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, 2021 _____

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. ☐

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 30, 2021 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 $1.66 billion based on the closing price of the registrant's common stock, as reported by the NYSE American on such date.

As of February 25, 2022, 463,145,879 shares of common stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2022 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:

- our ability to maintain regulatory approval and CE Certificates of Conformity of Eversense and Eversense E3 in the United States and the EU;
- the success of our collaboration and commercialization agreement with Ascensia Diabetes Care Holdings AG, or Ascensia;
- the timing of product launches, including Eversense E3;
- 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;
- 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;
- effects of the COVID-19 pandemic;
- 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 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 subsidiary. "Senseonics," the Senseonics logo, Eversense, Eversense XL 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 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 Eversense, Eversense XL and Eversense E3 continuous glucose monitoring, or 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, as compared to seven to 14 days for non-implantable CGM systems. We believe that Eversense provides a more convenient method of CGM by providing longer duration, superior accuracy, wireless communication, on-body vibratory alerts, gentle-on-the-skin adhesive patch, data sharing capability, and a removable smart transmitter. We affixed the CE mark to the original Eversense CGM system in June 2016, which marked the first certification for the product to be sold within the European Economic Area, or EEA. Subsequently, we affixed the CE mark to the extended life Eversense XL CGM system in September 2017 which is currently available in select markets in Europe and the Middle East. In June 2018, the U.S. Food and Drug Administration, or FDA, approved the Eversense CGM system. In June 2019, we received FDA approval for the non-adjunctive indication (dosing claim) for the 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. In February 2022, the extended life Eversense E3 CGM system was approved by the FDA and we expect Ascensia Diabetes Care Holdings AG, or Ascensia, to begin commercializing Eversense E3 in the United States in the second quarter of 2022.

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. Following information gathered from this sub-set and continued development efforts and pending developments at the FDA relating to the ongoing COVID-19 pandemic, in the first half of 2022 we plan to seek Investigational Device Exemption, or IDE, from the FDA to explore the 365 day sensor in a clinical trial. If the IDE is approved in a timely manner, we would target to begin enrollment of a clinical trial, which we also intend to include a pediatric population, in the second half of 2022.

During 2020, we initiated a new commercialization strategy and collaboration to bring our product to market. As described in detail below, in August 2020, we entered into a collaboration and commercialization agreement, or Commercialization Agreement, with Ascensia pursuant to which we granted Ascensia the exclusive right to distribute

our 90-day Eversense CGM system and our 180-day Eversense CGM system 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.

2021 and Significant Recent Developments

Eversense E3 CGM System Regulatory Approval

In February 2022, the U.S. Food and Drug Administration ("FDA") approved the Eversense E3 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 90-day Eversense CGM system and the six-month Eversense E3 system worldwide for people with diabetes, with certain initial exceptions. The Company and Ascensia have been designing the go-to-market strategy for the U.S. six-month product, and the Company expects that Ascensia will begin commercializing Eversense E3 in the U.S. in the second quarter of 2022.

As with any new product, the success of the commercial launch of the Eversense E3 product in the U.S. will be subject to significant uncertainty and risks, and will require time to ramp up. Key areas of strategic focus in the U.S. commercial launch of the six month product where performance will impact the success of the launch will be: (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 E3 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 six-month product and its benefits relative to the 90-day product, (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 90-day coverage to six month coverage, and (7) Ascensia's continued organizational development of its U.S. sales and marketing capabilities relative to CGM.

The Company and Ascensia are also developing plans for the roll-out of the Eversense E3 next generation six-month product in Europe, which, subject to receipt of regulatory approval or certification, including CE Certificates of Conformity and affixing the CE mark for the EEA, is expected to offer reduced calibration requirements from the Eversense XL six-month product currently marketed in Europe. The roll-out of this next generation product in Europe is similarly subject to uncertainties and potential delays, including regulatory approval and certification and launch timing, and European revenues are dependent, among other things, on success of the following: (1) Ascensia's continued organizational development of its European sales and marketing capabilities relative to CGM, and (2) more effective tender participation, particularly in Italian markets which favor an integrated offering. The U.S. and European commercialization plans are being designed with a goal of minimizing the impact to patients, providers, and ongoing sales of Eversense CGM systems.

COVID-19

On January 30, 2020, the World Health Organization, or the WHO, announced a global health emergency because of a new strain of coronavirus, or COVID-19, and the risks to the international community as the virus spreads globally. On March 11, 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. In response to the pandemic, many states and jurisdictions have issued stay-at-home orders and other measures aimed at slowing the spread of the coronavirus. The state of Maryland, where we are headquartered, has been affected by COVID-19. The Governor of Maryland issued an order closing all non-essential businesses, which took effect on March 23, 2020. Beginning with the initial outbreak and through 2021 substantially all of our workforce is still working from home either all or substantially all of the time. Additionally, because our sensor requires an in-clinic procedure, we saw a reduction in access to clinics and sensor insertions during multiple periods during the pandemic.

The COVID-19 pandemic infection rates in the United States are still high, vaccine distribution is ongoing, and it is difficult to predict the longevity and severity COVID-19 will have on our business.

Restructuring and Transition of Commercial Strategy

As a result of the COVID-19 pandemic's disruption to our operations, suppliers, employees, and the healthcare community in which we sell to and support, and our limited cash resources, we made significant reductions in our cost structure and operations to improve cash flow and generate future expenditure savings to ensure the long-term success of Eversense. Specifically, in the first quarter of 2020, we temporarily suspended commercial sales and marketing of the Eversense CGM System in the United States to new patients to solely focus our resources on supporting existing users, including ensuring broader insurance coverage for Eversense, and the development and regulatory submission of our new 180-day Eversense product in the United States. In connection with these actions, on March 26, 2020, we reduced our workforce by approximately 60%, over half of which were sales personnel.

As discussed further below, on August 9, 2020, we entered into the Commercialization Agreement with Ascensia pursuant to which we granted Ascensia the exclusive right to distribute our 90-day Eversense CGM system and our 180-day Eversense CGM system worldwide for people with diabetes. 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 assumed commercial responsibilities in the second quarter of 2021. In February 2022, the extended life Eversense E3 CGM system was approved by the FDA and we expect Ascensia to begin commercializing Eversense E3 in the United States in the second quarter of 2022.

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, or IDF, 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. In the next few years, we expect the growth in sales of CGM systems to be driven primarily by increased penetration of CGM in the type 1 patient population.

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, or 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 Centers for Medicare and Medicaid Services, or CMS, finalized a national payment rate for Eversense that was published in the calendar year 2020 Physician Fee Schedule Final Rule. The Eversense CGM system became the first CGM technology to be reimbursed through the Part B Medical Services benefit for Medicare beneficiaries and expands access to our product. In August 2020, the Centers for Medicare and Medicaid Services, or CMS, released its Calendar Year 2021 Medicare Physician Fee Schedule that establishes global payment for the device cost and procedure fees for healthcare providers across the United States. This includes the 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 updates global payment for the device cost and procedure fees.

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, Medtronic and Johnson and Johnson. Members of our team have contributed to the development, regulatory approval and commercialization of several glucose monitoring systems and insulin pumps.

Commercial Strategy

Historically, we have sold our product directly to our network of distributors and strategic fulfillment partners, who provide the Eversense CGM system to healthcare providers and patients through a prescribed request and invoice insurance payors for reimbursement. As noted above, we have now transitioned to selling our product globally through Ascensia and we expect Ascensia to begin commercializing Eversense E3 in the United States in the second quarter of 2022. Sales of the Eversense CGM system are widely dependent on the ability of patients to obtain coverage and adequate reimbursement from third-party payors or government agencies. Ascensia is leveraging and targeting regions where we have coverage decisions for patient device use and provider insertion and removal procedure payment.

As a result of the COVID-19 pandemic, in the first quarter of 2020, we temporarily suspended commercial sales and marketing of the Eversense CGM System in the United States to new patients to solely focus our resources on supporting existing users. In connection with these actions, on March 26, 2020, we reduced our direct sales organization that consists of sales representatives, clinical trainers, customer care, and other specialists to educate, train, and support the patient and healthcare provider in their diabetes management with CGM systems.

In the third quarter of 2020, we announced the formation of a strategic partnership with Ascensia, pursuant to which Ascensia became the exclusive worldwide distribution partner for Senseonics CGM systems, including Eversense®, Eversense® XL and future generations products. In the fourth quarter of 2020, Ascensia initiated U.S. marketing and sales activities and full transition of commercial activities took place in the second quarter of 2021 and included full marketing, market access, sales, healthcare provider training and frontline patient and provider support responsibilities.

Addressing reimbursement and access barriers has been a top priority for us and during 2021, we reached over 200 million covered lives in the U.S. through positive insurance payor coverage decisions. In 2020, we continued the Eversense Bridge Program, a patient access program in the U.S. that provides financial assistance to eligible patients whose insurance coverage either does not yet cover Eversense, or in cases where Eversense is covered but the patient's co-insurance is limiting their ability to adopt Eversense. Having played an important role in our journey to obtain broader payor policy and long-term patient retention, the Eversense Bridge Program ended on December 31, 2020. In 2021, Ascensia initiated to a patient assistance program to provide financial assistance to patients on Eversense. In 2022,

we expect Ascensia, in consultation with us, to initiate a broad patient assistance program for patients adopting Eversense E3.

In our overseas markets, we had entered into distribution agreements that allow third-party collaborators with direct sales forces and established distribution systems to market and promote Eversense XL primarily in the EMEA. These distribution arrangements have been replaced by our Commercialization Agreement with Ascensia. Our exclusive distribution agreement for sales in Scandinavia with Rubin Medical and our exclusive distribution agreement with Roche Diabetes Care for sales in the rest of the EMEA, excluding Israel and Scandinavia, and in 17 additional countries, including Brazil, Russia, India, and China, as well as select markets in the Asia Pacific and Latin American regions expired in 2021. Upon conclusion of each of these agreements, Ascensia assumed commercialization activities in select countries where Eversense XL has already launched, beginning February 1, 2021 for Germany, Italy, Switzerland, Spain, Poland, and Netherlands. The transition of Rubin markets began in June 2021.

Our net revenues are derived from sales of the Eversense CGM system which is sold in two separate kits: the disposable Eversense Sensor Pack which includes the sensor, insertion tool, and adhesive patches, and the durable Eversense Smart Transmitter Pack which includes the transmitter and charger.

Collaboration and Commercialization Agreement with Ascensia Diabetes Care Holdings AG

On August 9, 2020, we entered into a Commercialization Agreement with Ascensia Diabetes Care Holdings AG pursuant to which we have granted Ascensia the exclusive right to distribute the Company's 90-day Eversense CGM system and our 180-day Eversense CGM system worldwide for use in people with diabetes, with the following initial exceptions: (i) until January 31, 2021, the territory did not include countries 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 does 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, the extended life Eversense E3 CGM system was approved by the FDA and we expect Ascensia to begin commercializing Eversense E3 in the United States in the second quarter of 2022. Ascensia will receive a portion of net revenue at specified tiered percentages ranging from the mid-teens to the mid-forty's 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 will purchase 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 have agreed to establish a joint alliance committee and joint marketing committee, each with equal representation from each party, in order to collaborate.

Prior Distribution Agreement with Roche Diabetes Care

On May 24, 2016, we entered into an exclusive distribution agreement with Roche Diagnostics International AG and Roche Diabetes Care GmbH, or collectively, Roche. Pursuant to the agreement, as amended, we granted Roche the exclusive right to market, sell and distribute Eversense in the EMEA, excluding Scandinavia and Israel. In addition, Roche had exclusive distribution rights in 17 additional countries, including Brazil, Russia, India and China, as well as select markets in the Asia Pacific and Latin American regions.

On December 12, 2019, we amended the distribution agreement to lower minimum volumes for 2020 and increase pricing for the remaining period of the contract.

On November 20, 2020, we amended the distribution agreement and entered into a settlement agreement to facilitate transition to Ascensia as Roche sales concluded on January 31, 2021, including final purchases and transition

support activities, and Roche's obligation to purchase certain quantities of products at certain prices under the distribution agreement have now terminated.

The distribution rights under the agreement expired January 31, 2021, subject to Roche providing certain transition and wind-down services for approximately six months in markets where Ascensia was not initiating distribution.

Clinical Development and Regulatory Pathway

Overview

We affixed the CE mark to the Eversense XL CGM system in the EEA in September 2017. The Eversense XL CGM system is also being sold commercially in our overseas markets. Our Promise U.S. pivotal trial was completed during 2020. We received a Premarket Approval, or PMA, from the FDA for the Eversense E3 system in February 2022 for up to six months and we expect Ascensia to begin commercializing Eversense E3 in the United States in the second quarter of 2022.

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. Eighty-seven of the ninety enrollees completed the 90-day trial.

The clinical trial population consisted of subjects at least 18 years of age who had a clinically confirmed diagnosis of diabetes. Subjects who had a history of severe hypoglycemia, defined as hypoglycemia resulting in loss of consciousness or seizure, or diabetic ketoacidosis, in the six months prior to the trial, were excluded from participation in the clinical trial. Accuracy measurements were taken at 1 day, 30 days, 60 days, and 90 days post-insertion. These sensor measurements were continued through the earlier of the failure of the sensor or 90 days post-insertion.

The purpose of this clinical trial was to evaluate the accuracy of Eversense measurements, measured by the Mean Absolute Relative Difference, or 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.

During the trial, 75 subjects underwent unilateral sensor insertions and 15 subjects underwent bilateral sensor insertions in the clinic and used Eversense's smart transmitter and mobile app at home for the next 90 days. Subjects were blinded to the real-time glucose readings and trends during home-use and sensor readings were not used to adjust their treatment. Clinic visits were scheduled at approximately 30-day intervals in order to obtain lab reference glucose values for comparison with the sensor values and to evaluate hyperglycemic and hypoglycemic challenges in a controlled setting.

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 Eversense system. We are distributing the 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.

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. We completed enrollment in September 2019 and had our last patient complete their 180-day visit during the first quarter of 2020.

The clinical trial population consists of subjects at least 18 years of age who have had a clinically confirmed diagnosis of diabetes for at least one year. Subjects with a history of unexplained severe hypoglycemia, defined as hypoglycemia resulting in loss of consciousness or seizure, or diabetic ketoacidosis, in the six months prior to the trial were excluded from participation in the clinical trial. After screening, sensor(s) were inserted and accuracy measurements were taken at multiple visits during the first 30 days and then every 30 days to 180 days post-insertion or until sensor failure, if earlier than 180 days post-insertion. In the trial, we observed performance matching that of the current Eversense 90-day product available in the United States, with a mean absolute relative difference, or 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. As described elsewhere, we received PMA approval from the FDA for the Eversense E3 CGM system in February 2022, and we expect Ascensia to begin commercializing Eversense E3 in the United States in the second quarter of 2022.

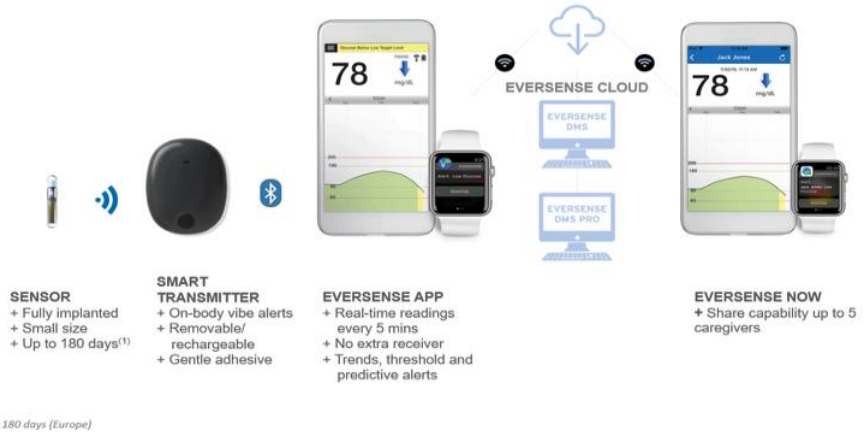
On February 26, 2020, we announced that the FDA approved a subgroup of PROMISE trial participants to continue for a total of 365 days to gather feasibility data on the safety and accuracy of a 365-day sensor. This sub-set of 30 participants who all had sensors with the modified chemistry were left undisturbed for 365 days with the goal of measuring accuracy and longevity over the full 365 days. Following information gathered from this sub-set and continued development efforts, and pending developments at the FDA relating to the ongoing the ongoing COVID-19 pandemic, in the first half of 2022 we plan to seek Investigational Device Exemption, or IDE, from the FDA. If the IDE is approved in a timely manner, we would target to begin enrollment of a clinical trial, in which we also intend to include a pediatric population, in the second half of 2022.

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 six months. Eversense requires twice daily fingerstick calibrations through day 21 and then primarily once daily fingerstick calibrations. 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 and was launched in December 2019.

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

- ***Accuracy***: Exceptional accuracy particularly in the low glucose range throughout the sensor life.
- ***Duration***: Longest available sensor duration at up to six months.
- ***Convenience***: Our Eversense CGM system supports the patient's lifestyle; the smart transmitter is water resistant, rechargeable and 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 with up to five people, including health care providers, and tracking of meals and workouts for further diabetes treatment management.
- ***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.



(1) Labeled up to 90 days (US) or 180 days (Europe)

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 six months, 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, or 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, or 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, or BLE. Our transmitter is functional for at least 24 hours following a full charge and can be fully charged in 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 reducing the once or twice daily calibrations towards a once per week calibration. Our next generation sensor under feasibility testing now is designed to extend the sensor duration even longer at up to 365 days. We expect the next generation sensor to support our goal of extending the market for long-term implantable CGM to include Type 2 patients not on intensive insulin therapy. We are also developing our “Freedom” product variation to allow for a 2-in-1 glucose monitoring system combining the functionality of CGM and Flash Glucose Monitoring, or FGM, in an implantable sensor 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 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 intensively managed patients and their healthcare providers.

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 90-day Eversense CGM system and our six-month 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 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, the extended life Eversense E3 CGM system was approved by the FDA and we expect Ascensia to begin commercializing Eversense E3 in the United States in the second quarter of 2022. In anticipation of the launch, we and Ascensia have been designing the go-to-market strategy for the U.S. six-month product.

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, or 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.

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 European experience and our feedback in the United States indicates 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.

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 200 million people in the United States may have coverage and access to the Eversense 90-day product via commercial or government (i.e., Medicare) payors. We believe that transitioning commercial payors from 90-day coverage to six-month coverage will be important for the successful commercialization of the Eversense E3 six-month CGM system.

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. Our patient access programs and patient appeals support, including the Eversense Bridge Program, which was discontinued on December 31, 2020, 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.

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, or 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 agencies 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 materials principally from only one source. 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 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 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 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 product and we expect all other CGM companies besides Dexcom 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.

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, 2021, we held a total of approximately 527 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 104 issued United States patents, 250 patents issued in countries outside the United States and 173 pending patent applications worldwide. Our patents expire between 2021 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 2044 to 2060.

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 one pending U.S. trademark applications and six pending foreign trademark applications, as well as 14 U.S. trademark registrations and 132 foreign trademark registrations.

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, or 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, or 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 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 cGMP requirements, as set forth in the 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, or 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 local government regulations, which may vary substantially from country to country. The time required to obtain approval 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 26 May 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, or 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, prior to 25 May 2017 will remain valid until the expiration of the CE Certificate of Conformity, except for EC verification CE Certificates of Conformity issued in accordance with Annex IV to the MDD and Annex 4 to the AIMD which shall become void at the latest on 27 May 2022. In addition, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD, from 25 May 2017 will remain valid until the expiration of the CE Certificate of Conformity and at the latest on 27 May 2024. Medical devices with such valid CE Certificates of Conformity issued under the MDD or the AIMD may continue to be placed on the market for the remaining validity of the CE Certificate of Conformity or until May 27, 2024 at the latest, provided that (i) the devices continue to comply with the requirements of the MDD or AIMD, (ii) there are no significant changes in the design or intended purpose and (iii) from 26 May 2021, compliance with the EU 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.

