 2024 and 2023, the Company's authorized capital stock included 5,000,000 shares of undesignated preferred stock, par value $0.001 per share. The Company had 12,000 shares of Series B Preferred Stock outstanding as of December 31, 2024 and 2023. Since the Preferred stock has a redemption feature at the option of the holder, it is classified as temporary equity.

Voting Rights

The holders of Series B Preferred Stock generally are entitled to vote with the holders of the shares of common stock on all matters submitted for a vote of holders of shares of common stock (voting together with the holders of shares of common stock as one class) on an as-converted basis and shall be entitled to a number of votes per share equal to $1,000 divided by $1.24, subject to a cap of 29.0% of total voting power.

Dividends

The Series B Preferred Stock is not entitled to dividends.

Conversion Rights

Each share of Series B Preferred Stock is initially convertible into the number of shares of the common stock of the Company, $0.001 par value per share, equal to $1,000 divided by the conversion price of $0.3951 per share, subject to customary anti-dilution adjustments, including in the event of any stock split.

Stock Purchase Warrants

On June 30, 2016, the Company issued the Oxford/SVB Warrants to purchase an aggregate of 116,581, 63,025 and 80,645 shares of common stock at an exercise price of $3.86, $2.38 and $1.86 per share, respectively. The warrants were recorded within equity based on their fair value of $0.5 million. These warrants expire on June 30, 2026, November 22, 2026, and March 29, 2027, respectively, and are classified in equity.

On March 13, 2023, the Company issued to PHC, the Purchase Warrant to purchase 15,425,750 shares of common stock. The Purchase Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per Purchase Warrant Share. The Company received aggregate gross proceeds of $15.0 million, before deducting private placement expenses payable by the Company. The warrant was recorded in equity based on its fair value of $14.3 million. Because PHC was an existing stockholder of the Company at the time of the transaction, the $0.7 million excess of the purchase price over the fair value of the Purchase Warrant was recognized as an equity transaction and recorded as a capital contribution made by PHC to the Company as additional paid-in-capital. All or any part of the Purchase Warrant is exercisable by the holder at any time and from time to time.

In addition, on March 13, 2023, the Company entered into an Exchange Agreement with PHC, and, on March 31, 2023, issued the PHC Exchange Warrant to purchase up to 68,525,311 shares of common stock in exchange for the cancellation in full of the PHC Notes, including accrued interest thereon. The PHC Exchange Warrant is a "pre-funded" warrant with a nominal exercise price of $0.001 per PHC Exchange Warrant Share. The warrant was recorded in equity based on its fair value of $48.6 million. All or any part of the Purchase Warrant is exercisable by the holder at any time and from time to time.

On September 8, 2023, the Company entered into the Loan and Security Agreement with the Lenders and issued the Tranche 1 Warrants to acquire an aggregate of 832,362 shares of common stock at an exercise price of $0.6007 per share. The Tranche 1 Warrants were recorded in equity based on their fair value of $0.4 million. On January 2, 2024, in connection with the issuance of the Tranche 2 Loan the Company issued the Tranche 2 Warrants to acquire an aggregate of 347,887 shares of common stock at an exercise price of $0.5749 per share. The Tranche 2 Warrants were recorded in equity based on their fair value of $0.1 million. The Tranche 1 Warrants and Tranche 2 Warrants may be exercised through the earlier of (i) the seventh anniversary of the issuance date and (ii) the consummation of certain acquisition transactions involving the Company, as set forth in the warrant agreement. The number of shares for which the Tranche 1 Warrants and Tranche 2 Warrants are exercisable and the associated exercise price are subject to certain customary proportional adjustments for fundamental events, including stock splits and reverse stock splits, as set forth in the warrant agreement.

On October 24, 2024, the Company entered into a securities purchase agreement with certain institutional investors and in a private placement issued the PP Warrants to purchase an aggregate of 45,714,286 shares of common stock at an exercise price of $0.35 per share. The PP Warrants were recorded within equity based on its relative fair value of $6.1 million. The PP Warrants are non-exercisable for the first six months after issuance and expire on April 29, 2030. The number of shares for which the PP Warrants are exercisable and the associated exercise price are subject to certain customary proportional adjustments for fundamental events as set forth in the warrant agreement.

15. Stock-Based Compensation

2015 Plan

In December 2015, the Company adopted the 2015 Equity Incentive Plan (the "2015 Plan"), under which incentive stock options and non-qualified stock options may be granted to the Company's employees and certain other persons in accordance with the 2015 Plan provisions. In February 2016, the Company's board of directors adopted and the Company's stockholders approved an Amended and Restated 2015 Equity Incentive Plan (the "amended and restated 2015 Plan"), which became effective on February 20, 2016. The Company's board of directors may terminate the amended and restated 2015 Plan at any time. Options granted under the amended and restated 2015 Plan expire ten years after the date of grant.

