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, 2019 _____

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:	**Name of Each Exchange on which Registered**
Common Stock, $0.001 par value	**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 is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 28, 2019, 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 $216.5 million based on the closing price of the registrant's common stock, as reported by the NYSE American on such date.

As of March 10, 2020, 204,113,102 shares of common stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2020 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the timing of, and our ability to obtain and maintain regulatory approval of, Eversense XL in the United States;
- our ability to maintain regulatory approval of Eversense in the United States;
- our ability to maintain regulatory approval of Eversense and Eversense XL in Europe;
- the clinical utility of Eversense;
- our ability to develop future generations of Eversense;
- our ability to access our credit facilities in the future;
- our ability to continue as a going concern;
- the timing and availability of data from our clinical trials;
- the timing of our planned regulatory filings;
- 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;
- 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.

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PART I

Item 1. Business

Overview

We are a medical technology company focused on the development and commercialization of a long-term, implantable continuous glucose monitoring, or CGM, system to improve the lives of people with diabetes by enhancing their ability to manage their disease with relative ease and accuracy. Our Eversense and Eversense XL 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 90 and 180 days, respectively, 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. The original Eversense CGM system received a CE mark in June 2016, which marked the first approval for the product to be sold within the European Economic Area. Subsequently, the extended life Eversense XL CGM system received its CE mark in September 2017 and is currently available in select markets in Europe, the Middle East, and Africa, or EMEA. 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.

Our focus on the development and approval of the extended life Eversense XL to the U.S. market is ongoing and in September 2019, we completed enrollment of the PROMISE 180-day U.S. pivotal clinical trial of Eversense XL with over 180 subjects enrolled across eight clinical sites. We expect to report topline data from the PROMISE trial in the second quarter of 2020. If the data from the PROMISE trial are positive, we intend to use the data in a regulatory submission to the FDA to expand the Eversense system use for up to 180 days in the United States and expect this approval by the end of 2020. We also intend to use data from the first 90 days of the PROMISE trial, if positive, to support a regulatory submission to the FDA for an integrated, or iCGM, designation for our current Eversense 90-day system, which the FDA could potentially approve in the second half of 2020. This would allow Eversense to integrate with other compatible medical devices and electronic interfaces, such as automated insulin dosing systems, insulin pumps, and blood glucose meters.

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 2019 International Diabetes Federation, or IDF, Atlas, an estimated 463 million people worldwide had diabetes as of the date of the report. The number of people with diabetes worldwide is estimated to grow to 700 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 device regulators 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 recently published in the calendar year 2020 Physician Fee Schedule Final Rule. The Eversense CGM system will be the first CGM technology to be reimbursed through the Part B Medical Services benefit for Medicare beneficiaries and expands access to our product. We expect Medicare beneficiaries to be able to use Eversense as part of their diabetes treatment plan in 2020.

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

We sell 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. 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. We leverage and target regions where we have coverage decisions for patient device use and provider insertion and removal procedure payment.

Addressing reimbursement and access barriers is a top priority for us and during 2019 we reached over 100 million covered lives through positive insurance payor coverage decisions. We launched 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. Participants in the Eversense Bridge Program who do not currently have coverage for Eversense are enrolled in a follow-on appeals program that utilizes patients’ right to appeal to help obtain approval for Eversense beyond the limited financial assistance of the Eversense Bridge Program. These programs play an important role in our journey to obtain broader payor policy and long-term patient retention.

In the United States, we have a 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. Our field sales team target endocrinologists in the country who are clinically active and diabetes focused.

In our overseas markets, we 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. We have an exclusive distribution agreement for sales in Scandinavia and an 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. Currently Eversense is available in 15 countries outside of the United States.

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.

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 have granted Roche the exclusive right to market, sell and distribute Eversense in the EMEA, excluding Scandinavia and Israel. In addition, Roche has 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.

The distribution agreement has a term through January 31, 2021. Roche is obligated to purchase from us specified minimum volumes of Eversense 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.