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 agencies 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 Similar Foreign and State Laws and Regulations Affecting the Transmission, Security and Privacy of Health Information

We may also be subject to 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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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), or GDPR, went into effect on May 25, 2018 and replaced Directive 95/46/EC (the EU Privacy Directive). 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 EU/EEA. Under the GDPR, fines of up to €20.0 million or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for certain categories of infractions that constitute significant non-compliance. The GDPR includes more stringent operational requirements for data processors and data controllers and creates additional rights for data subjects.

Further, the exit of the United Kingdom, or UK, from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, the UK exited the EU on January 1, 2020, subject to a transition period that ended December 31, 2020. The UK has implemented legislation similar to the GDPR, the UK GDPR, including the UK Data Protection Act, which provides for fines of up to the greater of 17.5 million British Pounds or 4% of a company's worldwide turnover, whichever is higher. Additionally, the relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear following Brexit, including with respect to regulation of data transfers between EU Member States and the UK. On June 28, 2021, the European Commission announced a decision of "adequacy" concluding that the UK ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA to the UK. Some uncertainty remains, however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. We cannot fully predict how the Data Protection Act, the UK GDPR, and other UK data protection laws or regulations may develop in the medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the UK will be regulated.

Additionally, California recently enacted legislation, effective January 1, 2020, that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered

companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allows for new causes of action for data breaches. As currently written, the CCPA could impact our business activities and is an example of the type of activity in an evolving regulatory environment related to personal data and protected health information that could continue to affect our operations.

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, or, 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, or 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.

State Fraud and Abuse Provisions

Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act, some of which apply regardless of source of payment and do not have the same exceptions as the federal laws. We believe that we are in conformance to 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.

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. The payment information is made publicly available in a searchable format on a CMS website. Over the next several years, we will need to dedicate significant resources to establish and maintain systems and processes in order to comply with these regulations. 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.

Healthcare 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 significant developments in, and continued legislative activity around, attempts to repeal or repeal and replace the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated medical device tax and the "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the PPACA. Congress and the Biden administration are considering additional health reform measures. 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 United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom, or 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 United Kingdom and the European Union have signed a EU-UK Trade and Cooperation Agreement, or 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 United Kingdom 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. 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.

Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate and may create logistical complications with respect to the movement and delivery of our products, which undergo certain manufacturing steps in the United Kingdom. Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the UK from the EU would have and how such withdrawal would affect us. Several of our contract manufacturers are located in the UK. Any of these effects of Brexit, among others, could adversely affect our business, financial condition and operating results.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, or 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.

Employees and Human Capital Resources

We believe that our future success largely 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, 2021, we had 89 employees, of whom over half hold Ph.D., M.D., master's degree or other post graduate degrees, and all of whom are located in the United States. Most employees are in operations and research and development positions aligned with our corporate focus of 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 important to us, and we focus on continuously enhancing our corporate culture. In 2021, our employees updated our core values by providing input through workshops and as a result we launched, "It Just Makes Sense," to describe how our employees are living our corporate values. 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 continue to survey our employees around culture, engagement, work experience, communication and other topics and incorporate and respond to their feedback. We will continue to conduct similar surveys and response efforts in the future. We conduct frequent company calls to update all employees on what is happening in various departments to ensure our employees understand our strategic vision as well as our day-to-day objectives. After each meeting, we hold separate open question and answer sessions that give our employees an opportunity to question or comment on anything that is on their minds.

Diversity, Equity, and Inclusion

Our success thrives on the diversity of backgrounds, knowledge, skills, ideas, and capabilities within our workforce. We aspire to create 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. At the end of 2021, our employee base was comprised of approximately one third female and two thirds male. We work to support our goals of diversifying our workforce through recruiting, retention, people development, and inclusion.

Health and Safety

We are committed to the health and safety of our employees and have safety training programs that ensure our workforce know 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 response to COVID-19, we organized an internal cross-functional task force to manage our response to the pandemic and maintain business continuity while aligning with safety protocols recommended by the World Health Organization (WHO) , the U.S. Centers for Disease Control and Prevention (CDC), and other local health agencies. In addition, to ensure the safety of our essential employees who work in our facilities during the pandemic, we implemented social distancing requirements and provided masks, hand sanitizer, and other personal protective equipment (PPE).

Organization 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, and discuss opportunities to support their career goals. During 2021, the executive team spent substantial time meeting routinely for strategic, operational, and organizational planning. Many of these meetings were focused on organization development including succession planning and the identification of high potential and high performing individuals to create development plans to ensure we foster and retain top talent. We encourage professional certification and continuing education by reimbursement for professional certification classes, testing, maintenance and tuition reimbursement of up to $5,250 annually. We continue to evaluate and enhance our learning delivery to meet the needs of our workforce.

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 made market adjustments to many of our employees effective January 1, 2022, to ensure pay equity between existing and new hires and to better position us to retain our valuable employees. 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. On December 7, 2015, pursuant to the Merger Agreement and the transactions contemplated thereby, or the Acquisition, 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, we reincorporated in Delaware and changed our name to Senseonics Holdings, Inc. 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.

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.
- 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.
- The COVID-19 pandemic has, and may continue to, materially affect our operations, including at our headquarters in Maryland and at our clinical trial sites, as well as the business and operations of our manufacturers, distributors or other third parties with whom we conduct business. We are unable to predict the extent to which the pandemic and related restrictions will impact our business, operations, financial performance and the achievement of our strategic objectives.
- 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.
- The markets in which we participate are highly competitive, and our primary competitors, as well as a number of other companies, medical researcher 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 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.
- 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 agencies, among others. Failure to comply with applicable laws and regulations should harm our business and we may incur significant expenditures related to compliance efforts.
- Holders of convertible notes 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, including net losses of $302.5 million, $175.2 million, and $115.5 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $951.0 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 and Eversense and Eversense XL 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 and do not expect to be profitable for at least the next several years. We expect our expenses to increase significantly 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, diversify our product offerings or continue our operations.

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

We have entered into a Commercialization Agreement with Ascensia, pursuant to which we have granted Ascensia the exclusive right to distribute Eversense worldwide, subject to initial exceptions based on our other current exclusive distribution agreements. 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 in future years. 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 covert 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 recent debt and preferred stock transactions 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. In addition, under the terms of the PHC Notes, we may be required to make significant payments to redeem these notes upon a change of control.

Our business, product sales and results of operations could be adversely affected by the effects of health epidemics, including the recent COVID-19 outbreak, in regions where we or third parties distribute our products or where we or third parties on which we rely have significant manufacturing facilities, concentrations, clinical trial sites or other business operations. The COVID-19 pandemic has and may continue to, materially affect our operations, including at our headquarters in Maryland and at our clinical trial sites, as well as the business or operations of our manufacturers, distributors or other third parties with whom we conduct business.

Our business could be adversely affected by health epidemics in regions where we sell products, where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and distributors upon whom we rely.

For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and several European countries. Our headquarters is located in Maryland, and our contract manufacturers are located in Germany, the United Kingdom and the United States. Our distributors are located in the United States and various countries in Europe.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government-imposed travel restrictions on travel between the United States, Europe and certain other countries. Further, the President of the United States declared the COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. Similarly, the Governor of Maryland issued an order closing all non-essential businesses, which took effect on March 23, 2020. Beginning with the initial outbreak and through 2021, substantially all of our workforce is now working from home either all or substantially all of the time. The effects of the Maryland order and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs, regulatory and commercialization timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. In particular, some of our suppliers of certain materials used in the production of our sensors and transmitters are located in Germany, the United Kingdom, China, Japan and the

United States. For example, any manufacturing supply interruption of Eversense or future generation products, could adversely affect our ability to conduct planned clinical trials and commercialization activities.

Sales and demand for Eversense have been and may continue to be adversely affected by the global COVID-19 pandemic. Disruptions in the distributions of Eversense could result if patients are physically quarantined, if physicians restrict access to their facilities for a material period of time, if we are unable to train new physicians, if patients are unable or unwilling to visit health care providers, or if health care providers prioritize treatment of acute or communicable illnesses over diabetes management. At various times during the COVID-19 pandemic, (i) our or our partners' ability to visit physician offices have been restricted, and (ii) insertions of Eversense have been adversely impacted. During the pandemic, these and other risks could recur or continue. In addition, in the Spring of 2020 we announced changes in our ability to market Eversense in the U.S., substantially reduced our sales and marketing capabilities, and limited or ceased our efforts to secure new Eversense patients in the U.S. The impact of these actions on patients and health care providers could delay or negatively impact our ability to stabilize and grow sales of Eversense in the U.S.

In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread 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 spread of COVID-19 could materially affect our business and the value of our common stock.

The review of our products by the FDA and other foreign regulatory authorities and Notified Bodies has been and may continue to be adversely affected by the COVID-19 pandemic. The timing to completion and outcome of such a review is uncertain, as is the impact of COVID-19 on review timelines or possible delays.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, commercialization efforts, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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 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, including the launch of the Eversense E3 CGM system which we expect to in the second quarter of 2022. Our product is a new product for Ascensia globally and they must additionally 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, including the launch of the Eversense E3 six-month product 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 Quality System Regulation, or 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 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 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; and
- 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 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.

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 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 varies 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 will apply from 2025.

In March 2019, we launched a patient access program, the Eversense Bridge Program, to assist those patients who do not have insurance coverage for Eversense, or whose insurance is denied or insufficient. Pursuant to this program, we provided financial assistance to eligible patients purchasing Eversense, which may have been substantial depending on a patient's insurance coverage. We also assisted patients in their appeal of adverse coverage decisions made by insurance providers. In December 2020, we terminated the Eversense Bridge Program. We expect our partner Ascensia to implement patient assistance programs and related programs as part of its commercialization efforts. The lack of a patient assistance program, or a program's design being ineffective, 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 intensively managed diabetes market 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 intensively managed diabetes, their caregivers and healthcare providers that represent only a small percentage of the overall intensively managed 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 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 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 product 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, is 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.

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 or destruction of our manufacturers' equipment or facilities.

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 and Eversense XL versions, manufacturing these 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 agencies, 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.

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 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 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 incident, 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.

If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage patient requisitions and data, customer service cases and replacement obligations, marketing data, accounting and financial functions, inventory and order management, product quality records, research and development data, and technical support functions. Despite our security measures, our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures. In addition, our data management application and a variety of our software systems, including the software in our smart transmitter, are hosted by third-party service providers whose security and information technology systems are subject to similar risks, which could be subject to computer viruses or hacker attacks or other failures. If our or our third-party service provider's security systems are breached or fail, unauthorized persons may be able to obtain access to sensitive data. If we or our third-party service providers were to experience a breach compromising sensitive data, our brand and reputation could be adversely affected, and the use of our products could decrease.

The failure of our or our service providers' information technology systems or our transmitter's software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation or adversely affect our products and could result in decreased sales, increased overhead costs, and product shortages, all of which could negatively affect our reputation, business, financial condition and operating results.

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.

Risks Related to our Financial Results and Need for Financing

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

We intend 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.

Covenants under the PHC Note Purchase Agreement and the indentures related to the 2023 Notes and the 2025 Notes may result in the acceleration of outstanding indebtedness and limit the manner in which we operate.

The PHC Note Purchase 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 Note Purchase Agreement also contains customary events of default, after which the PHC Notes 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.

In addition, the indentures related to the 2023 Notes and the 2025 Notes contain, and any future indebtedness we incur may contain, various negative covenants that restrict, among other things, our ability to:

- incur additional indebtedness, guarantee indebtedness or issue disqualified stock or, in the case of such subsidiaries, preferred stock;
- declare or pay dividends on, repurchase or make distributions in respect of, their capital stock or make other restricted payments;
- make investments or acquisitions;
- create liens;
- enter into agreements restricting certain subsidiaries' ability to pay dividends or make other intercompany transfers;
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets and the assets of our restricted subsidiaries;
- enter into transactions with affiliates;
- sell, transfer or otherwise convey certain assets; and
- prepay certain types of indebtedness.

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 2023 Notes and the 2025 Notes and PHC Notes, 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.

Prolonged negative economic conditions could adversely affect us, our customers and third-party suppliers, which could harm our financial condition.

We are subject to the risks arising from adverse changes in general economic and market conditions. Uncertainty about future economic conditions could negatively impact our existing and potential customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, and cause delays or other problems with key suppliers.

Healthcare spending in the United States and Europe has been, and is expected to continue to be, under significant pressure and there are many initiatives to reduce healthcare costs. As a result, we believe that some insurers are scrutinizing insurance claims more rigorously and delaying or denying coverage and reimbursement more often. Because the sale of Eversense will generally depend on the availability of third-party coverage and reimbursement, any delay or decline in coverage and reimbursement will adversely affect our sales.

Our business may be exposed to foreign exchange risks.

We incur some of our expenses and derive revenues from Eversense XL 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.

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 premarket approval application, or 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. For example, subject to regulatory clearance of our IDE, we are planning to initiate a pivotal trial to support a future PMA supplement for a 365-day sensor. 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.

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 for such modifications;
- be delayed in obtaining marketing approval 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 or marketing approvals. 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, Nick Tressler, 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 expect 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, 2021, we had 89 employees. As our commercialization progresses, we expect to 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 anticipated 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, 2021, we held a total of approximately 527 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 104 issued United States patents, 250 patents issued in countries outside the United States, and 173 pending patent applications worldwide. Our patents expire between 2022 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 2044 to 2060. 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 one pending U.S. trademark applications and 6 pending foreign trademark applications, as well as 14 U.S. trademark registrations and 132 foreign trademark registrations.

We have applied for patent protection relating to certain existing and proposed products and processes. Currently, several of our issued U.S. 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 two pending applications in the United States for the "Eversense" trademark. 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, or USPTO, the European Patent Office, or 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. 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. In particular, any delay in obtaining CE Certificate of Conformity of Eversense E3 system in the EEA, could significantly impair our commercial strategy in Europe and our ability to generate revenue in Europe, which would have a material, adverse effect on our business.

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. 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, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the U.K. Bribery Act of 2010, or the 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.

Although we will not provide healthcare services, submit claims for third-party payor reimbursement, or receive payments directly from government health insurance programs or other third-party payors for Eversense, 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 potentially 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 the Health Information Technology for Economic and Clinical Health Act, or 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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care Education Reconciliation Act of 2010, or collectively, the PPACA, on device manufacturers regarding the annual reporting to the Centers for Medicare and Medicaid Services, or 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. 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; 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;
- the California Consumer Privacy Act, or CCPA, that creates new individual privacy rights for consumers (which is broadly defined) and places increased privacy and security obligations on entities handling certain personal data; and
- foreign data privacy regulations, such as the European General Data Protection Regulation (EU) 2016/679, or GDPR, which impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, and may be stricter than U.S. laws.

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.

The collection and use of personal health data in the European Economic Area, or EEA (being the European Union plus Norway, Iceland and Liechtenstein) is governed by the General Data Protection Regulation 2016/679, or GDPR, which entered into application on May 25, 2018. The GDPR applies to the processing of personal data by any company established in the EEA 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. 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 GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States and Norway, Iceland and Liechtenstein may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional controls and processes ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition and results of operations. There has been limited enforcement of the GDPR to date, so we face uncertainty as to the exact interpretation of the new requirements on trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

The GDPR and accompanying laws are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. Because of the remote work policies, we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal data, including health data. We may also need to collect more extensive health-related information from our employees to manage our workforce.

In addition, further to the United Kingdom's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the European Union and the UK to continue without additional requirements. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision and remains under review by the European Commission during this period. The relationship between the UK and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

If we or our third-party partners fail to comply or are alleged to have failed to comply with data protection and privacy laws and regulations, or if we were to experience a data breach involving personal data, we could be subject to government enforcement actions or private lawsuits. 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, 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.

In February 2021, in conjunction with a communication to users regarding our distribution changes and securing customer and technical support, we made an unintended disclosure of certain user e-mail addresses to other users in Italy. In response, we communicated with affected parties and self-reported the disclosure to the appropriate authorities in Italy for the GDPR. Subsequently, we have engaged in communications with the Italian authorities concerning the disclosure and other GDPR-related obligations. In January 2022, we were notified by the Italian authorities of their determination that our unintended disclosure constituted a violation of the GDPR. In February 2022, we responded to the Italian authorities regarding the alleged GDPR violations. We expect the Italian authorities to issue a formal decision on this matter in the second quarter of 2022. This unintended disclosure or the outcome of the proceedings with the Italian authorities could cause an adverse reaction by users of our product, negative publicity, financial penalties or negative regulatory implications under GDPR, any of which could have a material adverse effect on our business.

Our activities, including our research, sales and marketing, and patient reimbursement support activities, 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.

For example, to enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, 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 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 MDR, 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 twice daily 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 obtain future approvals 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 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 is currently available 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 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.

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 European Notified Bodies, as well as other regulatory agencies 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. Among other things, the PPACA:

- establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research; and
- implements payment system reforms including value-based payment programs, increased funding for comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments).

There have been executive, judicial and Congressional challenges to certain aspects of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, starting January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance and delaying the implementation of certain PPACA-mandated fees. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated medical device tax and "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden 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 2030 with the exception of a temporary suspension

from May 1, 2020 through March 31, 2021 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. Congress and the Biden administration are considering additional health reform measures.

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 extreme volatility that has often been unrelated to the operating performance of particular companies. From December 1, 2020 through February 25, 2022, the trading price of our common stock has been as low as $0.36 per share and as high as $5.56 per share. This extreme stock price volatility has been accompanied by extremely high trading volume in our common stock in comparison to historical experience. During this period, the average daily trading volume of our common stock has been approximately 24 million shares and on January 19, 2021, our trading volume exceeded 409 million shares, whereas the average daily trading volume from January 1, 2021 to December 31, 2021 was 26.4 million shares.

The extreme increase in trading volume and volatility 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, whether due to the global COVID-19 pandemic or otherwise;
- 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 900,000,000 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. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

The PHC Notes are, and the Convertible preferred stock issuable under our Equity Line Agreement with Energy Capital, will be convertible into shares of our common stock and, upon conversion, will dilute your percentage of ownership.

The PHC Notes are also convertible into our common stock at the option of the holder. Accordingly, any conversion of convertible preferred stock or the PHC Notes would dilute the ownership of our holders of common stock. Additionally, under the Equity Line Agreement, subject to the satisfaction of certain conditions, including that we have less than $8 million of cash, cash equivalents and other available credit (aside from availability under the Equity Line Agreement), we have the right, in our sole discretion, to present Energy Capital with a purchase notice directing Energy Capital (as principal) to purchase shares of Series B Preferred Stock at a price of $1,000 per share (not to exceed $4.0 million worth of shares) once per month, up to an aggregate of $12.0 million of our Series B Preferred Stock, with such shares convertible into common stock at a price of $0.3951 per share. Also, under the Equity Line Agreement, subject to the satisfaction of certain conditions, Energy Capital has the option to purchase any Series B Preferred Stock that we have not already sold to it under the agreement at a price of $1,000 per share. The potential dilutive effect of the conversion of shares of convertible preferred stock or convertible notes may also adversely affect our ability to obtain additional financing on favorable terms or at all.

Holders of our convertible notes have the ability exert substantial influence over us in a manner adverse to your interests.

Subject to maintaining specified ownership thresholds, the former holders of our Series A convertible preferred stock, which has now been converted to common stock, and the PHC Notes have the ability to designate, in the aggregate, up to three members of our board of directors.

As a result, the holders of the PHC Notes and the former holders of our convertible preferred stock are able to 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. Some of these persons or entities may have interests different the interests of the holders of our common stock.

The future funding pursuant to agreements to sell convertible preferred stock to PHC and Energy Capital is not guaranteed.