Pursuant to the amended and restated 2015 Plan, the number of shares of the Company's common stock reserved for issuance will automatically increase on January 1 of each year, beginning on January 1, 2017 and ending on January 1, 2026, by 3.5% of the total number of shares of its common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by its board of directors. As of December 31, 2024, 31,465,256 shares remained available for grant under the amended and restated 2015 Plan. Effective January 1, 2025, by virtue of the automatic increase described above, the total number of shares remaining available for grant under the amended and restated 2015 Plan was increased to 52,302,548 shares.

Inducement Plan

On May 30, 2019, the Company adopted the Senseonics Holdings, Inc. Inducement Plan (the "Inducement Plan") pursuant to which the Company reserved 1,800,000 shares of the Company's common stock for issuance. The only persons eligible to receive grants of awards under the Inducement Plan are individuals who satisfy the standards for inducement grants in accordance with NYSE American Company Guide Section 711(a), including individuals who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company. An "Award" is any right to receive the Company's common stock pursuant to the Inducement Plan, consisting of non-statutory options, restricted stock unit awards and other equity incentive awards. As of December 31, 2024, 427,569 shares remained available for grant under the Inducement Plan.

Commercial Equity Plan

On January 30, 2023, the Company adopted the Senseonics Holdings, Inc. 2023 Commercial Equity Plan (the "Commercial Equity Plan"), pursuant to which the Company reserved 10,000,000 shares of common stock for issuance. Eligible recipients under the plan are non-employees of Senseonics, including employees of our global commercial partner, Ascensia, who assist with the commercialization of our products. An "Award" is any right to receive the Company's common stock pursuant to the Commercial Equity Plan, consisting of non-statutory options and restricted stock unit awards. As of December 31, 2024, 9,360,000 shares remained available for grant under the Commercial Equity Plan.

2016 Employee Stock Purchase Plan

In February 2016, the Company adopted the 2016 Employee Stock Purchase Plan (the "2016 ESPP"). The 2016 ESPP became effective on March 17, 2016. The maximum number of shares of common stock that may be issued under the 2016 ESPP was initially 800,000 shares and will automatically increase on January 1 of each year, beginning on January 1, 2017 and ending on and including January 1, 2026, by 1.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; provided, however, the Board of Directors may act prior to the first day of any calendar year to provide that there will be no January 1 increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of common stock. At December 31, 2024 there were 22,521,176 shares of common stock available for issuance under the 2016 ESPP. Effective January 1, 2025, by virtue of the automatic increase described above, the total number of shares remaining available for issuance under the 2016 ESPP was increased to 28,474,688 shares.

The 2016 ESPP permits participants to purchase shares of the Company's common stock through payroll deductions of up to 15% of their earnings. Unless otherwise determined by the administrator, the purchase price of the shares will be 85% of the lower of the fair market value of common stock on the first day of an offering or on the date of purchase. Participants may end their participation at any time. The Company initiated its first 2016 ESPP offering period on August 1, 2019. On January 31, 2024, there were 199,066 shares purchased in connection with the offering period. On July 31, 2024, there were 207,982 shares purchased in connection with the offering period. The 2016 ESPP is considered compensatory for financial reporting purposes.

1997 Plan

On May 8, 1997, the Company adopted the 1997 Stock Option Plan (the "1997 Plan"), under which incentive stock options, non-qualified stock options, and restricted stock awards may be granted to the Company's employees and certain other persons in accordance with the 1997 Plan provisions. All awards issued under the 1997 plan are fully vested. Approximately 683,312 shares of the Company's common stock underlying remain outstanding under the 1997 Plan. Upon the effectiveness of the 2015 Plan, the Company no longer grants any awards under the 1997 Plan.

Stock Options

The Company recognizes the cost of employee and non-employee services received in exchange for awards of equity instruments, such as stock options, based on the fair value of those awards at the date of grant. The estimated fair value of stock options on the date of grant is amortized on a straight-line basis over the requisite service period for each separately vesting portion of the award for those awards with service conditions only. For awards that also contain performance conditions, expense is recognized beginning at the time the performance condition is considered probable of being met over the remaining vesting period.

Stock option activity under the plans during the years ended December 31, 2024 and 2023 is as follows:

	Number of Shares in (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Options outstanding as of December 31, 2022	11,779	$ 2.45	
Options granted	3,589	0.64	
Options exercised	(6)	0.46	
Options canceled/forfeited	(1,622)	1.22	
Options outstanding as of December 31, 2023	13,740	2.12	5.18
Options granted	3,220	0.52	
Options exercised	(12)	0.47	
Options canceled/forfeited	(2,671)	0.74	
Options outstanding as of December 31, 2024	14,277	$ 2.01	4.66
Options vested and expected to vest as of December 31, 2024	14,277	$ 2.01	
Options exercisable as of December 31, 2024	10,425	$ 2.55	3.11

The weighted average grant-date fair value of stock option awards granted in 2024 and 2023 was $0.39 and $0.47 per share, respectively.

For the years ended December 31, 2024 and 2023, 11,861 and 5,925 options were exercised, respectively, with an aggregate intrinsic value at the time of exercise of less than $0.1 million for each year.

The total fair value of options that vested during 2024 and 2023 was approximately $0.2 million and $0.5 million, respectively.

The aggregate intrinsic value of the options currently exercisable at December 31, 2024 was less than $0.1 million. The aggregate intrinsic value of stock options outstanding at December 31, 2024 was $0.07 million, which approximated the aggregate intrinsic value of options vested and expected to vest as of December 31, 2024.

The weighted average grant date fair value of the unvested stock option awards outstanding at December 31, 2024 and 2023 was $0.42 and $0.54 per share, respectively. The weighted average grant date fair value of the stock option awards vested, exercised, and forfeited/cancelled for the year ended December 31, 2024 was $0.82, $0.37 and $0.49 per share, respectively.

Fair value is estimated at each grant date under the plans using the Black-Scholes Model with assumptions summarized in the following table:

	For the year ended December 31,	
	2024	2023
Expected term of options (in years)	6.0 - 6.5	6.0 - 6.5
Expected volatility rate	83.37 - 84.99%	82.55 - 94.38%
Risk-free interest rate	3.54 - 4.45 %	3.37 - 4.73 %
Expected dividend yield	0 %	0 %

The risk-free interest rate assumption is based upon observed U.S. treasury yields for a period consistent with the expected term of the Company's employee and non-employee stock options. The expected term is the period of time for which the stock-based options are expected to be outstanding. The expected term is determined using the "simplified method" which is defined as the mid-point between the vesting date and the end of the contractual term. The Company does not pay a dividend, and is not expected to pay a dividend in the foreseeable future.

The Company utilizes comparable public companies' volatility rates as a proxy of its expected volatility for purposes of the Black-Scholes Model. Stock-based compensation expense is recorded monthly and is adjusted periodically for actual forfeitures as they occur.

Stock-based compensation expense for employee and non-employee stock options for each of the years ended December 31, 2024 and 2023, is as follows (in thousands):

	December 31,	
	2024	2023
Cost of sales	$ 44	$ 46
Research and development	230	322
Selling, general and administrative	472	290
Total stock-based compensation expense related to stock options	$ 746	$ 658

As of December 31, 2024, there was $1.1 million of total unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a weighted average period of 2.60 years.

Restricted Stock Units

The Company issued a total of 19,242,847 and 8,415,992 restricted stock units to employees of the Company during 2024 and 2023, respectively, as incentive compensation. Restricted stock units granted to employees in 2024 and 2023 vest in eight equal installments beginning with an initial accelerated vesting tranche in the month following the grant, followed by seven vesting dates every six months.

The Company issued 2,065,107 and 1,362,807 restricted stock units to members of the Board of Directors during 2024 and 2023, respectively, under the non-employee director compensation policy. These grants includes an annual grant that vests on the earlier of the first anniversary of the grant date or the next year's annual meeting of stockholders and grants issued in lieu of compensation that immediately vest upon issuance. New members of the Board of Directors may be granted initial restricted stock units which vest over a three-year period.

Restricted stock units activity under the Plans during the years ended December 31, 2024 and 2023, is as follows:

	Number of Shares in (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
RSU's outstanding as of December 31, 2022	9,779	$ 1.10	2.19
Granted	13,633	0.74	
Vested	(9,309)	0.89	
Forfeited	(234)	0.97	
RSU's outstanding as of December 31, 2023	13,869	0.89	2.29
Granted	21,308	0.45	
Vested	(11,463)	0.74	
Forfeited	(1,655)	0.60	
RSU's outstanding as of December 31, 2024	22,059	$ 0.57	2.23

For the year ended December 31, 2024, the weighted average grant date fair value of the restricted stock units granted, vested, and forfeited were $0.45, $0.74 and $0.60 per share, respectively. The weighted average grant date fair value of total restricted stock units outstanding at December 31, 2024 was $0.57 per share.