We have entered into agreements with PHC and Energy Capital that, collectively, provide for our receipt of up to $27 million of aggregate funding pursuant to the sale of convertible preferred stock to PHC and Energy Capital. Pursuant to our agreement with PHC, we have the option to sell and issue to PHC up to $15.0 million of convertible preferred stock on or before December 31, 2022, which was contingent upon our obtaining FDA approval for the 180-day Eversense product for marketing in the United States before such date. In February 2022, the extended life Eversense E3 CGM system was approved by the FDA. On November 9, 2020, we entered into the Equity Line Agreement with

Energy Capital. Under the Equity Line Agreement, subject to the satisfaction of certain conditions, including that we have less than $8 million of cash, cash equivalents and other available credit (aside from availability under the Equity Line Agreement), we have the right, in our sole discretion, to present Energy Capital with a purchase notice directing Energy Capital (as principal) to purchase shares of Series B Preferred Stock at a price of $1,000 per share (not to exceed $4.0 million worth of shares) once per month, up to an aggregate of $12.0 million of our Series B Preferred Stock, with such shares convertible into common stock at a price of $0.3951 per share. Also, under the Equity Line Agreement, subject to the satisfaction of certain conditions, Energy Capital has the option to purchase any Series B Preferred Stock that we have not already sold to it under the agreement at a price of $1,000 per share. Because of the contingencies of each transaction, there can be no guarantee that we will be able to sell the additional convertible preferred stock to PHC or Energy Capital. If we are unable to do so, we may be forced to seek to raise additional capital on less advantageous terms, if available at all, which would likely have a material adverse effect on our liquidity and the trading price of our common stock.

Our application for the PPP Loan could, in the future, be determined to have been impermissible or could result in damage to our reputation.

On April 22, 2020 we received proceeds of $5.8 million from a loan under the Paycheck Protection Program of the CARES Act, a portion of which may be forgiven, which used to retain current employees, maintain payroll and make lease and utility payments. The PPP Loan matures on April 21, 2022 and bears annual interest at a rate of 1.0%. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight-week period beginning on the date of loan approval. Not more than 25% of the forgiven amount may be for non-payroll costs. We have elected not to apply for forgiveness and are making monthly payments of principal and interest until the loan is paid in full in the second quarter of 2022.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act. The certification described above does not contain any objective criteria and is subject to interpretation. On April 23, 2020, the SBA issued guidance stating that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. Subsequently, on April 29, 2020 the SBA issued guidance that it will review all PPP loans of more than $2 million, following the lender’s submission of the borrower’s loan forgiveness application. The lack of clarity regarding loan eligibility under the Paycheck Protection Program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that given our Company's circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any of the laws or governmental regulations that apply to us in connection with the PPP Loan, such as the False Claims Act, or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties. In addition, receipt of a PPP Loan may result in adverse publicity and damage to reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Should we be audited or reviewed by federal or state regulatory authorities, such audit or review could result in the diversion of management’s time and attention and legal and reputational costs. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

Our GAAP operating results could fluctuate substantially due to changes in fair value of the liability options and the derivatives related to the embedded conversion option, interest make-whole provision and make-whole fundamental change provision features of the notes.

Our liability options related to the Energy Capital Agreement and Masters Capital Agreement are classified as liabilities in accordance with ASC 480 on the Company’s balance sheet and are recorded at fair value. These options are required to be remeasured to fair value at each reporting period with the change recorded in change in fair value of derivatives that is a component of other income (expense).

Our convertible senior subordinated notes contain certain embedded features that require bifurcation of the embedded conversion option along with the fundamental change make-whole provision, interest 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 the Company's consolidated balance sheets in accordance with Accounting Standards Codification, or ASC, Topic 815, *Derivatives and Hedging*.

ASC 815 requires companies to bifurcate certain embedded derivatives from their host instruments and account for them as free-standing derivative financial instruments according to certain criteria. The fair value of the derivative is remeasured to fair value at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value of the derivative being charged to earnings (loss). We utilize a third-party valuation expert and the binomial option pricing method to determine the fair value of the derivative instruments at each reporting date using inputs based on recent trading prices (Level 2) and other observable inputs, including our common stock price, implied volatility, interest rates and credit spreads, or unobservable inputs (Level 3) where there is an absence of recent trading prices.

We cannot predict the effect that the accounting for the options and notes and the associated fluctuations in the fair value of the liability options and embedded features of the notes will have on our future GAAP financial results, the trading of our common stock and the trading price of the notes, which could be material. Continued extreme volatility in our stock price, as we have experienced recently, could exacerbate such effects.

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: (i) any derivative action or proceeding brought on our behalf, (ii) 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, (iii) 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 (iv) 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, 2021. 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.

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

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. Securities or industry analysts may elect not to initiate or continue to provide coverage of our common stock, and such lack of coverage may adversely affect the market price of our common stock. Even if we have securities or industry analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our stock could decline if one or more securities or industry analysts downgrade our stock or issue other unfavorable commentary or research. If one or more securities or industry analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

We are subject to taxation in numerous U.S. states and territories. 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 places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, 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 federal net operating loss carryforwards to reduce our income taxes.

At December 31, 2021, we had federal and state net operating loss, or NOL, carryforwards of $585.1 million and had research and experimental credit carryforwards of $14.1 million. NOL carryforwards in the amount of $198.5 million will expire in varying amounts between 2022 and 2037. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act of 2017, as modified by the CARES Act, federal NOL carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but in the case of tax years beginning after 2020, may only be used to offset 80% of our taxable income annually. Federal NOL carryforwards generated in taxable years beginning in 2018 will similarly carry forward indefinitely but will not be subject to such 80% of annual taxable income limitation. In addition, under Section 382 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 ownership changes in the past and if a portion of our NOL and tax credit carryforwards are subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of 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 materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal offices occupy approximately 33,000 square feet of leased office space in Germantown, Maryland pursuant to a lease that expires in 2023. We have an option to renew the lease for one additional five-year term. Additionally, on July 31, 2019, we entered into a new, non-cancellable operating sub-lease agreement for approximately 30,500 square feet of office space which commenced on September 2, 2019, expiring in 2023. This facility was decommissioned in 2021 and we will continue making lease payments until the lease expiration. 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.

In February 2021, we 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. 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. Outside counsel, on behalf of the Company, has filed a motion to dismiss the action for failure to state a claim. The motion is currently pending before the court.

In February 2021, in compliance with the data breach notification obligations laid out in the GDPR, the Company notified the Italian Data Protection Authority, or the Garante, of an unintended disclosure of certain user e-mail addresses to other users in Italy. Subsequent to this notification, the Company engaged in communications with the Garante concerning additional details about the data breach and other GDPR-related obligations of the Company. In January 2022, the Garante informed the Company of its determination that certain violations of the GDPR had occurred,

and invited the Company to submit defensive arguments. In February 2022, the Company filed a brief with the Garante setting forth its defensive arguments to the alleged violations. The Company's brief is pending before the Garante and the Company expects a decision from the Garante in the second quarter of 2022.

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.

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

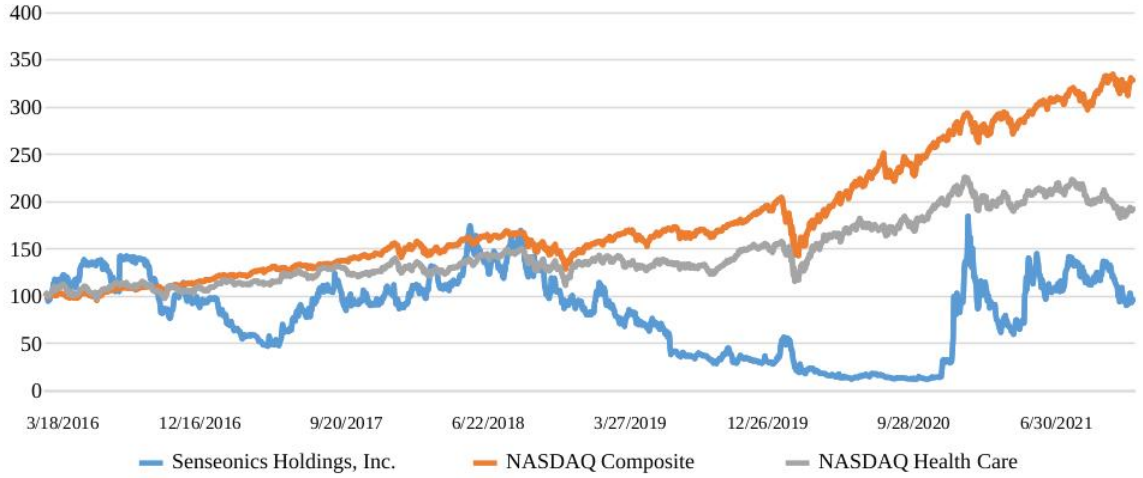
We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our ability to pay dividends on shares 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 25, 2022, we had 463,145,879 shares of common stock outstanding held by 177 holders of record.

Performance Graph

The following graph compares the performance of our common stock since March 18, 2016, the date on which our common stock commenced trading on the NYSE American, with the Nasdaq Composite Index and the Nasdaq Healthcare Index. The comparison assumes a $100 investment on March 18, 2016 in our common stock, the stocks comprising the Nasdaq Composite Index and the Nasdaq Healthcare Index, and assumes reinvestment of the full amount of all dividends, if any. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.



The comparisons in the graph are not intended to forecast or be indicative of possible future performance of our common stock. The performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or Exchange Act.

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 Eversense, Eversense XL and Eversense E3 CGM system 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, respectively, as compared to seven to 14 days for non-implantable CGM systems. We affixed the CE mark to

the original 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 is currently available in select markets in Europe and the Middle East. In June 2018, the U.S. Food and Drug Administration, or FDA, approved the Eversense CGM system and it is currently available throughout the United States. In June 2019, we received FDA approval for the non-adjunctive indication (dosing claim) for the 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. In February 2022, the extended life Eversense E3 CGM system was approved by the FDA and we expect Ascensia Diabetes Care Holdings AG, or Ascensia, to begin commercializing Eversense E3 in the second quarter of 2022.

Our net revenues are derived from sales of the Eversense system which is sold in two separate kits: the disposable Eversense Sensor Pack which includes the sensor, insertion tool, and adhesive patches, and the durable Eversense Smart Transmitter Pack which includes the transmitter and charger.

We sell directly to our network of distributors and strategic fulfillment partners, who provide the Eversense system to healthcare providers and patients through a prescribed request and invoice insurance payors for reimbursement. 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. During 2020, we received positive payor coverage decisions from Cigna Corporation, who has more than 17 million medical customers and offers a Medicare Advantage plan in 17 states and Washington, DC, Blue Cross and Blue Shield plans, and announced local coverage determinations, or LCD, proposals for implantable therapeutic CGMs such as Eversense by all the Medicare Administrative Contractors to enable Eversense to be used by Medicare beneficiaries as a Part B physician service. We continue to see momentum of broad national payor acceptance, including on August 3, 2020, the Center for Medicare and Medicaid Services, or 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 Scheduled that update global payments for the device cost and procedure fees.

We are in the early commercialization stages of the Eversense brand and are focused on driving awareness of our CGM system amongst intensively managed patients and their healthcare providers. In both the United States and our overseas markets, we entered into a 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, Eversense XL and future generation products.

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, or 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, or 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 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 6 months in the United States. In September 30, 2019, we completed enrollment of the PROMISE trial. In the trial, we observed performance matching that of the current Eversense 90-day product available in the United States, with a mean absolute relative difference, or 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 Premarket Approval, or 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 extended life Eversense E3 CGM system was approved by the FDA and we expect Ascensia Diabetes Care Holdings AG, or Ascensia, to begin commercializing Eversense E3 in the second quarter of 2022.

In March 2019, we launched a patient access program, the Eversense Bridge Program, to assist those patients who do not have insurance coverage for Eversense, or whose insurance is denied or insufficient. Pursuant to this program, we provided financial assistance to eligible patients purchasing Eversense, which may have been substantial depending on a patient's insurance coverage. We also assisted patients in their appeal of adverse coverage decisions made by insurance providers. In December 2020, we terminated the Eversense Bridge Program. In 2021, Ascensia initiated a patient assistance program to provide financial assistance to patients on Eversense. The lack of a patient assistance program, or a program's design being ineffective, 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, or previously the Bridge Program. 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.

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. Following information gathered from this sub-set and continued development efforts, and pending developments at the FDA relating to the ongoing the ongoing COVID-19 pandemic, in the first half of 2022 we plan to seek Investigational Device Exemption, or IDE, from the FDA to explore the 365-day sensor in a clinical trial. If the IDE is approved in a timely manner, we would target to begin enrollment of a clinical trial, in which we intend to include a pediatric population, in the second half of 2022.

On August 9, 2020, we entered into a collaboration and commercialization agreement with Ascensia pursuant to which we granted Ascensia the exclusive right to distribute our 90-day Eversense CGM system and our 180-day Eversense CGM system worldwide for people with diabetes, with the following initial exceptions: (i) until January 31, 2021, the territory did not include countries 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 does 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, the extended life Eversense E3 CGM system was approved by the FDA and we expect Ascensia to begin commercializing Eversense E3 in the United States in the second quarter of 2022.

European Commercialization of Eversense

In September 2017, we affixed the CE mark to the Eversense XL, which is indicated for a sensor life of up to six months. 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.

In May 2016, we entered into a distribution agreement with Roche Diagnostics International AG and Roche Diabetes Care GmbH, together referred to as Roche. Pursuant to the agreement, as amended, we had granted Roche the exclusive right to market, sell and distribute Eversense in the EMEA, excluding Scandinavia and Israel. In addition, Roche had exclusive distribution rights in 17 additional countries, including Brazil, Russia, India and China, as well as select markets in the Asia Pacific and Latin American regions. Roche was obligated to purchase from us specified minimum volumes of Eversense XL CGM components at pre-determined prices. On December 12, 2019, we further amended the distribution agreement to lower minimum volumes for 2020 and increase pricing for the remaining period of the contract. On November 30, 2020 we entered into a final amendment and settlement agreement with Roche to facilitate the transition of distribution to Ascensia as sales concluded on January 31, 2021, including final purchases, and transition support activities. The distribution rights under the agreement expired January 31, 2021.

COVID-19

On January 30, 2020, the World Health Organization, or the WHO, announced a global health emergency because of a new strain of coronavirus, or COVID-19, and the risks to the international community as the virus spreads globally. On March 11, 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. In response to the pandemic, many states and jurisdictions have issued stay-at-home orders and other measures aimed at slowing the spread of the coronavirus. The state of Maryland, where we are headquartered, has been affected by COVID-19. The Governor of Maryland issued an order closing all non-essential businesses, which took effect on March 23, 2020. Beginning with the initial outbreak and through 2021 substantially all of our workforce is still working from home either all or substantially all of the time. Additionally, because our sensor requires an in-clinic procedure, we saw a reduction in access to clinics and sensor insertions during multiple periods during the pandemic.

The COVID-19 pandemic infection rates in the United States are still high, vaccine distribution is on-going, and it is difficult to predict the longevity and severity COVID-19 will have on our business.

As a result of the COVID-19 pandemic's disruption to our operations, suppliers, employees, and the healthcare community in which we sell to and support, and our limited cash resources, in March 2020, we made significant reductions in our cost structure and operations to improve cash flow and generate future expenditure savings to ensure the long-term success of Eversense. Specifically, in the first quarter of 2020, we temporarily suspended commercial sales and marketing of the Eversense CGM System and we reduced our workforce by approximately 60%.

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, warranty obligations, 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, 2021. We do not expect any material changes in the near term to the underlying assumptions during the year ended December 31, 2022.

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 product revenue from sales of the Eversense system and related components and supplies to Ascensia, through the Commercialization Agreement, third-party distributors in the European Union and to strategic fulfillment partners in the United States, or 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.

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.

Our contracts may contain some form of variable consideration such as prompt-pay discounts, tier-volume price discounts and for the Ascensia commercial 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 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.

Contract assets consist of trade receivables and unbilled receivables from customers and are recorded at net realizable value. Unbilled receivables relate to the revenue share variable consideration from the Ascensia commercial agreement.

Warranty Obligations

We provide a one-year warranty on our smart transmitters to our customers. We 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 revenues.

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. 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 the product 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 quality or 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.

In July 2019, we issued $82.0 million in aggregate principal amount of convertible senior subordinated notes due 2025, or the 2025 Notes. In connection with the 2025 Notes, 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.

On April 21, 2020, we entered into the Highbridge Loan Agreement, in which we borrowed an aggregate principal amount of $15.0 million through the issuance and sale of the First Lien Notes and issued 1,500,000 shares of our common stock to the Lenders as a commitment fee. The First Lien Notes also contained redemption features that were evaluated for bifurcation as separate derivative instruments including the permitted prepayment put option, the mandatory accelerated redemption and the mandatory redemption and reinvestment upon an asset sale. We recorded the fair value of the embedded features in the amount of $1.0 million as a debt premium and derivative asset in our 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 recorded in change in fair value of derivatives that is a component of other income (expense) in our consolidated statements of operations and comprehensive loss. On August 14, 2020, we prepaid the First Lien Notes in full, including the discounted prepayment premium, in the amount of approximately $17.6 million and recognized a loss on extinguishment in the amount of $0.7 million.

On April 21, 2020, we entered into a Note Purchase and Exchange Agreement with certain funds managed by Highbridge providing for the exchange (the "Exchange") of $24.0 million aggregate principal amount of our outstanding 2025 Notes for (i) $15.7 million aggregate principal amount of newly issued Second Lien Notes, (ii) 11,026,086 shares of common stock, (iii) warrants to purchase up to 4,500,000 shares of common stock at an exercise price of $0.66 per share, and (iv) $0.3 million in accrued and unpaid interest on the 2025 Notes being exchanged. On August 9, 2020, we entered into a First Amendment to Note Purchase and Exchange Agreement with Highbridge (as amended by the Amendment, the "Exchange Agreement"). The Second Lien Notes also contained redemption features that were evaluated for bifurcation as separate derivative instruments including the permitted prepayment put option, the mandatory accelerated redemption and the mandatory redemption and reinvestment upon an asset sale. Unlike the First Lien Notes, the Second Lien Notes also permit voluntary conversion at the option of the holder as described above. We recorded the fair value of these embedded features in the amount of $1.9 million as a derivative asset in our 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 our consolidated statement of operations and comprehensive loss. During the fiscal year ended December 31, 2020, Highbridge elected to convert the full $15.7 million of outstanding principal on the Second Lien Notes.

In August 2020, we issued $35.0 million in aggregate principal amount of 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 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, 2021 and 2020

The following table sets forth our results of operations for the years ended December 31, 2021 and 2020.

	Year Ended December 31,		Period-to-Period Change
	2021	2020	
	(in thousands)		(in thousands)
Revenue, net	$ 1,394	$ 1,368	$ 26
Revenue, net - related parties	12,281	3,581	8,700
Total revenue	13,675	4,949	8,726
Cost of sales	14,486	22,315	(7,829)
Gross profit (loss)	(811)	(17,366)	16,555
Expenses:			
Sales and marketing expenses	5,483	20,550	(15,067)
Sales and marketing expenses- related parties	2,133	—	2,133
Total Sales and marketing expenses	7,616	20,550	(12,934)
Research and development expenses	27,217	20,413	6,804
General and administrative expenses	21,538	20,801	737
Operating loss	(57,182)	(79,130)	21,948
Other (expense) income, net:			
Interest income	243	175	68
Loss on fair value adjustment of option	(53,152)	(30,721)	(22,431)
Gain (Loss) on extinguishment of debt and option	330	(21,112)	21,442
Loss on issuance of debt & other issuance costs	—	(12,706)	12,706
Interest expense	(16,720)	(16,167)	(553)
Debt issuance costs	—	(1,216)	1,216
Loss on change in fair value of derivatives	(174,173)	(11,641)	(162,532)
Impairment cost	(1,647)	(2,339)	692
Other expense	(173)	(311)	138
Total other (expense) income, net	(245,292)	(96,038)	(149,254)
Net loss	$ (302,474)	$ (175,168)	$ (127,306)

Components of Results of Operations

Revenue, net

Our total net revenue increased to $13.7 million for the year ended December 31, 2021, compared to $4.9 million for the year ended December 31, 2020, an increase of $8.7 million. This increase was due to the transition of commercial responsibility for Eversense to Ascensia and its orders for Eversense for distribution in the European Union and in the United States. Ascensia assumed commercial responsibilities for Eversense XL beginning on February 1, 2021 and for the 90-day Eversense product during the second quarter of 2021.