For the year ended December 31, 2023, the weighted average grant date fair value of the restricted stock units granted, vested, and forfeited were $0.74, $0.89 and $0.97 per share, respectively. The weighted average grant date fair value of restricted stock units outstanding at December 31, 2023 was $0.89 per share.

For the years ended December 31, 2024 and 2023, 11,463, and 9,309, restricted stock units were vested, respectively, with an aggregate intrinsic value at the time of vest of $4.3 million and $6.4 million, respectively.

The total fair value of the restricted stock units that vested during 2024 and 2023 were approximately $8.5 million and $8.3 million, respectively.

The aggregate intrinsic value of the restricted stock units currently outstanding at December 31, 2024 was $11.5 million.

Employee stock-based compensation expense for restricted stock units granted to employees for the years ended December 31, 2024 and 2023, respectively, is as follows (in thousands):

	December 31,	
	2024	2023
Cost of sales	$ 110	$ 63
Research and development	1,745	1,523
Selling, general and administrative	6,624	6,429
Total stock-based compensation expense related to RSUs	$ 8,479	$ 8,015

As of December 31, 2024, there was $11.3 million of total unrecognized compensation cost related to non-vested restricted stock units, which is expected to be recognized over a weighted average period of 2.23 years.

16. Income Taxes

No provision for U.S. federal or state income taxes has been recorded as the Company has incurred net operating losses since inception and provides a full valuation allowance against its net deferred income tax assets. The tax effect of temporary differences that give rise to the net deferred income tax assets (liabilities) at December 31, 2024 and 2023 is as follows (in thousands):

	December 31,	
Deferred income tax assets (liabilities)	**2024**	**2023**
Deferred Tax Assets:		
Net operating loss carryforwards	$ 152,908	$ 139,610
Capitalized start-up costs	4,999	5,721
Research and development credit carryforwards	17,057	15,326
Research and development expenditures	20,490	16,284
Stock-based compensation	1,501	1,684
Fair value of derivative liability	—	22
Other	4,146	3,181
Gross total deferred tax assets	201,101	181,828
Valuation allowance	(199,455)	(179,517)
Total deferred tax assets	$ 1,646	$ 2,311
Deferred tax liabilities:		
Right of use asset amortization	(1,601)	(1,774)
Amortization of debt discount	(45)	(537)
Total deferred tax liabilities	(1,646)	(2,311)
Net deferred tax assets (liabilities)	$ —	$ —

The net change in valuation allowance for the years ended December 31, 2024 and 2023 was a net increase of $19.9 million and $16.3 million, respectively.

The increase in valuation allowance is primarily due to deferred tax assets generated from net operating losses, research and experimental costs capitalized, and tax credits generated in 2024. This increase in valuation allowance is based on management's assessment that it is not more likely than not that the Company will realize these deferred tax assets. At December 31, 2024, the Company had gross federal and state NOL carryforwards of $703.3 million and $89.7 million, respectively and research and experimental credit carryforwards of $17.1 million. Research and experimental credit carryforwards will expire in varying amounts between 2025 and 2044. Federal NOL carryforwards in the amount of $193.3 million will expire in varying amounts between 2025 and 2037. Federal NOL carryforwards incurred in tax years 2018 and forward have an indefinite carryforward period, although limited to eighty percent of taxable income annually. State NOLs have various expiration dates beginning in 2032. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company’s ownership may result in a limitation on the amount of NOL carryforwards and research and experimental credit carryforwards which can be available in future years.

A reconciliation of the Company's estimated U.S. federal statutory rate to the Company's effective income tax rate for years ended December 31, 2024 and 2023 is as follows:

	Year Ended December 31,	
	2024	2023
Tax at U.S. Federal Statutory rate	21.00 %	21.00 %
State taxes, net	0.47	0.25
Research and development credit	2.20	3.83
State tax rates changes	4.54	(1.75)
Convertible debt transactions	—	5.73
Equity based compensation	(1.14)	(0.62)
Officers compensation	(0.76)	(0.99)
Other	(0.95)	(0.75)
(Increase) decrease in valuation allowance	(25.36)	(26.70)
Effective income tax rate	0.00 %	0.00 %

Deferred income taxes reflect temporary differences in the recognition of revenue and expense for tax reporting and financial statement purposes. Deferred tax assets (liabilities) are adjusted for changes in tax laws or tax rates of the various tax jurisdictions as of the enacted date.

A breakdown of the Company's uncertain tax positions during 2024 and 2023 is as follows (in thousands):

	2024	2023
Gross unrecognized tax benefit at beginning of year	$ 3,832	$ 3,280
Increase from tax positions taken in prior years	—	(27)
Increase from tax positions in current year	497	617
Lapse of statute of limitations / expiration	(65)	(38)
Gross unrecognized tax benefit at end of year	$ 4,264	$ 3,832

During 2023 and 2024, the Company incurred no significant amounts related to penalties and interest for filed tax returns due to taxing authorities.

If recognized, the entire amount of gross unrecognized tax benefit would favorably affect the effective income tax rate, although, due to the Company's valuation allowance there would be no net impact. The Company does not expect a significant change in its unrecognized tax positions to occur in the next twelve months.

The Company's U.S. Federal and state income tax returns from 2004 to 2024 remain subject to examination by the tax authorities. The Company's prior tax years remain open for examination, even though the statute of limitations has expired, due to the net operating losses and credits carried forward for use in prospective years.

17. Related Party Transactions

PHC has a noncontrolling ownership interest in the Company. In addition, PHC has representation on the Company's board of directors. The Company entered into a financing agreement with PHC on August 9, 2020 (see Note 13 for further discussion of the PHC Notes). Ascensia, through the ownership interests of its parent company, PHC, is a related party. For the year ended December 31, 2024, revenue from Ascensia was $18.5 million and the amount due from Ascensia was $4.9 million as of December 31, 2024. At December 31, 2024, the Company had commissions due to Ascensia in the amount of $1.2 million, estimated replacement obligations under warranties in the amount of $0.3 million and other amounts due to Ascensia of $0.3 million. We also purchase certain medical supplies from Ascensia for our clinical trials. We paid Ascensia $0.1 million for the year ended December 31, 2024 under this arrangement.

For the year ended December 31, 2023, revenue from Ascensia was $20.7 million and the amount due from Ascensia was $3.7 million as of December 31, 2023. At December 31, 2023 the Company had estimated replacement obligations under warranties in the amount of $0.5 million and other amounts due to Ascensia of $0.5 million. We also

purchase certain medical supplies from Ascensia for our clinical trials. We paid Ascensia $0.6 million for the year ended December 31, 2023 under this arrangement.

18. Fair Value Measurements

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company defines fair value as the price that would be received from selling 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 that are required to be recorded at fair value, the Company considers the principal or most advantageous market in which the Company would transact and the market-based risk measurements or assumptions that market participants would use to price the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risk. Fair value is estimated by applying the following hierarchy, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement:

Level 1 - Quoted prices in active markets for identical assets or liabilities.
Level 2 - Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3 - Inputs that are generally unobservable and typically reflect management's estimate of assumptions that market participants would use in pricing the asset or liability.

Cash and Cash Equivalents

The fair value of money market funds and other investments classified as cash and cash equivalents are based on period-end statements supplied by the various banks and brokers that hold the majority of the funds.

Derivative Financial Instruments

The valuation technique used to measure the fair value of the Company's embedded derivative instruments is valued using the binomial lattice model to estimate the fair value of the notes. Using this lattice model, the Company values the embedded derivative using the "with" and "without" approach to determine the fair value of the embedded derivatives associated with the convertible note. Under this approach, the instrument is valued "with" and "without" the bifurcated feature and the fair value of the derivative is the difference in value between the two scenarios. The lattice model incorporates assumptions such as management's assumptions for probabilities of conversion occurrence through maturity, stock price, volatility, risk-free rate, estimated credit spread, bond recovery rates and trade data when available.

The following table represents the fair value hierarchy of the Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2024 and 2023 (in thousands):

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds[1]	$ 70,613	70,613	—	—

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds[1]	$ 72,953	72,953	—	—
Commercial paper	7,598	—	7,598	—
Corporate debt securities	7,982	—	7,982	—
Government and agency securities	18,167	18,167	—	—
Liabilities				
Embedded features of the 2025 Notes	102	—	—	102

(1) Classified as cash and cash equivalents due to their short-term maturity

The following table provides a reconciliation of the beginning and ending balances of items measured at fair value on a recurring basis that used significant unobservable inputs (Level 3) (in thousands):

	Year ended December 31	
	2024	2023
Beginning Balance	$ 102	$ 52,050
Conversion of financial instruments	—	(1,109)
Gain on change in fair value of derivatives	(102)	(50,839)
Ending balance	$ —	$ 102

The recurring Level 3 fair value measurements of the embedded features of the 2025 Notes include the following significant unobservable inputs:

Unobservable Inputs	2025 Notes Assumptions	
Stock price volatility	45.0	%
Probabilities of conversion provisions	10.0 - 90.0	%
Credit spread	14.30	%

Significant changes to these assumptions would result in increases/decreases to the fair value of the liability.