Cost of sales

Our cost of sales decreased to $14.5 million for the year ended December 31, 2021, compared to $22.3 million for the year ended December 31, 2020, a decrease of $7.8 million. The decrease was primarily attributed to the reduction of inventory impairment, write-offs and scrap expense of $13.9 million and a reduction of $0.2 million in salaries &

related costs, partially offset by an increase of $6.3 million in production costs, freight and logistic cost and warranty and replacement costs related to the commercialization of Eversense under the Ascensia commercialization and collaboration agreement.

Gross profit (loss) was $(0.8) million and $(17.4) million for the years ended December 31, 2021 and 2020, respectively. Gross profit as a percentage of revenue, or gross margin, was (5.9)% and (350.9)% for the years ended December 31, 2021 and 2020, respectively. The improved gross margin was primarily due to the fulfillment of orders utilizing existing written off inventory as a result of the COVID-19 pandemic.

Sales and marketing expenses

Sales and marketing expenses were $7.6 million for the year ended December 31, 2021, compared to $20.6 million for the year ended December 31, 2020, a decrease of $12.9 million. The decrease was primarily the result of the reduction in sales support due to the transition to Ascensia for the commercialization of Eversense.

Research and development expenses

Research and development expenses were $27.2 million for the year ended December 31, 2021, compared to $20.4 million for the year ended December 31, 2020, an increase of $6.8 million. The increase was due to the expansion of our R&D workforce which was $2.2 million increase in personnel-related costs. Also, the increase was due to various R&D efforts to improve our sensor & transmitter technology in 2021 that led to $4.1 million increase in consulting, contract fabrication and other R&D support services and an increase of $0.5 million in clinical studies.

General and administrative expenses

General and administrative expenses were $21.5 million for the year ended December 31, 2021, compared to $20.8 million for the year ended December 31, 2020, an increase of $0.7 million. The increase was due to higher salaries and related expenses of $1.3 million, primarily related to stock-based compensation and related expenses, offset by a reduction of $0.6 million in other administrative expenses including accounting and consulting costs.

Total other income (expense), net

Total other income (expense), net, was ($245.3) million for the year ended December 31, 2021, compared to ($96.0) million for the year ended December 31, 2020, an increase of $149.3 million expense. The increase in expense was primarily due to a $162.5 million change in fair value of the embedded derivatives in our convertible notes, $22.4 million change in non-cash loss on fair value adjustment of the Energy Capital Option and an increase of $0.6 million in interest expense, offset by a $21.4 million reduction in loss on extinguishment of debt, a $12.7 million reduction in loss on issuance of debt & issuance costs, a reduction of $1.2 million in debt issuance cost a decrease of $0.7 million in impairment cost, a decrease of $0.1 million in other expenses and a $0.1 million increase in interest income.

Comparison of the Years Ended December 31, 2020 and 2019

For the discussion of our financial condition and results of operations for the year ended December 31, 2020 compared to the year ended December 31, 2019, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 5, 2021.

Liquidity and Capital Resources

From our founding in 1996 until 2010, we devoted substantially all of our resources to researching various sensor technologies and platforms. Beginning in 2010, we narrowed our focus to developing and refining a commercially viable glucose monitoring system. However, to date, we have not generated any significant revenue from product sales. We have incurred substantial losses and cumulative negative cash flows from operations since our inception in October

1996. We have never been profitable and our net losses were $302.5 million, $175.2 million, and $115.5 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $951.0 million. To date, we have funded our operations principally through the issuance of preferred stock, common stock, convertible note issuance and debt. As of December 31, 2021, we had cash, cash equivalents and marketable securities of $181.8 million.

In November 2021, we entered into an Open Market Sale Agreement, or 2021 Sales Agreement, with Jefferies LLC, or 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 will receive a commission up to 3.0% of the gross proceeds of any common stock sold through Jefferies under the 2021 Sales Agreement. As of the date of this Annual Report on Form 10-K, we have received $8.1 million in net proceeds from the sale of 3,077,493 shares of our common stock under the 2021 Sales Agreement.

In November 2019, we entered into an Open Market Sale Agreement, or 2019 Sales Agreement, with 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 $50.0 million through Jefferies as our sales agent in an "at the market" offering. In June 2021, we received $48.4 million in net proceeds from the sale of 12,830,333 shares of our common stock utilizing the full capacity under the 2019 Sales Agreement. For the twelve months ended December 31, 2020, we had received $0.1 million in net proceeds from the sale of 175,289 shares of our common stock under the 2019 Sales Agreement.

On January 21, 2021, we entered into an underwriting agreement, which was subsequently amended and restated on the same day, or the Underwriting Agreement, with H.C. Wainwright & Co., LLC, as representative of the underwriters, the Underwriters, to issue and sell 51,948,052 shares of common stock, in an underwritten public offering pursuant to effective registration statements on Form S-3, including and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission, the Offering. The price to the public in the Offering was $1.925 per share of common stock. The Underwriters agreed to purchase the shares from the Company pursuant to the Underwriting Agreement at a price of $1.799875 per share and the Company also agreed to reimburse them for customary fees and expenses. The initial closing of the Offering occurred on January 26, 2021. Subsequent to the initial closing, the Underwriters exercised their option to purchase an additional 7,792,207 shares of Common Stock. Total net proceeds from the Offering were $106.1 million after deducting underwriting discounts and commissions and estimated offering expenses.

On January 17, 2021, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional purchasers, the Purchasers, pursuant to which we sold to the Purchasers, in a registered direct offering, the Registered Direct Offering, an aggregate of 40,000,000 shares, the Shares, of common stock, $0.001 par value per share. The Shares were sold at a purchase price of $1.25 per share for aggregate gross proceeds to the us of $50 million, before deducting fees to the placement agent and other estimated offering expenses payables. The Shares were offered and sold by us pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the Securities and Exchange Commission on November 27, 2019. The net proceeds to us from the Registered Direct Offering, after deducting fees and expenses and the estimated offering expenses payable by us, are approximately $46.1 million.

On November 9, 2020, we entered into an equity line agreement, the Equity Line Agreement, with Energy Capital, LLC, or Energy Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Energy Capital is committed to purchase up to an aggregate of $12.0 million of shares of our newly designated series B convertible preferred stock, or the Series B Preferred Stock, at our request from time to time during the 24-month term of the Equity Line Agreement. Under the Equity Line Agreement, beginning January 21, 2021, subject to the satisfaction of certain conditions, including that we have less than $8 million of cash, cash equivalents and other available credit (aside from availability under the Equity Line Agreement), we have the right, in our sole discretion, to present Energy Capital with a purchase notice, or a Regular Purchase Notice, directing Energy Capital (as principal) to purchase shares of Series B Preferred Stock at a price of $1,000 per share (not to exceed $4.0 million worth of shares) once per month, up to an aggregate of $12.0 million of our Series B Preferred Stock at a per share price, or the Purchase Price, equal to $1,000 per share of Series B Preferred Stock, with each share of Series B Preferred Stock initially convertible into common stock, beginning nine months after the date of its issuance, at a conversion price of

$0.3951 per share. The Equity Line Agreement provides that we shall not affect any Regular Purchase under the Equity Line Agreement on any date where the closing price of the common stock on the NYSE American is less than $0.25 without the approval of Energy Capital.

On August 9, 2020, we entered into a financing agreement with Ascensia's parent company, PHC, pursuant to which we issued $35.0 million in aggregate principal amount 2024 Notes, to PHC. We also issued PHC 2,941,176 shares of common stock to PHC as a financing fee. We also have 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 product for marketing in the United States before such date. Upon the closing of the 2024 Notes, we prepaid the First Lien Notes in full in the amount of approximately $17.6 million, which includes the discounted prepayment premium.

Additionally, on August 9, 2020, we entered into a Stock Purchase Agreement with Masters Special Solutions, LLC and certain affiliates thereof, or Masters, pursuant to which we issued and sold to Masters 3,000 shares of convertible preferred stock, designated as Series A Preferred Stock, the Series A Preferred Stock, at a price of $1,000.00 per share in an initial closing. Masters also had the option to purchase up to an additional 27,000 shares of Series A Preferred Stock at a price of $1,000.00 per share in subsequent closings, subject to the terms and conditions of the Stock Purchase Agreement, as amended, through January 11, 2021. In January 2021, Masters and its assignees purchased in aggregate an additional 22,783 shares of Series A Preferred Stock, resulting in additional gross proceeds of $22.8 million. Each share of Series A Preferred Stock is initially convertible into a number of shares of common stock equal to $1,000 divided by the conversion price of $0.476 per share, subject to customary anti-dilution adjustments, including in the event of any stock split. All shares of Series A Preferred Stock have been converted to common stock as of December 31, 2021.

Warrants

On July 16, 2019, we issued Solar warrants to purchase an aggregate of 1,125,000 shares of the Company's common stock with an exercise price of $1.20 per share, or the Solar Warrants. The Solar Warrants are exercisable until July 25, 2029. As of December 31, 2021, the Solar Warrants have been exercised in full, on a net basis.

On November 9, 2020, we issued Energy Capital warrants to purchase up to 10,000,000 shares of Company's common stock with an exercise price of $0.3951 per share, or the Energy Capital Warrants. The Energy Capital Warrants have a vesting date of May 9, 2021. The Warrants can be exercised, in either a cashless exercise or a cash basis, at any time after the vesting date but prior to November 9, 2030. Energy Capital may exercise the Warrants at any time after the vesting date, without contingencies and independently of whether any shares of Series B preferred stock are issued.

Indebtedness

Term Loans

On July 16, 2019, we entered into a Loan and Security Agreement, or the Solar Loan Agreement, with Solar Capital, Ltd., or Solar. Pursuant to the Solar Loan Agreement, on July 25, 2019, or the effective date, we borrowed the Solar Term Loan in an aggregate principal amount of $45.0 million, or the Solar Term Loan. We used $11.6 million of the Solar Term Loan to repay in full the term loans, or the Oxford/SVB Term Loans and together with the Solar Term Loan, the Term Loans, borrowed pursuant to our Amended and Restated Loan and Security Agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB.

On March 22, 2020 we terminated our Loan and Security Agreement with Solar and repaid the $45.0 million principal balance in full.

PPP Loan

On April 22, 2020, we received $5.8 million in loan funding from the PPP pursuant to the CARES Act, as amended by the Flexibility Act, and administered by the SBA. The unsecured loan, or the PPP Loan, is evidenced by the

PPP Note dated April 21, 2020, or the PPP Note, in the principal amount of $5.8 million with Silicon Valley Bank, or the Bank.

Under the terms of the PPP Note and the PPP Loan, interest accrues on the outstanding principal at a rate of 1.0% per annum. We have elected not to apply for forgiveness and are making monthly payments of principal and interest until the loan is paid in full in the second quarter of 2022. The term of the PPP Note is two years, though it may be payable sooner in connection with an event of default under the PPP Note.

The PPP Note may be prepaid in part or in full, at any time, without penalty. The PPP Note provides for certain customary events of default, including (i) failing to make a payment when due under the PPP Note, (ii) failure to do anything required by the PPP Note or any other loan document, (iii) defaults of any other loan with the Bank, (iv) failure to disclose any material fact or make a materially false or misleading representation to the Bank or SBA, (v) default on any loan or agreement with another creditor, if the Bank believes the default may materially affect our ability to pay the PPP Note, (vi) failure to pay any taxes when due, (vii) becoming the subject of a proceeding under any bankruptcy or insolvency law, having a receiver or liquidator appointed for any part of our business or property, or making an assignment for the benefit of creditors, (viii) having any adverse change in financial condition or business operation that the Bank believes may materially affect our ability to pay the PPP Note, (ix) if we reorganize, merge, consolidate, or otherwise change ownership or business structure without the Bank's prior written consent, or (x) becoming the subject of a civil or criminal action that the Bank believes may materially affect our ability to pay the PPP Note. Upon the occurrence of an event of default, the Bank has customary remedies and may, among other things, require immediate payment of all amounts owed under the PPP Note, collect all amounts owing from us, and file suit and obtain judgment against us.

Highbridge Loan Agreement

On April 21, 2020, we entered into the Highbridge Loan Agreement, with certain funds managed by Highbridge Capital Management, LLC, or Highbridge, as the lenders (together with the other lenders from time to time party thereto, or the Lenders) and Wilmington Savings Fund Society, SCB, as collateral agent.

Pursuant to the Highbridge Loan Agreement, we borrowed an aggregate principal amount of $15.0 million on April 24, 2020 through the issuance and sale of First Lien Notes. In connection with the Highbridge Loan Agreement and receipt of the first tranche of borrowing, we issued 1,500,000 shares of our common stock to the Lenders as a commitment fee.

Upon the closing of the PHC Notes, we prepaid the First Lien Notes in full in the amount of approximately $17.6 million, which includes the discounted prepayment premium.

Exchange Agreement with Highbridge

On April 21, 2020 we entered into a Note Purchase and Exchange Agreement, or the Exchange Agreement, which we subsequently amended on August 9, 2020, with certain funds managed by Highbridge providing for the exchange of $24.0 million aggregate principal amount of our outstanding senior convertible notes due January 15, 2025, or the 2025 Notes, for (i) $15.7 million aggregate principal amount of newly issued Second Lien Secured Notes, or the Second Lien Notes, (ii) 11,026,086 shares of our common stock, (iii) warrants to purchase up to 4,500,000 shares of our common stock at an exercise price of $0.66 per share, and (iv) $0.3 million in accrued and unpaid interest on the 2025 Notes being exchanged. The exchange closed on April 24, 2020. The warrants may be exercised for cash or on a cashless basis at any time through the three year anniversary of the issuance date.

As amended by the Amendment, effective as of the Closing Date, the holders of the Second Lien Notes had the right to convert the aggregate principal of the Second Lien Notes (together with any applicable prepayment premium) to common stock at a price per share equal to 90% of the greater of (i) the daily volume weighted average of the price per share of the common stock, on the conversion date, or if the conversion date is not a trading date, the trading day immediately prior to the conversion date and (ii) $0.33 per share. This conversion option had a daily limit of $1,000,000 in aggregate converted principal (inclusive of principal amount of First Lien Notes that were voluntarily converted).

During the fiscal year ended December 31, 2020, Highbridge elected to convert the full $15.7 million of outstanding principal on the Second Lien Notes for issuance of 42,776,936 shares of common stock, which included prepayment premiums and were based off of our election of PIK interest.

Convertible Notes

The following table summarizes our outstanding senior convertible note obligations at December 31, 2021:

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
2023 Notes	January 2018	5.25%	$ 15.7	February 1, 2023	294.1176	$ 3.40
2025 Notes	July 2019	5.25%	$ 51.2	January 15, 2025	757.5758	$ 1.32
PHC Notes	August 2020	9.50%	$ 35.0	October 31, 2024	1867.4136	$ 0.53

See Note 11 in the accompanying notes to our consolidated financial statements included elsewhere in this Annual Report for further discussion of the 2023 Notes, PHC Notes and 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 2022 and beyond.

Management has concluded that based on our current operating plans, existing cash and cash equivalents and cash flows from our future operations will be sufficient to meet our anticipated operating needs through 2023. As part of our liquidity strategy, we will continue to monitor our capital structure and operating plans and we may access the capital markets or debt markets for additional funding if the opportunity arises to enhance our capital structure for changes to our operating plans, for financing strategic initiatives and to provide financial flexibility.

Cash Flows

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

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (56,078)	$ (67,422)
Net cash used in investing activities	(148,749)	(181)
Net cash provided by (used in) financing activities	220,083	(10,130)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 15,256	$ (77,733)

Net cash used in operating activities

Net cash used in operating activities was $56.1 million for the year ended December 31, 2021, and consisted of a net loss of $302.5 million, a net change in operating assets and liabilities of $1.5 million, and $0.3 million of loss on extinguishment of debt, offset by a change in fair value of derivative liabilities of $174.2 million, a change of $53.2 million in the fair value adjustment related to the Energy Capital transactions, other non-cash charges, net of $9.6 million, stock-based compensation expense of $9.0 million, and $2.2 million of impairment costs.

Net cash used in operating activities was $67.4 million for the year ended December 31, 2020, and consisted of a net loss of $175.2 million and provision for inventory obsolescence of $4.2 million, offset by a change in the fair value adjustment of $30.7 million, related to the Master and Energy Capital transactions, loss on extinguishment of debt in the amount of $21.1 million, non-cash interest expense of $11.0 million, a net change in operating assets and liabilities of $13.8 million, change in fair value of derivative liabilities of $11.6 million, loss on issuance of debt, other issuance cost and impairment of asset of $15.0 million, stock-based compensation expense of $7.3 million and other non-cash charges of $1.5 million.

Net cash used in investing activities

Net cash used in investing activities was $148.7 million for the year ended December 31, 2021, and consisted of $154.5 million from the purchase of marketable securities and $0.2 million of capital expenditures for laboratory equipment, offset by $6.0 million form sale and maturity of marketable securities.

Net used in investing activities was $0.2 million for the year ended December 31, 2020, and consisted of $0.2 million of capital expenditures, primarily for production equipment.

Net cash provided by (used in) financing activities

Net cash provided by financing activities was $220.1 million for the year ended December 31,2021, primarily consisted of $200.4 million from issuance of common stock, proceeds of $22.8 million for the issuance of Series A preferred stock and $5.0 million for proceeds related to exercise off stock options and warrants, offset by repayment of $2.8 million of PPP loan and $5.3 million taxes paid related to net share settlement of equity awards.

Net cash used in financing activities was $10.1 million for the year ended December 31, 2020, and primarily consisted of $66.1 million for the repayment of outstanding principal on our Solar Loan Agreement and Highbridge First Lien Notes, offset by proceeds from issuance of debt for $56.0 million, consisting $33.6 million from issuance of PHC notes, net proceeds of $14.4 million from the issuance of First Lien Notes, the PPP loan of $5.8 million and net proceeds from issuance of preferred stock of $2.5 million.

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, 2021, we had cash, cash equivalents and marketable securities of $181.8 million and at December 31, 2020 we had cash, cash equivalents and restricted cash of $18.2 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 interest rate on all of our notes payable are fixed. 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.

In addition, the uncertainty that exists with respect to the economic impact of the global COVID-19 pandemic has introduced significant volatility in the financial markets subsequent to our quarter ended December 31, 2021, which could increase our foreign currency and interest 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 Shareholders and the Board of Directors of Senseonics Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Senseonics Holdings, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2021, and the related notes, (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

	Valuation of Derivatives Instruments and Options
Description of the Matter	As discussed in Note 16 of the consolidated financial statements, the Company measures financial assets and liabilities at fair value using Level 3 inputs. As of December 31, 2021, the financial liabilities measured at fair value are $224.3 million and the financial assets measured at fair value are $0.2 million. To determine fair value of each financial asset and liability the Company determines the appropriate valuation methodology and assumptions,

including unobservable inputs. For example, the derivative liabilities are measured at fair value using a binomial option pricing model that uses observable and unobservable market data for inputs, including the Company's stock price, implied volatility of the Company's shares, and probability of conversion occurrence through maturity.

Auditing management's estimate for the fair value of the financial assets and liabilities involved subjective auditor judgment because the fair value calculations were sensitive to changes in assumptions described above, and certain inputs used in the determination of fair values were based on unobservable data, including, but not limited to, the implied volatility and probability of conversion.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's assets and liability valuation process. This included controls over management's assessment of the significant inputs and estimates included in the fair value measurements.

Our audit procedures included, among others, evaluating the methodologies used in the valuation model and the significant assumptions. We involved our valuation specialist to assist in the evaluation including to develop an independent valuation of the instruments. We also performed a sensitivity analysis of the significant assumptions, including the implied volatility and probability of conversion, to evaluate the change in the fair value that would result from changes in the assumptions.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

Tysons, VA
March 1, 2022

Senseonics Holdings, Inc.

Consolidated Balance Sheets
(in thousands, except for share and per share data)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 33,461	$ 18,005
Restricted cash	—	200
Short term investments, net	96,445	—
Accounts receivable, net	205	565
Accounts receivable, net - related parties	1,768	2,421
Inventory, net	6,316	5,281
Prepaid expenses and other current assets	6,218	3,774
Total current assets	144,413	30,246
Option	239	1,886
Deposits and other assets	1,086	2,229
Long term investments, net	51,882	—
Property and equipment, net	1,308	1,557
Total assets	$ 198,928	$ 35,918
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,204	$ 1,762
Accrued expenses and other current liabilities	10,667	11,674
Accrued expenses and other current liabilities- related parties	3,597	—
Term Loans, net	2,926	3,202
Total current liabilities	18,394	16,638
Long-term debt and notes payables, net	59,798	57,216
Derivative liabilities	236,291	62,119
Option	69,401	39,734
Other liabilities	579	1,483
Total liabilities	384,463	177,190
Preferred stock and additional paid-in-capital, subject to possible redemption: $0.001 par value per share; 0 shares issued and outstanding as of December 31, 2021 and 3,000 shares issued and outstanding as of December 31, 2020	—	2,811
Total temporary equity	—	2,811
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value per share; 900,000,000 shares authorized; 447,282,263 and 265,582,688 shares issued and outstanding as of December 31, 2021 and December 31, 2020	447	266
Additional paid-in capital	765,215	504,162
Accumulated other comprehensive income, net of tax	(212)	—
Accumulated deficit	(950,985)	(648,511)
Total stockholders' deficit	(185,535)	(144,083)
Total liabilities and stockholders' deficit	$ 198,928	$ 35,918

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,		
	2021	**2020**	**2019**
Revenue, net	$ 1,394	$ 1,368	$ 4,924
Revenue, net - related parties	12,281	3,581	16,377
Total revenue	13,675	4,949	21,301
Cost of sales	14,486	22,315	40,749
Gross profit (loss)	(811)	(17,366)	(19,448)
Expenses:			
Sales and marketing expenses	5,483	20,550	49,555
Sales and marketing expenses- related parties	2,133	—	—
Total sales and marketing expenses	7,616	20,550	49,555
Research and development expenses	27,217	20,413	38,430
General and administrative expenses	21,538	20,801	23,229
Operating loss	(57,182)	(79,130)	(130,662)
Other income (expense), net:			
Interest income	243	175	1,933
Loss on fair value adjustment of option	(53,152)	(30,721)	—
Gain (Loss) on extinguishment of debt and option	330	(21,112)	(398)
Loss on issuance of debt & other issuance costs	—	(12,706)	—
Interest expense	(16,720)	(16,167)	(11,799)
Debt issuance costs	—	(1,216)	(3,344)
Gain (Loss) on change in fair value of derivatives	(174,173)	(11,641)	29,232
Impairment cost	(1,647)	(2,339)	—
Other expense	(173)	(311)	(511)
Total other income (expense), net	(245,292)	(96,038)	15,113
Net Loss	(302,474)	(175,168)	(115,549)
Other comprehensive loss, net of tax			
Unrealized loss on marketable securities	(212)	—	—
Total other comprehensive loss, net of tax	(212)	—	—
Total comprehensive loss, net of tax	$ (302,686)	$ (175,168)	$ (115,549)
Basic net loss per common share	$ (0.72)	$ (0.77)	$ (0.61)
Basic weighted-average shares outstanding	422,321,023	227,912,358	188,754,160
Diluted net loss per common share	$ (0.72)	$ (0.77)	$ (0.61)
Diluted weighted-average shares outstanding	422,321,023	227,912,358	188,754,160

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

Senseonics Holdings, Inc.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(in thousands)

	Common Stock		Additional Paid-In	Accumulated Other	Accumulated	Total Stockholders'	Series A Convertible Preferred Stock Temporary
	Shares	Amount	Capital	Comprehensive Loss	Deficit	Equity (Deficit)	Equity
Balance, December 31, 2018	176,918	177	428,878	—	(357,794)	71,261	$ —
Issuance of common stock, net	26,136	26	26,731	—	—	26,757	—
Exercise of stock options and warrants	256	—	108	—	—	108	—
Conversion of 2023 Notes	143	—	8,052	—	—	8,052	—
Stock-based compensation expense and vesting of RSU's	—	—	722	—	—	722	—
Net loss	—	—	—	—	(115,549)	(115,549)	—
Balance, December 31, 2019	203,453	$ 203	$ 464,491	$ —	$ (473,343)	$ (8,649)	$ —
Issuance of convertible preferred stock, net	—	—	—	—	—	—	2,811
Issuance of common stock, net	329	—	(26)	—	—	(26)	—
Exercise of stock options and ESPP purchases	3,329	3	573	—	—	576	—
Exchange and conversion of convertible notes, net	58,470	60	27,199	—	—	27,259	—
Stock-based compensation expense and vesting of RSU's	—	—	7,314	—	—	7,314	—
Issuance of warrants related to debt, net	—	—	4,611	—	—	4,611	—
Net loss	—	—	—	—	(175,168)	(175,168)	—
Balance, December 31, 2020	265,581	$ 266	$ 504,162	$ —	$ (648,511)	$ (144,083)	$ 2,811
Issuance of convertible preferred stock, net	—	—	—	—	—	—	42,756
Conversion of preferred stock	54,166	54	45,511	—	—	45,565	(45,567)
Issuance of common stock, net	112,571	113	200,252	—	—	200,365	—
Exercise of stock options and warrants	5,732	5	4,988	—	—	4,993	—
Exchange and conversion of convertible notes, net	4,925	5	6,496	—	—	6,501	—
Issuance of common stock for vested RSUs and ESPP purchase	5,816	6	68	—	—	74	—
Shares withheld related to net share settlement	(1,509)	(2)	(5,291)			(5,293)	
Stock-based compensation expense	—	—	9,029	—	—	9,029	—
Net loss	—	—	—	—	(302,474)	(302,474)	—
Other comprehensive income, net of tax	—	—	—	(212)	—	(212)	—
Balance, December 31, 2021	447,282	$ 447	$ 765,215	$ (212)	$ (950,985)	$ (185,535)	$ —

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

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

	Years Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities			
Net loss	$ (302,474)	(175,168)	$ (115,549)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	1,239	1,141	1,001
Non-cash interest expense (debt discount and deferred costs)	8,462	10,977	8,457
Change in fair value of derivatives	174,173	11,641	(29,232)
Loss on fair value adjustment of option	53,152	30,721	—
(Gain) Loss on extinguishment of debt and option	(330)	21,112	398
Loss on issuance of debt	—	12,706	—
Impairment of right-of-use asset	518	—	—
Impairment of option	1,647	2,339	—
Stock-based compensation expense	9,029	7,314	8,052
Loss on disposal of assets	10	181	310
Changes in assets and liabilities:			
Accounts receivable	1,013	7,393	(3,282)
Prepaid expenses and other current assets	(2,444)	737	(527)
Inventory	(1,036)	11,648	(6,698)
Deposits and other assets	(164)	117	(3,442)
Accounts payable	(559)	(2,522)	(122)
Accrued expenses and other liabilities	1,314	(6,585)	4,827
Deferred revenue	—	—	(628)
Accrued interest	372	(379)	388
Operating lease liabilities	—	(795)	—
Net cash used in operating activities	(56,078)	(67,422)	(136,047)
Cash flows from investing activities			
Capital expenditures	(210)	(181)	(1,045)
Purchase of marketable securities	(154,514)	—	—
Proceeds from sale and maturity of marketable securities	5,975	—	—
Net cash used in investing activities	(148,749)	(181)	(1,045)
Cash flows from financing activities			
Issuance of common stock, net	200,365	(26)	26,757
Proceeds from exercise of stock options, stock warrants and ESPP purchases	5,066	576	108
Taxes paid related to net share settlement of equity awards	(5,293)	—	—
Proceeds from debt issuance, net	—	55,971	127,000
Note issuance costs	—	(601)	(4,301)
Proceeds from Solar term loan, net of cost	—	—	(2,049)
Proceeds from issuance of Masters preferred stock, net	22,783	—	—
Proceeds from issuance of warrants, net of costs	—	—	722
Repayment of term loans	(2,838)	(66,050)	(15,000)
Repurchase of 2023 Notes	—	—	(37,000)
Net cash provided by (used in) financing activities	220,083	(10,130)	96,237
Net increase (decrease) in cash, cash equivalents and restricted cash	15,256	(77,733)	(40,855)
Cash, cash equivalents and restricted cash, at beginning of period	18,205	95,938	136,793
Cash, cash equivalents and restricted cash, at ending of period	$ 33,461	$ 18,205	$ 95,938
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	$ 7,822	$ 4,726	$ 5,233
Lease liabilities arising from obtaining right-of-use assets	—	—	2,974
Supplemental disclosure of non-cash investing and financing activities			
Property and equipment purchases included in accounts payable and accrued expenses	30	—	32
Issuance of common stock converted from preferred shares	54,166	—	—
Issuance of common stock converted from notes payables	4,925	227	—

Issuance of common stock and warrants - Highbridge transactions	—	55,303	—
Issuance of warrants - Energy Capital	—	3,399	—
Exchange of 2025 Notes for Second Lien Notes	—	(24,000)	—
Issuance of Second Lien Notes	—	15,675	—

The accompanying notes are an integral part of these 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 system 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 and was originally incorporated on October 30, 1996 and commenced operations on January 15, 1997. Senseonics Holdings and Senseonics, Incorporated are hereinafter collectively referred to as the "Company" unless otherwise indicated or the context otherwise requires.

2. Liquidity

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, lack of operating history 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® CGM System (for use up to 90 days) in the United States and the Eversense CGM and Eversense XL CGM Systems (for use up to six months) in Europe, the Middle East, and Africa. The Company has not generated significant revenue 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 2022 and beyond.

The Company generated a net loss of $302.5 million for the twelve months ended December 31, 2021 and had an accumulated deficit of $951.0 million at December 31, 2021. To date, we have funded its operations principally through the issuance of preferred stock, common stock, convertible note issuance and debt. As of December 31, 2021, we had cash, cash equivalents and marketable securities of $181.8 million

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 will receive a commission 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, 2021, the Company did not execute any sales of common stock under the 2021 Sales Agreement. However, as of the date of this Annual Report on Form 10-K, the Company received $8.1 million in net proceeds from the sale of 3,077,493 shares of its common stock under the 2021 Sales Agreement.

In November 2019, the Company entered into an Open Market Sale Agreement (the "2019 Sales Agreement") with 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 $50.0 million through Jefferies as the sales agent in an "at the market" offering. In June 2021, the Company received $48.4 million in net proceeds from the sale of 12,830,333 shares of its common stock utilizing the full capacity under the 2019 Sales Agreement. For the twelve months ended December 31, 2020, the Company received $0.1 million in net proceeds from the sale of 175,289 shares of its common stock under the 2019 Sales Agreement.

On January 21, 2021, the Company entered into an underwriting agreement, which was subsequently amended and restated on the same day (the "Underwriting Agreement") with H.C. Wainwright & Co., LLC, as representative of the underwriters (the "Underwriters"), to issue and sell 51,948,052 shares of common stock, in an underwritten public offering pursuant to effective registration statements on Form S-3, including and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission (the "Offering"). The price to the public in the Offering was $1.925 per share of common stock. The Underwriters agreed to purchase the shares from the Company

pursuant to the Underwriting Agreement at a price of $1.799875 per share and the Company also agreed to reimburse them for customary fees and expenses. The initial closing of the Offering occurred on January 26, 2021. Subsequent to the initial closing, the Underwriters exercised their option to purchase an additional 7,792,207 shares of Common Stock. Total net proceeds from the Offering were $106.1 million after deducting underwriting discounts and commissions and estimated offering expenses.

On January 17, 2021, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional purchasers (the "Purchasers"), pursuant to which the Company sold to the Purchasers, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 40,000,000 shares (the "Shares") of common stock, $0.001 par value per share. The Shares were sold at a purchase price of $1.25 per share for aggregate gross proceeds to the Company of $50 million, before deducting fees to the placement agent and other estimated offering expenses payable by the Company. The Shares were offered and sold by the Company pursuant to an effective shelf registration statement on Form S-3, which was originally filed with the Securities and Exchange Commission on November 27, 2019. The net proceeds to the Company from the Registered Direct Offering, after deducting fees and expenses and the estimated offering expenses payable by the Company, are approximately $46.1 million.

On November 9, 2020, the Company entered into an equity line agreement, ("Equity Line Agreement"), with Energy Capital, LLC ("Energy Capital"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Energy Capital is committed to purchase up to an aggregate of $12.0 million of shares of the Company's newly designated series B convertible preferred stock, or the Series B Preferred Stock, at the Company's request from time to time during the 24-month term of the Equity Line Agreement. Under the Equity Line Agreement, beginning January 21, 2021, subject to the satisfaction of certain conditions, including that the Company has less than $8 million of cash, cash equivalents and other available credit (aside from availability under the Equity Line Agreement), the Company has the right, in its sole discretion, to present Energy Capital with a purchase notice, or a Regular Purchase Notice, directing Energy Capital (as principal) to purchase shares of Series B Preferred Stock at a price of $1,000 per share (not to exceed $4.0 million worth of shares) once per month, up to an aggregate of $12.0 million of its Series B Preferred Stock at a per share price, or the Purchase Price, equal to $1,000 per share of Series B Preferred Stock, with each share of Series B Preferred Stock initially convertible into common stock, beginning nine months after the date of its issuance, at a conversion price of $0.3951 per share. The Equity Line Agreement provides that the Company shall not affect any Regular Purchase under the Equity Line Agreement on any date where the closing price of the common stock on the NYSE American is less than $0.25 without the approval of Energy Capital.

On August 9, 2020, the Company entered into a Collaboration and Commercialization Agreement with Ascensia Diabetes Care Holdings AG ("Ascensia") and entered into a financing agreement pursuant to which the Company issued $35.0 million in aggregate principal amount of Senior Secured Convertible Notes due in October 2024 (the "PHC Notes") to Ascensia's parent company, PHC Holdings Corporation ("PHC") on August 14, 2020 (the "Closing Date"). The Company also issued PHC 2,941,176 shares of common stock to PHC as a financing fee. The Company also has the option to sell and issue PHC up to $15.0 million of convertible preferred stock on or before December 31, 2022. Upon the closing of the PHC Notes, we prepaid the Highbridge First Lien Notes in full, in the amount of approximately $17.6 million, which includes the discounted prepayment premium.

Additionally, on August 9, 2020, the Company entered into a Stock Purchase Agreement with Masters Special Solutions, LLC and certain affiliates thereof ("Masters"), pursuant to which the Company issued and sold to Masters 3,000 shares of convertible preferred stock, designated as Series A Preferred Stock (the "Series A Preferred Stock"), at a price of $1,000.00 per share in an initial closing. Masters also had the option to purchase up to an additional 27,000 shares of Series A Preferred Stock at a price of $1,000.00 per share in subsequent closings, subject to the terms and conditions of the Stock Purchase Agreement, as amended, through January 11, 2021. In January 2021, Masters and its assignees purchased in aggregate an additional 22,783 shares of Series A Preferred Stock, resulting in additional gross proceeds of $22.8 million. Each share of Series A Preferred Stock is initially convertible into a number of shares of common stock equal to $1,000 divided by the conversion price of $0.476 per share, subject to customary anti-dilution adjustments, including in the event of any stock split. All shares of Series A Preferred Stock have been converted to common stock as of December 31, 2021.

The Company believes that these agreements provide the financial resources and mutual commitment to support the growth of Eversense and specifically for the Company, the manufacturing of Eversense and continued product development, including the U.S. launch of the new Eversense E3 product. The timing and success of these collaborations and financings are dependent on certain events occurring in accordance with the Company's plans, and may be influenced by uncontrollable external factors, including restrictions or impacts of COVID-19. Management has concluded that based on the Company's current operating plans, its existing cash and cash equivalents will be sufficient to meet the Company's anticipated operating needs through 2023.

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"). The consolidated financial statements reflect the accounts of Senseonics Holdings and its wholly owned subsidiary Senseonics. All intercompany balances and transactions have been eliminated in consolidation.

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, deferred taxes and valuation allowances, derivative assets and liabilities, obsolete inventory, warranty obligations, variable consideration related to revenue, 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.

Segment Information

The Company views its operations and manages its business in one segment, glucose monitoring products.

Comprehensive Loss

Comprehensive income (loss) comprises net income (loss) and other changes in equity that are excluded from net income (loss). For the twelve months ended December 31, 2021, the Company's comprehensive income (loss) included $0.2 million of other comprehensive loss related to the unrealized loss on marketable securities. For the years ended December 31, 2020 and 2019, the Company's net loss equaled its comprehensive loss and, accordingly, no additional disclosure is presented.

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. Cash, cash equivalents and restricted cash consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Cash [1]	$ 4,264	$ 18,002

Money market funds	29,197	3
Cash and cash equivalents	$ 33,461	$ 18,005

(1) Includes overnight repurchase agreements.

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 33,461	$ 18,005
Restricted cash	—	200
Cash, cash equivalents and restricted cash	$ 33,461	$ 18,205

Concentration of Revenues and Customers

Net revenue from the Company's distribution arrangement with Ascensia, a related party, accounted for 90% of total net revenues for the year ended December 31, 2021. Net revenue from distribution arrangement with Roche Diabetes Care GmbH, a related party, accounted for 72% of total net revenues for the year ended December 31, 2020. Revenue from distribution arrangement with Edwards Healthcare Centers, Advanced Diabetes Supply, and Solara Medical Supply, strategic fulfillment partners and supplier of CGM systems to diabetic patients in the United States, accounted for 19%, 15%, and 10%, respectively, of total net revenues for the year ended December 31, 2020. During the year ended December 2019, the Company derived 77% of its total net revenue from Roche, and 12% from Advanced Diabetes Supply.

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, 2021, 2020 and 2019:

	December 31, 2021		December 31, 2020		December 31, 2019	
(Dollars in thousands)	Amount	% of Total	Amount	% of Total	Amount	% of Total
Revenue, net:						
Outside of the United States	$ 11,117	81.3 %	$ 3,821	77.2 %	$ 18,054	84.8 %
United States	2,558	18.7	1,128	22.8	3,247	15.2
Total	$ 13,675	100.0 %	$ 4,949	100.0 %	$ 21,301	100.0 %

Marketable Securities

Marketable securities 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.

Accounts Receivable

The Company grants credit to various customers in the normal course of business. Accounts receivable consist of amounts due from distributors and are reduced by an allowance for doubtful accounts at the time potential collection risk is identified. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible. The Company does not have a history of collectability concerns, and no allowance for uncollectible accounts was recorded as of December 31, 2021. The Company had an immaterial allowance for doubtful accounts as of December 31, 2020.

Property and Equipment

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.

Long-lived Assets

Management reviews long-lived assets, including property and equipment 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. Management identified indicators of impairment on right-of-use assets in 2021. Management did not identify any indicators of impairment in 2020 and 2019.

Derivative Financial Instruments

In connection with the Company's issuance of the convertible senior subordinated notes due 2023 (the "2023 Notes"), in January 2018, the Company 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 the Company's consolidated balance sheets in accordance with Accounting Standards Codification ("ASC") Topic 815, *Derivatives and Hedging*.

In July 2019, the Company issued $82.0 million in aggregate principal amount of convertible senior subordinated notes due 2025 (the "2025 Notes). In connection with the 2025 Notes, the Company 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 the Company's consolidated balance sheets in accordance with ASC Topic 815, *Derivatives and Hedging*.