The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain financial instruments within the fair value hierarchy. The Company's policy is to recognize transfers into and out of levels within the fair value hierarchy at the end of the fiscal quarter in which the actual event or change in circumstances that caused the transfer occurs. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. During the years ended December 31, 2024 and 2023, there were no transfers between Level 1, Level 2, or Level 3.

19. Segment Information

The Company views its operations and manages its business in one operating segment, which also represents one reportable segment which derives its revenues from diabetes products and services. Operating segments are defined

as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The Company CODM, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources.

The CODM assesses performance for the segment based on net loss, which is reported in the consolidated statements of operations and comprehensive loss and uses the financial information in deciding on how to invest into the Company. The measure of segment assets reported on the balance sheets as total assets.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2024 and 2023:

	Years Ended December 31,	
(in thousands)	**2024**	**2023**
Revenue	$ 22,472	$ 22,390
Less:		
Cost of goods sold	(21,939)	(19,299)
Sales and marketing expenses	(7,268)	(5,435)
Research and development expenses	(41,144)	(48,752)
General and administrative expenses	(26,963)	(24,507)
Other segment items[(1)]	(3,774)	15,211
Net loss	$ (78,616)	$ (60,392)

(1) Other segment items include interest income, interest expense, exchange related gains, gains on changes in fair value, and other income, and other expense as presented in the Company's consolidated statements of operations and comprehensive loss.

20. Litigation

From time to time, the Company is subject to litigation and claims arising in the ordinary course of business. The Company accrues for litigation and claims when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. The Company has evaluated claims in accordance with the accounting guidance for contingencies that it deems both probable and reasonably estimable, and for the periods ended December 31, 2024 and 2023 has no such contingencies.

21. Subsequent Events

The Company has evaluated all subsequent events through the filing date of this Form 10-K with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2024, and events which occurred subsequently but were not recognized in the financial statements. Except as described below there were no other subsequent events which required recognition, adjustment to or disclosure in the financial statements.

As previously disclosed in Note 13, on January 15, 2025, the Company repaid the outstanding principal and accrued interest for the 2025 Notes in the full amount of $20.9 million. The conversion option expired unexercised.

On January 31, 2025, Energy Capital converted its 12,000 shares of Series B Preferred Stock to common stock. The Company issued 30,372,058 shares of common stock to Energy Capital upon the conversion of the Series B Preferred Shares.

Subsequent to December 31, 2024, and through February 28, 2025, the Company received approximately $26.1 million in proceeds (net of commissions) from the sale of 27,628,704 shares of common stock under the Equity Distribution Agreement.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our chief executive officer, who is our principal executive officer, and our chief financial officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2024, the end of the period covered by this Annual Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission (the "SEC"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, 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 management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As we are no longer an emerging growth company and adapted our system of internal controls over financial reporting pursuant to Section 404(a) of the Sarbanes-Oxley Act, we did not identify any material weakness in our internal control over financial reporting at December 31, 2024.

Management's Report on Internal Control over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our 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. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

This Annual Report does not include an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2024 due to the Company's SOX 404(b) exemption based on Smaller Reporting Company status.

Item 9B. Other Information

During the fiscal quarter ended December 31, 2024, none of our officers or directors, as defined in Rule 16a-1(f), adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "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

We will file a definitive Proxy Statement for our 2025 Annual Meeting of Stockholders, or the 2025 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2025 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by Item 10 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Information Regarding the Board of Directors and Corporate Governance,” “Election of Directors,” “Information about our Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance.”

Item 11. Executive Compensation

The information required by Item 11 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Executive Compensation” and “Non-Employee Director Compensation.”

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

The information required by Item 12 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under Equity Compensation Plans.”

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

The information required by Item 13 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the captions “Transactions with Related Persons” and “Independence of the Board of Directors.”

Item 14. Principal Accounting Fees and Services

The information required by Item 14 is hereby incorporated by reference to the sections of the 2025 Proxy Statement under the caption “Ratification of Selection of Independent Registered Public Accounting Firm.”

PART IV

Item 15. Exhibit and Financial Statement Schedules

(a)(1) Financial Statements.

Our Consolidated Financial Statements are listed in the "Index to Consolidated Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules.

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

(a)(3) Exhibits

The exhibits listed below are filed as part of this Annual Report on Form 10-K, or are incorporated herein by reference, in each case as indicated below.