On April 21, 2020, the Company entered into the Highbridge Loan Agreement, in which an aggregate principal amount of $15.0 million was borrowed through the issuance and sale of the First Lien Notes and issued 1,500,000 shares of its common stock to the Lenders as a commitment fee. The First Lien Notes also contained redemption features that were evaluated for bifurcation as separate derivative instruments including the permitted prepayment put option, the mandatory accelerated redemption and the mandatory redemption and reinvestment upon an asset sale. The Company recorded the fair value of the embedded features in the amount of $1.0 million as a debt premium and derivative asset in its 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 recorded in change in fair value of derivatives that is a component of other income (expense) in its consolidated statements of operations and comprehensive loss. On August 14, 2020, the Company prepaid the First Lien Notes in full, including the discounted prepayment premium, in the amount of approximately $17.6 million and recognized a loss on extinguishment in the amount of $0.7 million.

On April 21, 2020, the Company entered into a Note Purchase and Exchange Agreement with certain funds managed by Highbridge providing for the exchange (the "Exchange") of $24.0 million aggregate principal amount of the outstanding 2025 Notes for (i) $15.7 million aggregate principal amount of newly issued Second Lien Notes, (ii) 11,026,086 shares of common stock, (iii) warrants to purchase up to 4,500,000 shares of common stock at an exercise price of $0.66 per share, and (iv) $0.3 million in accrued and unpaid interest on the 2025 Notes being exchanged. On August 9, 2020, the Company entered into a First Amendment to Note Purchase and Exchange Agreement with Highbridge (as amended by the Amendment, the "Exchange Agreement"). The Second Lien Notes also contained redemption features that were evaluated for bifurcation as separate derivative instruments including the permitted prepayment put option, the mandatory accelerated redemption and the mandatory redemption and reinvestment upon an asset sale. Unlike the First Lien Notes, the Second Lien Notes also permit voluntary conversion at the option of the holder as described above. The Company recorded the fair value of these embedded features in the amount of $1.9 million as a derivative asset in its 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 its consolidated statement of operations and comprehensive loss. During the fiscal year ended December 31, 2020, Highbridge elected to convert the full $15.7 million of outstanding principal on the Second Lien Notes for issuance of 42,776,936 shares of common stock, which included prepayment premiums and were based off of its election of PIK interest.

In August 2020, the Company issued $35.0 million in aggregate principal amount of convertible senior secured notes due PHC, 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. 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 financial instruments above 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.

Warranty Obligation

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.

At December 31, 2021 and December 31, 2020, the warranty reserve was $0.7 million and $0.6 million, respectively. The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Balance at beginning of the period	$ 646	$ 2,197
Provision for warranties during the period	781	(266)
Settlements made during the period	(704)	(1,285)
Balance at end of the period	$ 723	$ 646

Revenue Recognition

The Company generates product revenue from sales of the Eversense system and related components and supplies to Ascensia, through the Commercialization Agreement, third-party distributors in the European Union and to strategic fulfillment partners in the United States, or collectively, Customers, who then resell the products to health care providers and patients. The Company is paid for its sales directly to the Customers, regardless of whether or not the Customers resell the products to health care providers and patients.

Revenue from product sales is recognized at a point in time when the Customers obtain control of the Company's product based upon the delivery terms as defined in the contract at an amount that reflects the consideration which the Company expect to receive in exchange for the product. Contracts with the Company's 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.

The Company's contracts may contain some form of variable consideration such as prompt-pay discounts, tier-volume price discounts and for the Ascensia commercial 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 significant management judgment. Depending on the variable consideration, the Company develops estimates for the expected value based on the terms of the agreements, historical data, geographic mix, reimbursement rates, Ascensia's ability to sell through the inventory and market conditions.

Contract assets consist of trade receivables and unbilled receivables from customers and are recorded at net realizable value. Unbilled receivables relate to the revenue share variable consideration from the Ascensia commercial 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.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of salaries, commissions, and other related costs, including stock-based compensation, for personnel who perform sales, marketing, and customer support functions. Other significant costs include website design and advertising, educational and promotional materials, consultants, tradeshow expenses, marketing programs and support for Ascensia's marketing programs including direct to consumer campaigns.

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.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in the Company's executive, finance, accounting, business development, information technology, and human resources functions. Other significant costs include information technology, 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, future volatility of the Company's stock price, dividend yields, future employee turnover rates, and future employee stock option exercise behaviors. Changes in these assumptions can affect the fair value estimate.

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. 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 a peer group of comparable publicly traded companies in similar stages of development.

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 exposures 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 1998 and all subsequent periods due to the availability of NOL 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

The carrying amounts of cash, cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The Company's term loan under the 2025 Notes, PHC Notes, 2023 Notes, and Warrants are recorded at historical cost, net of discounts, and approximate fair value based on their borrowing rates. The associated embedded conversion features in the Notes are derivative instruments and along with Options are remeasured at fair value each reporting period.

Net Loss per Share

Basic loss per share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential common shares is anti-dilutive. The total number of anti-dilutive shares at December 31, 2021, 2020 and 2019, consisting of common stock options and stock purchase warrants, which have been excluded from the computation of diluted loss per share, was as follows:

	2021	2020	2019
Stock-based awards	26,140,291	30,013,407	24,218,612
Masters preferred shares	—	6,302,521	—
2023 Notes	4,617,646	6,672,500	6,672,500
PHC Notes	65,757,177	68,222,412	—
2025 Notes	39,689,142	44,728,676	63,565,883
Warrants	13,177,822	17,282,792	5,196,581
Total anti-dilutive shares outstanding	149,382,078	173,222,308	99,653,576

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options stock purchase warrants and employee stock purchases using the treasury stock method.

Recent Accounting Pronouncements

Recently Adopted

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes, which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. The Company has adopted this guidance as of January 1, 2021 and did not have a material impact on the consolidated financial statements and related disclosures.

Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments, which requires entities to record expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities in unrealized loss positions, the new standard requires allowances to be recorded instead of reducing the amortized cost of the investment. The Company currently holds investments in available-for-sale securities. The Company has not historically experienced collection issues or bad debts with trade receivables. Accordingly, the Company does not expect this to have a significant impact on its consolidated financial statements and related disclosures at this time. Since the Company qualified as a smaller reporting company as of June 28, 2019, it maintains its status as a smaller reporting company for the adoption of this standard. As such, the Company will adopt this guidance on the effective date for smaller reporting companies, January 1, 2023.

In August 2020, the FASB issued ASU 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contract in Entity’s Own Equity (Subtopic 815-40). This new guidance is intended to reduce the complexity of accounting for convertible instruments. The guidance also addresses how convertible instruments are accounted for in the diluted earnings per share calculation and requires enhanced disclosures about the terms of convertible instruments. Entities may adopt ASU 2020-06 using either partial retrospective or fully retrospective method of transition. This ASU is effective for public business entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning

December 15, 2020, including interim periods within that fiscal year. The Company adopted this guidance on its effective date of January 1, 2022 and does not expect this to have a significant impact on its consolidated financial statements and related disclosures at this time.

The Company evaluated all other issued unadopted ASUs and believes the adoption of these standards will not have a material impact on its consolidated statements of operations and comprehensive loss, balance sheets, or cash flows.

4. Marketable Securities

Marketable securities available for sale, were as follows (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
Commercial Paper	$ 57,369	—	—	$ 57,369
Corporate debt securities	$ 39,825	—	(77)	$ 39,748
Asset backed securities	$ 26,736	—	(29)	$ 26,707
Government and agency securities	$ 24,609	—	(106)	$ 24,503
Total	$ 148,539	$ —	$ (212)	$ 148,327

There were no marketable securities at December 31, 2020.

The following are the scheduled maturities as of December 31, 2021 (in thousands):

2022	$ 96,479
2023	45,478
2024	3,552
Thereafter	3,030
Total	$ 148,539

The Company periodically review 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 at December 31, 2021 were not significant and were primarily due to changes in interest rates and not due to increased credit risk associated with specific securities. The Company does not intend to sell these impaired 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.

5. Inventory, net

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

	December 31,	
	2021	2020
Finished goods	$ 1,012	$ 203
Work-in-process	3,770	2,626
Raw materials	1,534	2,452
Total	$ 6,316	$ 5,281

The Company recorded $2.4 million, $15.1 million and $5.3 million in cost of sales for the years ended December 31, 2021, 2020 and 2019, respectively, to reduce the value of inventory for items that are potentially obsolete, to adjust costs to their net realizable value, and for inventory in excess of product demand.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Contract manufacturing[1]	$ 5,036	$ 3,324
Interest receivable	443	—
IT and software	225	150
Clinical and Preclinical	142	11
Rent	105	102
Sales and Marketing	98	53
Insurance	74	50
Research and development	39	—
Other	29	—
Corporate and Finance Consulting	27	84
Total prepaid expenses and other current assets	$ 6,218	$ 3,774

(1) Includes deposits to contract manufacturers for manufacturing process.

7. Property and Equipment, net

Property and equipment, net consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Machinery and laboratory equipment	$ 2,357	$ 2,176
Office furniture and equipment	354	371
Leasehold improvements	127	112
	2,838	2,659
Less: Accumulated depreciation	(1,530)	(1,102)
Property and equipment, net	$ 1,308	$ 1,557

Depreciation expense for the years ended December 31, 2021, 2020, and 2019 was $0.5 million, $0.4 million, and $0.5 million, respectively. The Company disposed of less than $0.1 million of property and equipment in 2021 related to machinery and laboratory equipment, including machinery at contract manufacturers determined to be

impaired or obsoleted. The Company disposed of $0.3 million and $1.4 million of property and equipment in 2020 and 2019, respectively.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Compensation and benefits	$ 3,484	$ 4,344
Research and development	2,145	842
Interest on notes payable	2,144	1,773
Sales and marketing services	1,962	615
Product warranty and replacement obligations	1,697	646
Professional and administration services	1,011	880
Contract manufacturing	914	1,421
Operating lease	904	794
Other	3	151
Patient access programs	—	208
Total accrued expenses and other current liabilities	$ 14,264	$ 11,674

9. 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 operating 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 to rent expense over the related term.

The Company leases approximately 33,000 square feet of research and office space for its corporate headquarters under a non-cancelable operating lease expiring in 2023. The Company has an option to renew the lease for one additional five-year term. With the adoption of ASC 842, the Company has recorded a ROU asset and corresponding lease liability and does not include the additional five-year term under the option.

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 does not have the option to renew the lease for an additional term. 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 the Company will continue making lease payments until the lease expires. An impairment charge of $0.5 million was recorded during the twelve months ended December 31, 2021.

The Company recorded $0.8 million of associated ROU assets and $1.5 million in lease liabilities in its consolidated balance sheet at December 31, 2021.

Operating lease expense for the year ended December 31, 2021, 2020 and 2019 was $0.9 million, $0.9 million and $0.7 million, respectively.

The following table summarizes the lease assets and liabilities as of December 31, 2021 (in thousands):

Operating Lease Assets and Liabilities	Balance Sheet Classification	Amount
Assets		
Operating lease ROU assets	Deposits and other assets	$ 821
Liabilities		
Current operating lease liabilities	Accrued expenses and other current liabilities	$ 904
Non-current operating lease liabilities	Other non-current liabilities	579
Total operating lease liabilities		$ 1,483

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, 2021 (in thousands):

2022	1,002
2023	600
2024	-
2025	-
2026	-
Total	1,602
Present value adjustment	(119)
Present value of lease liabilities	$ 1,483

The following table summarizes the weighted-average lease term and weighted-average discount rate as of December 31, 2021 and 2020:

Remaining lease term (years)	2021	2020
Operating leases	1.6	2.6
Discount rate		
Operating leases	9.1 %	9.1 %

During the year ended December 31, 2021, the Company made cash payments of $0.9 million included in the measurement of its operating lease liabilities.

10. 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 1% up to 4% of the participant's contributions. Employer match expenses during the years ended December 31, 2021, 2020, 2019 were $0.3 million, $0.1 million and $0.2 million, respectively. Administrative expenses for the plan, which are paid by the Company, were not material in 2021, 2020 or 2019.

11. Notes Payable and Stock Purchase Warrants

Term Loans

PPP Loan

On April 22, 2020, the Company received $5.8 million in loan funding from the PPP pursuant to the CARES Act, as amended by the Flexibility Act, and administered by the Small Business Administration ("SBA"). The unsecured loan (the "PPP Loan") is evidenced by the PPP Note dated April 21, 2020 (the "PPP Note") in the principal amount of $5.8 million with SVB.

Under the terms of the PPP Note and the PPP Loan, interest accrues on the outstanding principal at a rate of 1.0% per annum. The term of the PPP Note is two years, though it may be payable sooner in connection with an event of default under the PPP Note. The Company has elected not to apply for forgiveness and began to make equal monthly payments of principal and interest, beginning in the third quarter of 2021.

The PPP Note may be prepaid in part or in full, at any time, without penalty. The PPP Note provides for certain customary events of default, including (i) failing to make a payment when due under the PPP Note, (ii) failure to do anything required by the PPP Note or any other loan document, (iii) defaults of any other loan with SVB, (iv) failure to disclose any material fact or make a materially false or misleading representation to SVB or SBA, (v) default on any loan or agreement with another creditor, if SVB believes the default may materially affect the Company's ability to pay the PPP Note, (vi) failure to pay any taxes when due, (vii) becoming the subject of a proceeding under any bankruptcy or insolvency law, having a receiver or liquidator appointed for any part of the Company's business or property, or making an assignment for the benefit of creditors, (viii) having any adverse change in financial condition or business operation that the SVB believes may materially affect the Company's ability to pay the PPP Note, (ix) if the Company reorganizes, merges, consolidates, or otherwise changes ownership or business structure without the SVB's prior written consent, or (x) becoming the subject of a civil or criminal action that SVB believes may materially affect the Company's ability to pay the PPP Note. Upon the occurrence of an event of default, SVB has customary remedies and may, among other things, require immediate payment of all amounts owed under the PPP Note, collect all amounts owing from the Company, and file suit and obtain judgment against the Company.

Highbridge Credit Facility

Highbridge Loan Agreement

On April 21, 2020, the Company entered into the Highbridge Loan Agreement with certain funds managed by Highbridge, the Lenders and Wilmington Savings Fund Society, SCB, as collateral agent.

Pursuant to the Highbridge Loan Agreement, the Company borrowed an aggregate principal amount of $15.0 million in aggregate principal through the issuance and sale of First Lien Notes (the "First Lien Notes") on April 24, 2020. In connection with the Highbridge Loan Agreement and receipt of the first tranche of borrowing, the Company issued 1,500,000 shares of its common stock to the Lenders as a commitment fee.

On August 14, 2020, the Company prepaid the First Lien Notes in full, including the discounted prepayment premium, in the amount of approximately $17.6 million and recognized a loss on extinguishment in the amount of $0.7 million.

The First Lien Notes were secured, senior obligations that bear interest at the annual rate of 12% or, at the Company's election, payment in kind ("PIK") at an annual rate of 13%, payable monthly in arrears. The First Lien Notes would have matured on October 24, 2021 (the "First Lien Maturity Date"). The obligations under the First Lien Notes were secured by substantially all the Company's assets.

The First Lien Notes also contained redemption features that were evaluated for bifurcation as separate derivative instruments including the permitted prepayment put option, the mandatory accelerated redemption and the mandatory redemption and reinvestment upon an asset sale. The Company recorded the fair value of the embedded features in the amount of $1.0 million as a debt premium and derivative asset 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 recorded in change in fair value of derivatives that was a component of other income (expense) in the Company's consolidated statements of operations and comprehensive loss.

The debt issuance costs incurred in connection with the Highbridge financings were allocated between the First Lien Notes, Second Lien Notes, common stock, and warrants. The Company incurred and deferred $1.5 million in debt issuance costs and debt discounts associated with the First Lien Notes, which were to be amortized as interest expense over the term of the First Lien Notes, along with $1.0 million of debt premium from the derivative bifurcation.

Exchange Agreement with Highbridge

On April 21, 2020, the Company entered into a Note Purchase and Exchange Agreement with certain funds managed by Highbridge providing for the exchange (the "Exchange") of $24.0 million aggregate principal amount of the Company's outstanding 2025 Notes for (i) $15.7 million aggregate principal amount of newly issued Second Lien Notes, (ii) 11,026,086 shares of common stock, (iii) warrants to purchase up to 4,500,000 shares of common stock at an exercise price of $0.66 per share, and (iv) $0.3 million in accrued and unpaid interest on the 2025 Notes being exchanged. The Exchange closed on April 24, 2020. The warrants may be exercised in cash or on a cashless basis at any time through the three-year anniversary of the issuance date.

On August 9, 2020, the Company entered into a First Amendment to Note Purchase and Exchange Agreement with Highbridge (as amended by the Amendment, the "Exchange Agreement"). The debt issuance costs incurred in connection with the Amendment were allocated to the Second Lien Notes. Loan modifications require third-party debt related costs to be expensed immediately. In connection with the Amendment, the Company recorded a total of $0.5 million in debt issuance costs which were expensed immediately.

The Second Lien Notes were secured, senior obligations of the Company, junior only to the First Lien Notes. Interest in cash at the annual rate of 7.5% or, at the Company's option, payment in kind at an annual rate of 8.25%, on the Second Lien Notes was payable monthly in arrears. The maturity date for the Second Lien Notes was August 9, 2023 (the "Second Lien Maturity Date"), unless earlier repurchased, redeemed or converted in accordance with their terms. The obligations under the Second Lien Notes were secured by substantially all of the Company's assets.

The Company had the right to prepay the Second Lien Notes at any time, subject to a prepayment premium, which in certain circumstances the Company may elect to pay in common stock, equal to the aggregate amount of interest payments through maturity.

The holders of the Second Lien Notes had the right to convert the aggregate principal of the Second Lien Notes (together with any applicable prepayment premium) to common stock at a price per share equal to 90% of the greater of (i) the daily volume weighted average of the price per share of the common stock, on the conversion date, or if the conversion date is not a trading date, the trading day immediately prior to the conversion date and (ii) $0.33 per share. This conversion option had a daily limit of $1.0 million in aggregate converted principal (inclusive of principal amount of First Lien Notes that are voluntarily converted by the Lenders). Subject to certain conditions, if the Company retains or reinvests proceeds of an asset sale pursuant to the Asset Sale Prepayment Provisions in the Exchange Agreement, the Holders shall be entitled to convert additional Second Lien Notes and the Lenders shall be entitled to convert First Lien Notes in aggregate combined principal amount equal to 45% of such net proceeds retained or reinvested (together with any applicable prepayment premium).

The Exchange Agreement contained customary terms and covenants, including without limitation: financial covenants, such as maintaining a minimum cash balance; 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 Exchange Agreement also contained customary events of default, after which the Second Lien Notes may be due and payable immediately, without limitation, payment defaults, material inaccuracy of representations and warranties, covenant defaults, material adverse changes, bankruptcy and insolvency proceedings, cross-defaults to certain other agreements, judgments against us, and change of control, termination of any guaranty, governmental approvals, and lien priority.

The Second Lien Notes also contained redemption features that were evaluated for bifurcation as separate derivative instruments including the permitted prepayment put option, the mandatory accelerated redemption and the mandatory redemption and reinvestment upon an asset sale. Unlike the First Lien Notes, the Second Lien Notes also permit voluntary conversion at the option of the holder as described above. The Company recorded the fair value of these embedded features in the amount of $1.9 million as a derivative asset 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.

Since Highbridge was a noteholder of the 2025 Notes and exchanged $24.0 million of outstanding principal of the 2025 Notes for Second Lien Notes, the Exchange qualifies as a loan modification. The debt issuance costs incurred in connection with the Highbridge financings were allocated between the First Lien Notes, Second Lien Notes, common stock, and warrants. Loan modifications require third-party debt related costs to be expensed immediately, whereas fees paid to lenders of the modified loans are deferred. In connection with the issuance of the Second Lien Notes, the Company recorded a total of $14.1 million in debt issuance costs and debt discounts, including $13.2 million allocated from the 2025 Notes for the $24.0 million outstanding principal exchanged and the discount from the bifurcated derivative. These costs were recorded as debt discounts to the Second Lien Notes and are amortized as interest expense over the term of the Second Lien Notes. Allocated third-party debt related costs of $0.8 million were expensed during the twelve months ended December 31, 2020.

For the twelve months ended December 31, 2020, Highbridge voluntarily converted all $15.7 million of outstanding principal amount of the Second Lien Notes for 42,776,936 shares of common stock, which included prepayment premiums and were based off the Company's election of PIK interest. Accordingly, $15.7 million of allocated deferred issuance costs, debt discounts and prepayment premiums were recognized as a loss on extinguishment of debt in the Company's consolidated statements of operations and comprehensive loss during the twelve months ended December 31, 2020.

Convertible Preferred Stock and Warrants

On November 9, 2020, the Company entered into an equity line agreement (the "Equity Line Agreement") with Energy Capital, LLC, a Florida limited liability company ("Energy Capital"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Energy Capital is committed to purchase up to an aggregate of $12.0 million of shares of the Company's newly designated series B convertible preferred stock (the "Series B Preferred Stock") at the Company's request from time to time during the 24-month term of the Equity Line Agreement. Under the Equity Line Agreement, beginning January 21, 2021, subject to the satisfaction of certain conditions, including the Company have less than $8 million of cash, cash equivalents and other available credit (aside from availability under the Equity Line Agreement), the Company has the right, in its sole discretion, to present Energy Capital with a purchase notice (each, a "Regular Purchase Notice") directing Energy Capital (as principal) to purchase shares of Series B Preferred Stock at a price of $1,000 per share (not to exceed $4.0 million worth of shares) once per month, up to an aggregate of $12.0 million of our Series B Preferred Stock at a per share price (the "Purchase Price") equal to $1,000 per share of Series B Preferred Stock, with each 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, subject to customary anti-dilution adjustments, including in the event of any stock split. The Equity Line Agreement provides that we shall not affect any Regular Purchase under the Equity Line Agreement on any date where the closing price of the Company's common stock on the NYSE American is less than $0.25 without the approval of Energy Capital. In addition, beginning on January 1, 2022, subject to the satisfaction of certain conditions, if the full $12.0 million of Series B Preferred Stock has not been sold pursuant to Regular Purchases, Energy Capital may, at its sole discretion, by its delivery to the Company of a Purchase Notice, from time to time, purchase up to the amount then remaining available under the Equity Line Agreement at the Purchase Price.

The Company accounted for the Equity Line Agreement as a put/call option. This put/call option is classified as a liability in accordance with ASC 480 on the Company's balance sheet and was recorded at the estimated fair value of $4.2 million upon issuance. In connection with the issuance of the Equity Line Agreement, the Company incurred and expensed $7.6 million in debt issuance costs. The put/call option is required to be remeasured to fair value at each reporting period with the change recorded in change in fair value of derivatives that is a component of other income (expense). The fair value as of December 31, 2021 was $69.4 million.

On August 9, 2020, the Company entered into a Stock Purchase Agreement with Masters, pursuant to which the Company issued and sold to Masters 3,000 shares of Series A Preferred Stock, at a price of $1,000.00 per share, on the Closing Date. Masters also had the option to purchase up to an additional 27,000 shares of Series A Preferred Stock at a price of $1,000.00 per share in a subsequent closing, subject to the terms and conditions of the Stock Purchase Agreement, as amended, through January 11, 2021. Each share of Series A Preferred Stock was initially convertible into a number of shares of common stock equal to $1,000 divided by the conversion price of $0.476 per share, subject to customary anti-dilution adjustments, including in the event of any stock split. The Series A Preferred Stock ranks senior to the common stock. Upon a liquidation, dissolution or winding up of the Company, each share of Series A Preferred Stock is entitled to receive an amount per share equal to the greater of the purchase price paid and the amount that the holder would have been entitled to receive at such time if the Series A Preferred Stock were converted into common stock. The holders are also entitled to participate in dividends declared or paid on the common stock on an as-converted basis. If we undergo a change of control, each holder has the right to cause us to redeem any or all of the Series A Preferred Stock for cash consideration equal to the liquidation amount. The holders of Series A 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. Additionally, certain matters will require the approval of the majority of the outstanding Series A Preferred Stock, voting as a separate class, including (i) altering or changing adversely the powers, privileges, preferences or rights of the Series A Preferred Stock, or (ii) amendments, modifications, repeal or waiver of any provision of the Company's certificate of incorporation, bylaws or of the certificate of designations that would adversely affect the rights, preferences, privileges or powers of the Series A Preferred Stock.

The Series A Preferred Stock was contingently redeemable upon occurrence of a change of control event which is considered outside the control of the Company, and therefore the Series A Preferred Stock was classified in temporary equity on the consolidated balance sheet. At each reporting period, the Company evaluated the probability of the Series A Preferred Stock being redeemed. The Company's policy is to recognize the difference in carrying value to redemption value once the redemption becomes probable.

The Company accounted for the option to purchase up to an additional 27,000 shares of preferred stock as a freestanding warrant instrument, as it is legally detachable and separately exercisable. This warrant is classified as a liability in accordance with ASC 480 on the Company's balance sheet and was recorded at the estimated fair value of $4.8 million upon issuance. The warrant was required to be remeasured to fair value at each reporting period with the change recorded in change in fair value of derivatives that is a component of other income (expense).

In January 2021, Masters and its assignees purchased in aggregate an additional 22,783 shares of Series A Preferred Stock, resulting in additional gross proceeds to the Company of $22.8 million. Each share of Series A Preferred Stock was initially convertible into a number of shares of common stock equal to $1,000.00 divided by the conversion price of $0.476 per share, subject to customary anti-dilution adjustments, including in the event of any stock split. All shares of Series A Preferred Stock have been converted to common stock as of December 31, 2021. Masters' option to purchase the remaining unissued shares of Series A Preferred Stock expired on January 11, 2021.

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 are accounted for as debt discount in the amount of $1.5 million.

The PHC Notes are senior secured obligations of the Company and will be guaranteed on a senior secured basis by the Company's wholly owned subsidiary, Senseonics, Incorporated. Interest at the annual rate of 9.5% will be payable semi-annually in cash or, at the Company's option, payment in kind. The interest rate will decrease to 8.0% if the Company obtains approval for 180-day Eversense for marketing in the United States, subject to certain conditions. The maturity date for the PHC Notes is October 31, 2024 (the "Maturity Date"), provided that the Maturity Date will accelerate if the Company has not repaid the Company's outstanding Second Lien Notes (other than an aggregate principal amount of up to $1.0 million) by 91 days prior to the maturity of the Second Lien Notes. The obligations under the PHC Notes are secured by substantially all of the Company's and its subsidiary's assets.

The Note Purchasers are entitled to convert the PHC Notes to common stock at a conversion rate of 1,867.4136 shares per $1,000 principal amount of the PHC Notes (including any interest added thereto as payment in kind), equivalent to a conversion price of approximately $0.54 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 will, in certain circumstances, 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 will be required to pay cash in lieu of delivering make whole shares unless the Company obtains stockholder approval to issue such shares.

Subject to specified conditions, on or after October 31, 2022, the PHC Notes are redeemable by the Company if the closing sale price of the common stock exceeds 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 are 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 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 Note Purchase Agreement also contains customary events of default, after which the PHC Notes 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 has the option to sell and issue PHC up to $15.0 million of convertible preferred stock on or before December 31, 2022. This purchased put option represents a freestanding financial instrument and is recognized as an asset in the Company's consolidated balance sheets at the fair value and subject to impairment testing in each reporting period prior to the options exercise or expiration. The Company acknowledges that while the purchased put option is subject to impairment testing, there is no explicit guidance regarding how impairment should be assessed and

measured for the PHC purchased put option. As such, the measurement alternative in ASC 321 for equity securities without readily determinable fair values can be applied by analogy to assess and measure impairment of the Purchased Put Option. The Company developed an estimated fair value at December 31, 2021 to be $0.2 million, and an impairment loss of $1.6 million was recognized in net income as the difference between the fair value of the investment and its carrying amount.

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. 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 is 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. The fair value of the derivative as of December 31, 2021 was $149.1 million.

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 are 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.

The PHC Notes do 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 and risky (bond) rate. The fair value of the Company's PHC Notes, excluding the embedded features, was $15.3 million as of December 31, 2021 and $12.7 million as of December 31, 2020.

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 will mature on January 15, 2025, unless earlier repurchased or converted.

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, and may be guaranteed by certain future subsidiaries. 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 are also deferred as discounts that are amortized as additional interest expense over the term of the notes. Of the $4.3 million, $3.3 million were expensed for loan modifications were recorded within other income (expense) on the consolidated statement of operations and comprehensive loss and $1.0 million were deferred as discounts to the debt in 2019.

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 is 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.

Based upon recent trading prices (Level 2-market approach) and other observable inputs, including the Company's common stock, implied volatility and risky (bond) rate, the fair value of the Company's 2025 Notes, excluding the embedded features, was $30.3 million as of December 31, 2021 and $29.0 million at December 31, 2020.

For the twelve months ended December 31, 2021, there were conversions of $6.5 million of outstanding principal amount of the 2025 Notes for 4,924,998 shares of common stock.

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 are 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 2023 Notes are general, unsecured, senior subordinated obligations of the Company. The Company pays 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. As the 2023 Notes have a maturity date of February 1, 2023, they are classified as a long-term liability on the Company's consolidated balance sheet at December 31, 2021.

Each $1,000 of principal of the 2023 Notes is 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 are being amortized to interest expense over the term of the 2023 Notes at an effective interest rate of 9.30%. The derivative is 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 2023 Notes do 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 and risky (bond) rate. The fair value of the Company's 2023 Notes, excluding the embedded features, was $14.2 million as of December 31, 2021 and $12.9 million at December 31, 2020. There were no conversions of 2023 Notes in the years ended December 31, 2021 or 2020.

The following carrying amounts are outstanding under the Company's notes payable as of December 31, 2021 and December 31, 2020 (in thousands):

	December 31, 2021			
	Principal ($)	Debt Discount ($)	Issuance Costs ($)	Carrying Amount ($)
2023 Notes	15,700	(1,499)	-	14,201
2025 Notes	51,199	(20,535)	(344)	30,320
PHC Notes	35,000	(18,587)	(1,136)	15,277
PPP Loan	2,926	-	-	2,926

	December 31, 2020			
	Principal ($)	Debt Discount ($)	Issuance Costs ($)	Carrying Amount ($)
2023 Notes	15,700	(2,755)	-	12,945
2025 Notes	57,700	(28,276)	(431)	28,993
PHC Notes	36,312	(22,237)	(1,359)	12,716
PPP Loan	5,763	-	-	5,763

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

	December 31, 2021					
	Effective Interest Rate	Interest ($)	Debt Discount and Fees ($)	Issuance Costs ($)	Loss on Extinguishment ($)	Total Interest Expense ($)
2023 Notes	5.25%	824	1,256	-	-	2,080
2025 Notes	5.25%	2,717	4,569	76	3,183	10,545
PHC Notes	9.50%	3,287	3,650	223	-	7,160
PPP Loan	1.00%	54	-	-	-	54
Total		6,882	9,475	299	3,183	19,839

	December 31, 2020					
	Effective Interest Rate	Interest ($)	Debt Discount and Fees ($)	Issuance Costs ($)	Loss on Extinguishment ($)	Total Interest Expense ($)
Solar Term Loan	8.98%	1,001	301		4,546	5,848
2023 Notes	5.25%	824	1,145	-	-	1,969
2025 Notes	5.25%	3,481	5,026	77	158	8,742
First Lien Notes	13.00%	627	29	49	689	1,394
Second Lien Notes	8.25%	288	786	11	15,719	16,804
PHC Notes	9.50%	1,312	1,141	70	-	2,523
PPP Loan	1.00%	31	5	5	-	41
Total		7,564	8,433	212	21,112	37,321

The following are the scheduled maturities of the outstanding debt, including the 2025 Notes, PHC Notes, 2023 Notes and PPP Loan as of December 31, 2021:

2022	$ 2,926
2023	15,700
2024	35,000
2025	51,199
Thereafter	—
Total	$ 104,825

12. Stockholders' Equity (Deficit)

In connection with the Company's acquisition of Senseonics, Incorporated in December 2015 (the "Acquisition"), (i) 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), (ii) 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 (iii) 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, 2021 and December 31, 2020, the Company's authorized capital stock included 900,000,000 shares of common stock, par value $0.001 per share. The Company had 447,282,263 and 265,582,688 shares of common stock issued and outstanding at December 31, 2021 and December 31, 2020, respectively.

Preferred Stock

As of December 31, 2021 and 2020, the Company's authorized capital stock included 5,000,000 shares of undesignated preferred stock, par value $0.001 per share. The Company had 0 shares of preferred stock outstanding as of December 31, 2021 and 3,000 shares of preferred stock outstanding as of December 31, 2020.

Stock Purchase Warrants

The Company also issued the Energy Capital Warrants to purchase an aggregate of 10,000,000 shares of the Company's common stock with an exercise price of $0.40 per share. The Energy Capital Warrants are exercisable until November 9, 2030. The warrants were recorded within equity based on their fair value of $3.4 million.

The Company issued the Highbridge 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. The Highbridge Warrants are exercisable until April 24, 2023. The proceeds from the Highbridge Notes were allocated between the debt and the Highbridge Warrants based on their fair value, and $1.3 million was recorded for the warrants within equity.

In connection with the issuance of the Oxford/SVB Notes, the Company 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. The cumulative fair value of the warrants, which the Company estimated to be $0.5 million, resulted in a discount to the Oxford/SVB Notes. These warrants expire on June 30, 2026, November 22, 2026, and March 29, 2027, respectively, and are classified in equity.

13. 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, 2021, 10,006,224 shares remained available for grant under the amended and restated 2015 Plan. Effective January 1, 2022, 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 25,661,103 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, 2021, 989,795 shares remained available for grant under the Inducement 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, 2021 there were 8,670,753 shares of common stock available for issuance under the 2016 ESPP.

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 February 1, 2021, there were 118,588 shares purchased in connection with the offering period. On August 1, 2021, there were 38,067 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. Approximately 2,109,815 shares of the Company's common stock underlying options have vested 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 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, 2021, 2020 and 2019 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, 2019	24,218	$ 2.16	
Granted	469	0.54	
Exercised	(201)	0.53	
Cancelled/forfeited	(8,711)	1.95	
Options outstanding as of December 31, 2020	15,775	2.16	6.51
Granted	224	2.98	
Exercised	(2,355)	1.61	
Cancelled/forfeited	(260)	3.06	
Options outstanding as of December 31, 2021	13,384		5.71
Options vested and expected to vest as of December 31, 2021	13,384	$ 2.38	
Options exercisable as of December 31, 2021	11,700	$ 2.36	5.46

The weighted average grant-date fair value of stock option awards granted in 2021, 2020 and 2019 was $1.97, $0.33 and $1.60 per share, respectively.

For the years ended December 31, 2021, 2020 and 2019, 2,354,566, 201,447, and 87,591, options were exercised, respectively, with an aggregate intrinsic value at the time of exercise of $4.4 million, $0.1 million, and $0.2 million, respectively.

The total fair value of options that vested during 2021 and 2020 were approximately $3.1 million and $5.8 million, respectively.

The aggregate intrinsic value of the options currently exercisable at December 31, 2021 was $5.1 million. The aggregate intrinsic value of stock options outstanding at December 31, 2021 was $5.7 million, which approximated the aggregate intrinsic value of options vested and expected to vest as of December 31, 2021.

The weighted average grant date fair value of the unvested stock option awards outstanding at December 31, 2021 and 2020 was $1.58 and $1.59 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, 2021 were $1.61, $1.05 and $1.89 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,		
	2021	2020	2019
Expected term of options (in years)	6.5	6.5	6.5
Expected volatility rate	69.93 -73.32 %	66.50 -67.41 %	64.49 -67.16 %
Risk-free interest rate	0.59 -1.25 %	0.41 -1.80 %	1.60 -2.64 %
Expected dividend yield	0 %	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 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.

Employee stock-based compensation expense for employee granted stock options was $3.2 million, $5.2 million and $7.8 million, for the years ended December 31, 2021 and 2020 and 2019, respectively, classified as follows (in thousands):

	December 31,		
	2021	2020	2019
Cost of sales	$ 30	59	153
Sales and marketing	545	1,570	3,001
Research and development	1,112	1,189	1,600
General and administrative	1,517	2,349	2,996
Total stock-based compensation	$ 3,204	$ 5,167	$ 7,750

As of December 31, 2021, there was $2.5 million of total unrecognized compensation cost related to non-vested employee stock option awards, which is expected to be recognized over a weighted average period of 1.41 years.

Restricted Stock Units

The Company issued 117,290 and 462,308 restricted stock units in lieu of cash payment for board and director fees to members of the Board of Directors during 2021 and 2020, respectively. These restricted stock units were immediately vested upon issuance. The Company also issued 4,603,440 and 17,455,264 restricted stock units to members of the Board of Directors as equity compensation under the Company's non-employee director compensation policy and to employees of the Company during 2021 and 2020, respectively, as incentive compensation. Of the restricted stock units granted in 2020, 3,893,278 were granted in December 2020 and are subject to performance-based vesting, and vested upon FDA approval of the U.S. E3 product in February 2022. All restricted stock units granted in 2021, and the remaining 13,288,909 restricted stock units granted in 2020 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. There were no restricted stock units granted in 2019 other than the issuance in lieu of cash to members of the Board of Directors in respect of director fees.

Restricted stock units activity under the Plans during the years ended December 31, 2021, 2020 and 2019 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, 2019	—	$ —	
Granted	17,918	0.45	
Vested	(3,322)	0.47	
Forfeited	(358)	0.48	
RSU's outstanding as of December 31, 2020	14,238	0.45	2.23
Granted	4,604	1.80	
Vested	(5,816)	0.71	
Forfeited	(270)	0.56	
RSU's outstanding as of December 31, 2021	12,756		2.44
RSU's vested and expected to vest as of December 31, 2021	12,756	$ 0.80	

The weighted average grant-date fair value of restricted stock units granted in 2021 and 2020 was $1.80 and $0.45 per share, respectively.

For the years ended December 31, 2021 and 2020, 5,816, and 3,322, restricted stock units were vested, respectively, with an aggregate intrinsic value at the time of vest of $15.9 million and $1.4 million, respectively.

The total fair value of the restricted stock units that vested during 2021 and 2020 were approximately $4.1 million and $1.5 million, respectively.

The aggregate intrinsic value of the restricted stock units currently outstanding at December 31, 2021 was $34.1 million.

The weighted average grant date fair value of the unvested restricted stock units outstanding at December 31, 2021 and 2020 was $0.80 and $0.45 per share, respectively. The weighted average grant date fair value of the restricted stock units granted, vested, and forfeited for the year ended December 31, 2021 were $1.80, $0.71 and $0.56 per share, respectively.

Employee stock-based compensation expense for employee granted restricted stock units was $5.8 million, $2.1 million and $0.3 million, for the years ended December 31, 2021 and 2020 and 2019, respectively, classified as follows (in thousands):

	December 31,		
	2021	2020	2019
Cost of sales	$ 14	8	—
Sales and marketing	548	338	—
Research and development	1,483	290	—
General and administrative	3,780	1,452	302
Total stock-based compensation	$ 5,825	$ 2,088	$ 302

As of December 31, 2021, there was $8.2 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 2.44 years.