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on March 23, 2016).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended June 30, 2018 (File No. 001-37717) filed on August 8, 2018).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on October 26, 2020).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Senseonics Holdings, Inc. (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on May 22, 2024).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on August 18, 2020).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on November 8, 2022).
3.7	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on March 23, 2016).
3.8	Amendment to Bylaws of Senseonics Holdings, Inc. (incorporated by reference to Exhibit 3.7 to the Registrant's Annual Report on Form 10-K (File No. 001-37717) filed on March 5, 2021).
4.1	Registration Rights Agreement, dated as of August 9, 2020, by and between the Registrant and PHC Holding Corporation (incorporated herein by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on August 31, 2020).
4.2	Investor Rights Agreement, dated as of August 9, 2020, by and between the Registrant and PHC Holding Corporation (incorporated herein by reference to Exhibit 4.3 to Amendment No. 1 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on August 31, 2020).
4.3*	Description of Senseonics Holdings, Inc. Common Stock

Exhibit Number	Description of Document
4.4	Registration Rights Agreement, by and between Senseonics Holdings, Inc. and PHC Holdings Corporation, dated as of March 13, 2023 (incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed with the Commission on March 15, 2023).
10.1	Lease Agreement, dated as of February 4, 2008, by and between Senseonics, Incorporated and Seneca Meadows Corporate Center III Limited Partnership, as amended by the First Amendment to Lease, dated as of September 25, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.1.1	Second Amendment to Lease, by and between Senseonics, Incorporated and Seneca Meadows Corporate Center III L.L.L.P., dated as of January 21, 2016 (incorporated by reference to Exhibit 10.1.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-208984) filed on February 17, 2016).
10.2+	Amended and Restated 1997 Stock Option Plan of Senseonics, Incorporated, as amended to date (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.3+	Form of Incentive Stock Option Agreement under Senseonics, Incorporated Amended and Restated 1997 Stock Option Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.4+	Form of Nonqualified Stock Option Agreement under Senseonics, Incorporated Amended and Restated 1997 Stock Option Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.5+	Amended and Restated 2015 Equity Incentive Plan, (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 (File No. 333-210586) filed on April 4, 2016).
10.6+	Form of Stock Option Grant Notice and Stock Option Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.7+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.8+	Form of Indemnification Agreement between the Registrant and its directors and executive officers (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.9+	Amended and Restated Executive Employment Agreement by and between Senseonics, Incorporated and Timothy T. Goodnow, dated as of July 24, 2015 (incorporated by reference to Exhibit 10.10 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.10+	Amended and Restated Executive Employment Agreement by and between Senseonics, Incorporated and Mukul Jain, dated as of August 12, 2017 (incorporated by reference to Exhibit 10.10+ to the Registrant's Annual Report on Form 10-K (File No. 001-37717) filed with the Commission on March 16, 2023).
10.11+	Amended and Restated Executive Employment Agreement by and between Senseonics, Incorporated and Kenneth L. Horton, dated as of April 1, 2023 (incorporated by reference to Exhibit 10.11+ to the Registrant's Annual Report on Form 10-K (File No. 001-37717) filed with the Commission on March 16, 2023).
10.12	Form of Replacement Warrant to Purchase Common Stock issued to Oxford Finance LLC by Senseonics, Incorporated, dated as of December 7, 2015 (incorporated by reference to Exhibit 10.17 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.13+	Form of 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 4.10 to the Registrant's Registration Statement on Form S-8 (File No. 333-210586) filed on April 4, 2016).
10.14	Form of Warrant to Purchase Stock issued by the Registrant to Oxford Finance LLC and Silicon Valley Bank, dated as of June 30, 2016 (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed on August 9, 2016).

Exhibit Number	Description of Document
10.15#	Senseonics Holdings, Inc. Inducement Plan (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on June 5, 2019).
10.16+	Form of Stock Option Grant Notice and Stock Option Agreement used in connection with the Senseonics Holdings, Inc. Inducement Plan (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on June 5, 2019).
10.17	Form of Warrant to Purchase Common Stock issued to Highbridge Tactical Credit Master Fund, L.P. (incorporated herein by reference to Exhibit 10.8 to Amendment No. 1 to the Registrant's Annual Report on Form 10-K (File No. 001-37717) filed with the Commission on April 28, 2020).
10.18#	Collaboration and Commercialization Agreement, by and between the Subsidiary and Ascensia Diabetes Care Holdings AG, dated as of August 9, 2020 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on November 9, 2020).
10.19#	First Amendment to Collaboration and Commercialization Agreement, by and between the Subsidiary and Ascensia Diabetes Care Holdings AG, dated as of March 31, 2021 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on August 9, 2021).
10.20#	Second Amendment to Collaboration and Commercialization Agreement, by and between Senseonics Incorporated and Ascensia Diabetes Care Holdings AG, dated as of June 21, 2022 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on August 9, 2022).
10.21#	Third Amendment to Collaboration and Commercialization Agreement, by and between the Subsidiary and Ascensia Diabetes Care Holdings AG, dated as of April 1, 2024 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on August 8, 2024).
10.22	2023 Commercial Equity Plan, dated as of January 10, 2023 (incorporated herein by reference to Exhibit 4.1 to the Registration Statement on Form S-3 (File No. 333-269177 filed with the Commission on January 10, 2023).
10.23	Securities Purchase Agreement, by and between Senseonics Holdings, Inc. and PHC Holdings Corporation, dated as of March 13, 2023 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed with the Commission on March 15, 2023).
10.24	Form of Warrant to Purchase Common Stock issued to PHC Holdings Corporation (incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed with the Commission on March 15, 2023).
10.25	Form of Stock Option Grant Notice and Stock Option Agreement under Senseonics Holdings, Inc. 2023 Commercial Equity Plan (incorporated herein by reference to Exhibit 4.2 to the Registration Statement on Form S-3 (File No.333-269177) filed with the Commission on January 10, 2023).
10.26	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under Senseonics Holdings, Inc. 2023 Commercial Equity Plan (incorporated herein by reference to Exhibit 4.3 to the Registration Statement on Form S-3 (File No. 333-269177) filed with the Commission on January 10, 2023).
10.27	Common Stock Purchase Warrant, dated April 1, 2023 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed with the Commission on March 15, 2023).
10.28	Securities Purchase Agreement dated October 24, 2024 between Senseonics Holdings, Inc. and the purchasers party thereto. (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on October 28, 2024).
10.29+	Non-Employee Director Compensation Policy (As amended on May 25, 2021) (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on May 9, 2023).

Exhibit Number	Description of Document
10.30	Loan and Security Agreement, dated September 8, 2023, by and among the Company and Hercules Capital, Inc. (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed with the Commission on September 11, 2023).
10.31	Form of Warrant Agreement (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed with the Commission on September 11, 2023).
10.32	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form -K (File No. 001-37717) filed with the Commission on October 28, 2024).
19.1*	Insider Trading Policy
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
23.1*	Consent of KPMG LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32.1* †	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Incentive Compensation Recoupment Policy, approved October 25, 2023, incorporated by reference to Exhibit 97.1 of the Registrant's Current Report on Form 10-K filed with the SEC on March 1, 2024.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

† These certifications are being furnished herewith solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

+ Indicates management contract or compensatory plan.

Certain portions of this exhibit, indicated by asterisks, have been omitted because they are not material and are the type that the registrant treats as private and confidential.

Item 16. Form 10-K Summary

Not applicable.

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.

SENSEONICS HOLDINGS, INC.
By: /s/ Timothy T. Goodnow, Ph.D.
Timothy T. Goodnow, Ph.D.
President and Chief Executive Officer

Date: March 3, 2025

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Timothy T. Goodnow, Ph.D., and Rick Sullivan, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Senseonics Holdings, Inc., and any or all amendments (including post-effective amendments) thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully 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 and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ TIMOTHY T. GOODNOW, PH.D. Timothy T. Goodnow, Ph.D.	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 3, 2025
/s/ RICK SULLIVAN Rick Sullivan	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 3, 2025
/s/ STEPHEN P. DEFALCO Stephen P. DeFalco	Chairman of the Board of Directors	March 3, 2025
/s/ STEVEN EDELMAN, M.D. Steven Edelman, M.D.	Director	March 3, 2025
/s/ EDWARD J. FIORENTINO Edward J. Fiorentino	Director	March 3, 2025
/s/ DOUGLAS S. PRINCE Douglas S. Prince	Director	March 3, 2025
/s/ DOUGLAS A. ROEDER Douglas A. Roeder	Director	March 3, 2025
/s/ FRANCINE KAUFMAN, M.D. Francine Kaufman, M.D.	Director and Chief Medical Officer	March 3, 2025

/s/ SHARON D. LARKIN Sharon D. Larkin	Director	March 3, 2025
/s/ KOICHIRO SATO Koichiro Sato	Director	March 3, 2025
/s/ BRIAN HANSEN Brian Hansen	Director	March 3, 2025

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