14. 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 asset at December 31, 2021 and 2020 is as follows (in thousands):

	December 31,	
Deferred income tax assets (liabilities)	**2021**	**2020**
Deferred Tax Assets:		
Net operating loss carryforwards	$ 125,242	115,531
Capitalized start-up costs	7,315	8,477
R&E credit carryforwards	11,251	10,208
Stock-based compensation	2,061	4,056
Change in fair value of derivative liability	8,853	9,222
Other	912	1,096
Total deferred tax asset	155,634	148,590
Valuation allowance	(146,463)	(136,031)
Net deferred tax assets	$ 9,171	$ 12,559
Deferred tax liabilities:		
ROU amortization	(318)	(477)
Amortization of debt discount	(8,853)	(12,082)
Total deferred tax liability	(9,171)	(12,559)
Net deferred tax assets	$ —	$ —

The net change in valuation allowance for the years ended December 31, 2021 and 2020 was a net increase of $10.4 million and a net increase of $22.8 million, respectively.

The increase in valuation allowance is primarily due to net losses incurred in 2021. This increase in valuation allowance is based on management's assessment that it is more likely than not that the Company will not realize these deferred tax assets. Capitalized start-up costs represent expenses incurred in the organization and start-up of the Company. For U.S. federal and state tax purposes, start-up and organizational costs incurred before October 22, 2004 will be amortized over sixty months and those incurred on and after October 22, 2004 will be amortized over one hundred and eighty months beginning in the current year. At December 31, 2021, the Company had NOL carryforwards of $585.1 million and had research and experimental credit carryforwards of $14.1 million. Research and experimental credit carryforwards will expire in varying amounts between 2022 and 2041. NOL carryforwards in the amount of $198.5 million will expire in varying amounts between 2022 and 2037. NOL carryforwards incurred in tax years 2018 and forward have an indefinite carryforward period. 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 development credit carryforwards which can be available in future years. No income tax benefit was recognized in the Company’s Statement of Operations for stock-based compensation arrangements due to the Company’s net loss position.

A reconciliation of the Company's estimated U.S. federal statutory rate to the Company's effective income tax rate for the years ended December 31, 2021, 2020 and 2019 is as follows:

	Year Ended December 31,		
	2021	2020	2019
Tax at U.S. Federal Statutory rate	21.00 %	21.00 %	21.00 %
State taxes, net	1.60	2.32	1.57
Research and development credit	0.34	0.46	1.32
State tax rates changes	(2.18)	(0.85)	(2.17)
Debt Transactions	(17.09)	(11.15)	—
Stock Comp DTA	(0.78)	—	—
Other non-deductible items	0.33	(0.44)	(0.91)
Decrease in valuation allowance	(3.22)	(11.34)	(20.81)
Effective income tax rate	0.00 %	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 liabilities and assets are adjusted for changes in tax laws or tax rates of the various tax jurisdictions as of the enacted date. The federal tax rate remained unchanged at 21% for the 2021 tax year. The change in state tax rate from 2019 to 2020 and from 2020 to 2021, respectively, is primarily due to changes in applicable state apportionment factors and change in jurisdictions.

A breakdown of the Company's uncertain tax position during 2021, 2020 and 2019 is as follows (in thousands):

	2021	2020	2019
Gross unrecognized tax benefit at beginning of year	$ 2,552	2,351	1,969
Increase from tax positions taken in prior years	—	—	—
Increase from tax positions in current year	267	201	396
Lapse of statute of limitations / expiration	(6)	—	(14)
Gross unrecognized tax benefit at end of year	$ 2,813	$ 2,552	$ 2,351

The Company did not incur any penalties or interest payable to taxing authorities in 2020 or 2019. In 2021, The Company incurred a minor penalty due to the State of California Franchise Tax Board for an adjustment to the 2020 filed California state tax return.

The Company's U.S. Federal and state income tax returns from 2001 to 2020 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.

15. Related Party Transactions

Ascensia, through the ownership interests of its parent company, PHC, has a noncontrolling ownership interest in the Company. Ascensia also has representation on the Company's board of directors. For the year ended December 31, 2021, revenue from Ascensia was $12.3 million and the amount due from Ascensia as of December 31, 2021 was $1.8 million. At December 31, 2021, the Company had estimated replacement obligations under warranties in the amount of $0.7 million and marketing campaign support obligations in the amount of $1.8 million. For the year ended December 31, 2020, revenues from Ascensia and amounts due from them were immaterial. There were not revenues or amounts due from Ascensia in 2019.

Roche Holding A.G, through its ownership interests in Roche Finance Ltd, has a noncontrolling ownership interest in the Company. For the year ended December 31, 2021 revenues from Roche were less than $0.1 million, and there were no amounts due from them. For the years ended December 31, 2020 and 2019, revenues from Roche were $3.6 million, and $16.4 million, respectively, and amounts due from them were $2.4 million and $7.1 million. At December 31, 2021, the Company did not have any replacement obligations under warranties due to Roche.

16. 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.

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. The valuation technique used to measure the fair value of the Company's PHC option and debt instruments is based on the binomial option pricing model and the Energy Capital option using the Monte Carlo simulation method and incorporate management's assumptions for probabilities of conversion occurrence through maturity, stock price, volatility, risky bond rate, 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, 2021 and 2020 (in thousands):

	December 31, 2021			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds[1]	$ 29,197	$ 29,197	—	—
Commercial paper	57,369	—	57,369	—
Corporate debt securities	39,748	—	39,748	—
Asset backed securities	26,707	—	26,707	—
Government and agency securities	24,503	19,957	4,546	—
PHC Option	239	—	—	239
Liabilities				
Energy Capital Option	$ 69,401	$ —	—	69,401
Embedded features of the 2023 Notes	5,817	—	—	5,817
Embedded features of the PHC Notes	149,058	—	—	149,058
Embedded features of the 2025 Notes	81,417	—	81,417	—

	December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds[1]	$ 3	$ 3	$ —	$ —
PHC Option	1,886	—	—	1,886
Liabilities				
Energy Capital Option	$ 16,255	$ —	$ —	$ 16,255
Masters Option	23,479	—	—	23,479
Embedded features of the 2023 Notes	622	—	—	622
Embedded features of the PHC Notes	45,647	—	—	45,647
Embedded features of the 2025 Notes	15,850	—	15,850	—

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):

	Level 3 Instruments
December 31, 2020	$ 84,117
Conversion of financial instruments	(19,973)
Loss on fair value adjustment of option	53,152
Loss on change in fair value of derivatives	108,606
Gain on extinguishment of option	(3,513)
Financial asset impairment cost	1,648
December 31, 2021	$ 224,037

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

Unobservable Inputs	2023 Notes Assumptions	PHC Notes Assumptions	PHC Option Assumptions	Energy Capital Option Assumptions
Risky (bond) rate	30.0 %	15.0 %	40.0 %	40.0 %
Stock price volatility	95.0 %	95.0 %	95.0 %	95.0 %
Probabilities of conversion provisions	5.0 - 90.0 %	5.0 - 85.0 %	5.0 - 25.0 %	0.0 - 100.0 %
Time period until maturity (yrs)	0.50 - 1.09	0.50 - 2.83	0.50 - 11.00	0.08 - 0.61
Dividend yield	— %	— %	— %	— %

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. There were no transfers between Level 1, Level 2, or Level 3 during the year ended December 31, 2021 and 2020. 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**.**

17. 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 period ended December 31, 2021 and 2020 has no such contingencies.

18. Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations. An adjustment has been made to the Consolidated Statements of Cash Flows for the twelve months ended December 31, 2020 and 2019, to reclass the provision for inventory obsolescence and net realizable value of ($4,171,000) and $3,970,000, respectively, to change in Inventory. This change in classification does not affect previously reported cash flows from operating activities in the Consolidated Statements of Cash Flows.

19. Subsequent Events

FDA Approval

On February 11, 2022, the Company issued a press release announcing the approval by the U.S. Food and Drug Administration ("FDA") of the Eversense E3 CGM system for marketing and sale in the U.S. As previously described, in August 2020, the Company entered into a collaboration and commercialization agreement (the "Commercialization Agreement") with Ascensia pursuant to which it granted Ascensia the exclusive right to distribute the 90-day Eversense CGM system and the six-month Eversense CGM system worldwide (subject to regulatory approval in certain jurisdictions) for people with diabetes, with certain initial exceptions. As previously announced on January 4, 2022, the Company and Ascensia have been designing the go-to-market strategy for the U.S. six-month product, subject to the receipt of regulatory approval for the Eversense E3 six-month product. Now that the six-month product has received regulatory approval for marketing and sale in the United States, the Company expects that Ascensia will begin commercializing Eversense E3 in the U.S. in the second quarter of 2022. As with any new product, the success of the commercial launch of the Eversense E3 product in the U.S. will be subject to significant uncertainty and risks, and will require time to ramp up. Key areas of strategic focus in the U.S. commercial launch of the six-month product where performance will impact the success of the launch will be: (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 E3 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 six month product and its benefits relative to the 90-day product, (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 90-day coverage to six month coverage, and (7) Ascensia's continued organizational development of its U.S. sales and marketing capabilities relative to CGM.

The Company and Ascensia are also developing plans for the roll-out of the Eversense E3 next generation six-month product in Europe, which, subject to receipt of regulatory approval or certification, including CE Certificates of Conformity and affixing the CE mark for the EEA, is expected to offer reduced calibration requirements from the Eversense XL six-month product currently marketed in Europe. The roll-out of this next generation product in Europe is similarly subject to uncertainties and potential delays, including regulatory approval and certification and launch timing, and European revenues are dependent, among other things, on success of the following: (1) Ascensia's continued organizational development of its European sales and marketing capabilities relative to CGM, and (2) more effective tender participation, particularly in Italian markets which favor an integrated offering. The U.S. and European commercialization plans are being designed with a goal of minimizing the impact to patients, providers, and ongoing sales of Eversense CGM systems.

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 will receive a commission up to 3.0% of the gross proceeds of any common stock sold through Jefferies under the 2021 Sales Agreement. In February 2022, the Company received $8.1 million in net proceeds from the sale of 3,077,493 shares of its common stock under the 2021 Sales 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, 2021, 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, 2021, 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, 2021 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(b) of the Sarbanes-Oxley Act, we did not identify any material weakness in our internal control over financing reporting at December 31, 2021.

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, 2021.

Attestation Report of the Registered Public Accounting Firm

Ernst & Young LLP, the independent registered public accounting firm that audited the Company's financial statements, has also audited the Company's internal control over financial reporting as of December 31, 2021. Ernst & Young LLP's attestation report on the Company's internal control over financial reporting appears directly below.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Senseonics Holdings, Inc.

Opinion on Internal Control over Financial Reporting
We have audited Senseonics Holdings Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Senseonics Holdings, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, changes in stockholder's equity (deficit) and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated March 1, 2022 expressed an unqualified opinion thereon.

Basis for Opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting
A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP
Tysons, VA
March 1, 2022

Item 9B. Other Information

None.

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

Not applicable

PART III

We will file a definitive Proxy Statement for our 2022 Annual Meeting of Stockholders, or the 2022 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 2022 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 2022 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 2022 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 2022 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 2022 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 2022 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm."

Item 15. Exhibits 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	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).
3.3	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).
3.4	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).
3.5	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).
3.6	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B 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 November 9, 2020).
3.7	Bylaw Amendment (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 by and among the Registrant and certain of its stockholders, dated as of December 7, 2015 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
4.2	Base Indenture, dated January 30, 2018, between the Registrant and U.S. Bank National Association, as Trustee (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on January 30, 2018).
4.3	First Supplemental Indenture, dated January 30, 2018, between the Registrant and U.S. Bank National Association, as Trustee (including the form of 5.25% convertible senior subordinated notes due 2023) (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on January 30, 2018).

Exhibit Number	Description of Document
4.4	Second Supplemental Indenture, dated July 25, 2019, between the Registrant and U.S. Bank National Association, as Trustee (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on July 27, 2019).
4.5	Indenture, dated July 25, 2019, between the Registrant and U.S. Bank National Association, as Trustee (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on July 29, 2019).
4.6	Form of Note representing the Company's 5.25% Convertible Senior Notes due 2025 (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on July 29, 2019).
4.7	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).
4.8	Registration Rights Agreement, dated as of August 9, 2020, by and between the Registrant and certain purchasers named therein (incorporated herein by reference to Exhibit 4.2 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).
4.9	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).
4.10	Investor Rights Agreement, dated as of August 9, 2020, by and between the Registrant and PHC Holding Corporation (incorporated herein by reference to Exhibit 4.4 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).
4.11	Description of Senseonics Holdings, Inc. Common Stock (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-K (File No. 001-37717) filed on March 16, 2020).
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+	2015 Equity Incentive Plan of Senseonics, Incorporated (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.5.1+	Amended and Restated 2015 Equity Incentive Plan, (incorporated by reference to Exhibit 10.7 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).

Exhibit Number	Description of Document
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 July 30, 2015 (incorporated by reference to Exhibit 10.11 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.11+	Executive Employment Agreement by and between Senseonics, Incorporated and Mirasol Panlilio, dated as of August 10, 2015 (incorporated by reference to Exhibit 10.12 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.12	Form of Secured Promissory Note issued to Oxford Finance LLC by Senseonics, Incorporated, dated as of July 31, 2014 and December 23, 2014 (incorporated by reference to Exhibit 10.15 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.13	Form of Secured Promissory Note issued to Oxford Finance LLC by Senseonics, Incorporated, dated as of December 7, 2015 (incorporated by reference to Exhibit 10.16 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.14	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).
10.15	Form of Warrant to Purchase Preferred Stock issued by Senseonics, Incorporated in bridge loan financings (incorporated by reference to Exhibit 10.18 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.16+	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).
10.17+	Non-Employee Director Compensation Policy, as amended (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (File No. 333-198168) filed on March 15, 2019).
10.18	Letter Agreement, by and among the Registrant, Senseonics, Incorporated and Stephen P. DeFalco, dated June 20, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on June 21, 2016).
10.19	Restricted Stock Award Grant Notice and Restricted Stock Award Agreement, by and between the Registrant and Stephen P. DeFalco, dated June 20, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on June 21, 2016).
10.20	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).
10.21	Open Market Sales Agreement, dated November 27, 2019, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on November 27, 2019).
10.22	Registration Rights Agreement, dated as of July 25, 2019, by and among the Company, the Subsidiary and Jefferies LLC (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 July 29, 2019).
10.23+	Executive Employment Agreement, by and between Senseonics, Incorporated and Francine Kaufman, effective as of May 4, 2019 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on May 9, 2019).
10.24#	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).
10.25+	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).

Exhibit Number	Description of Document
10.26+*	Amended and Restated Employment Agreement, by and between Senseonics, Incorporated and Nick B. Tressler, effective as of November 12, 2019 (incorporated herein by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K (File No. 0101-37717) filed with the Commission on March 16, 2020).
10.27	Registration Rights Agreement, dated as of April 21, 2020, by and between the Company and Highbridge Tactical Credit Master Fund, L.P. (incorporated herein by reference to Exhibit 10.2 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).
10.28	Registration Rights Agreement, dated as of April 21, 2020, by and between the Company and Highbridge Tactical Credit Master Fund, L.P. (incorporated herein by reference to Exhibit 10.3 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).
10.29	Loan and Security Agreement among Wilmington Savings Fund Society, SCB as collateral agent, Highbridge Tactical Credit Master Fund, L.P., the Company and the Subsidiary, dated as of April 21, 2020 (incorporated herein by reference to Exhibit 10.4 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).
10.30	Note Purchase and Exchange Agreement among Wilmington Savings Fund Society, SCB, as collateral agent, Highbridge Tactical Credit Master Fund, L.P., the Company and the Subsidiary, dated as of April 21, 2020 (incorporated herein by reference to Exhibit 10.5 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).
10.31	Form of Note representing the Registrant's Secured Promissory Second Lien Notes (incorporated herein by reference to Exhibit 10.7 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).
10.32	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).
10.33	Note Purchase Agreement, dated as of August 9, 2020, by and between the Registrant and PHC Holding Corporation (incorporated herein by reference to Exhibit 10.1 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).
10.34	Stock Purchase Agreement, dated as of August 9, 2020, by and between the Registrant and certain purchasers named therein (incorporated herein by reference to Exhibit 10.2 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).
10.35	Equity Line Agreement by and between the Company and Energy Capital, LLC dated as of November 9, 2020 (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 November 9, 2020).
10.36	Warrant to purchase common stock of the Company by and between the Company and Energy Capital, LLC, dated as of November 9, 2020 (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 November 9, 2020).
10.37	Side Letter Agreement by and between the Company and certain purchasers named therein, dated as of November 9, 2020 (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 November 9, 2020).
10.38#	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).
10.39#	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).
10.40	Form of Securities Purchase Agreement by and between the Company and certain purchases named therein, dated as of January 17, 2021 (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 January 19, 2021).

Exhibit Number	Description of Document
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 Ernst & Young 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.
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 1, 2022

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Timothy T. Goodnow, Ph.D., and Nick B. Tressler, 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 1, 2022
/s/ NICK B. TRESSLER Nick Tressler	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 1, 2022
/s/ Stephen P. DeFalco Stephen P. DeFalco	Chairman of the Board of Directors	March 1, 2022
/s/ Steven Edelman, M.D. Steven Edelman, M.D.	Director	March 1, 2022
/s/ Edward J. Fiorentino Edward J. Fiorentino	Director	March 1, 2022
/s/ Douglas Prince Douglas Prince	Director	March 1, 2022
/s/ DOUGLAS ROEDER Douglas Roeder	Director	March 1, 2022
/s/ FRANCINE KAUFMAN, M.D. Francine Kaufman, M.D.	Director and Chief Medical Officer	March 1, 2022
/s/ ROBERT SCHUMM Robert Schumm	Director	March 1, 2022

/s/ANTHONY RAAB Anthony Raab	Director	March 1, 2022
/s/JOHN MAROTTA John Marotta	Director	March 1, 2022
/s/SHARON LARKIN Sharon Larkin	Director	March 1, 2022

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration statement (Form S-8 No. 333-210586) pertaining to the equity incentive plans and employee stock purchase plan of Senseonics Holdings, Inc.,
(2) Registration statement (Form S-8 No. 333-224827) pertaining to the equity incentive plans and employee stock purchase plan of Senseonics Holdings, Inc.,
(3) Registration statement (Form S-8 No. 333-231334) pertaining to the equity incentive plans and employee stock purchase plan of Senseonics Holdings, Inc.,
(4) Registration statement (Form S-8 No. 333-232486) pertaining to the inducement plan of Senseonics Holdings, Inc.,
(5) Registration statement (Form S-3 No. 333-233656) of Senseonics Holdings, Inc.,
(6) Registration statement (Form S-3ASR No. 333-2352260940) of Senseonics Holdings, Inc.,
(7) Registration statement (Form S-3 No. 333-237937) of Senseonics Holdings, Inc.,
(8) Registration statement (Form S-3 No. 333-248659) of Senseonics Holdings, Inc. and
(9) Registration statement (Form S-3 No. 333-252939) of Senseonics Holdings, Inc.,

of our reports dated March 1, 2022, with respect to the consolidated financial statements of Senseonics Holdings, Inc. and the effectiveness of internal control over financial reporting of Senseonics Holdings, Inc. included in this Annual Report (Form 10-K) of Senseonics Holdings, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young, LLP

Tysons, VA

March 1, 2022

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy T. Goodnow, Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K of Senseonics Holdings, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

/s/ TIMOTHY T. GOODNOW, PH.D.
Timothy T. Goodnow, Ph.D.
President & Chief Executive Officer
(principal executive officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nick Tressler, certify that:

1. I have reviewed this annual report on Form 10-K of Senseonics Holdings, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

/s/ NICK B. TRESSLER
Nick Tressler
Chief Financial Officer
(principal financial officer)

EXHIBIT 32.1

CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Timothy T. Goodnow, Ph.D., Chief Executive Officer of Senseonics Holdings, Inc. (the "Company"), and Nick Tressler, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company as of the end of the period covered by the Annual Report and results of operations of the Company for the periods covered by the Annual Report.

In Witness Whereof, the undersigned have set their hands hereto as of the 1st day of March, 2022.

/s/ TIMOTHY T. GOODNOW, PH.D.

Timothy T. Goodnow, Ph.D.
President & Chief Executive Officer

/s/ NICK B. TRESSLER

Nick Tressler
Chief Financial Officer

* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.