The distribution agreement, as amended, is terminable by us under a number of circumstances, including if Roche materially breaches the terms of the agreement or fails to make certain minimum sales requirements. The agreement is terminable by Roche under a number of circumstances, including if we materially breach the agreement, if the distribution of Eversense is enjoined in the covered territories or in the case of certain intellectual property infringement claims. The agreement is terminable by either party if the other party becomes insolvent or subject to bankruptcy proceedings. The termination rights contained in the agreement are generally subject to advance notice requirements and an opportunity to cure. Further, Roche may terminate the agreement upon a change of control of our company with a transition period of the shorter of 18 months or the remaining term of the agreement.

Clinical Development and Regulatory Pathway

Overview

The Eversense XL CGM system received a CE mark in Europe in September 2017 and is being sold commercially in our overseas markets. Our PRECISE II U.S. pivotal trial was completed during 2016. We received PMA approval from the FDA for the Eversense system in June 2018 and began selling commercially in the third quarter of 2018.

In September 2019, we announced the enrollment completion for the PROMISE pivotal trial to evaluate the safety and accuracy of Eversense for a period of up to 180 days in the United States. 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 180 days 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 expect to report topline data in the second quarter of 2020. If the data from the PROMISE trial are positive, we intend to use the data in a regulatory submission to the FDA to expand the Eversense system use for up to 180 days in the United States. We expect such approval will happen by the end of 2020. We also intend to use data from the first 90 days of the PROMISE trial, if positive, to support a regulatory submission to the FDA for an iCGM designation for our current Eversense 90-day system, which the FDA could potentially approve in the second half of 2020.

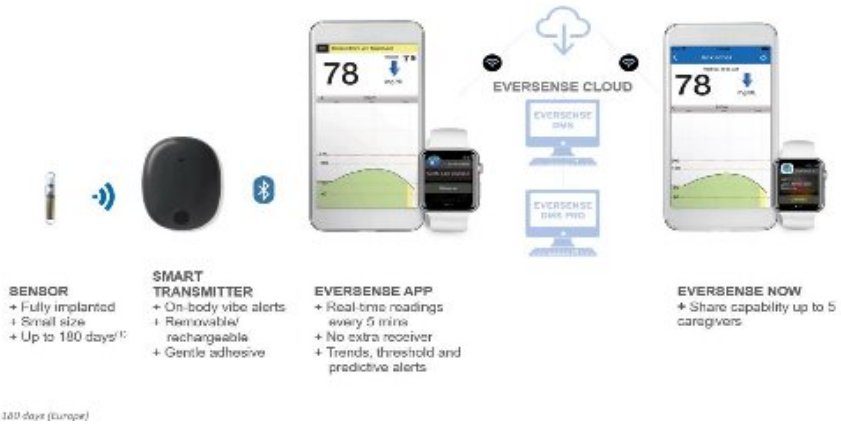
The clinical trial population consists of subjects at least 18 years of age who have had a clinically confirmed diagnosis of diabetes for at least one year. Subjects with a history of unexplained severe hypoglycemia, defined as hypoglycemia resulting in loss of consciousness or seizure, or diabetic ketoacidosis, 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.

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 180 days. Eversense requires twice 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 now 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 90 to 180 days.
- ***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.



Sensor

The sensor is approved 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 180 days, 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 by offering an iCGM for interoperability with other diabetes tech devices for use in automatic insulin delivery and decision support systems. Additional near-term efforts include reducing the twice daily calibrations to once a day calibration, and further progressing to once a 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 “Gemini” product variation to allow for a 2-in-1 glucose monitoring system combining the functionality of CGM and Flash Glucose Monitoring, or FCM, 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.

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. Building strong adoption with an implantable device requires a strong network of healthcare providers trained on the Eversense sensor placement procedure. Our clinical training team works directly with healthcare providers across the United States beginning with their initial training through full certification status. 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 the

second half of 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. We have seen a strong desire of these specialists to become a CES as well as the willingness of the prescribing provider to refer the procedure to a CES, and we expect this program to be instrumental to ensuring patients have convenient and high quality placement of the Eversense sensor.

We launched our "Be Unstoppable" campaign in June 2019 targeting current and former CGM users as well as naïve CGM users. Through digital marketing, we are able to create interests amongst patients and these leads are then converted to prescriptions and purchases. We continue to utilize social media to promote user experience with the product and we participate in major diabetes conferences around the world to create continued awareness amongst endocrinologists, diabetologists, diabetes educators, researchers, and the managed care community.

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, we have received positive reimbursement decisions from U.S. third-party payors that cover approximately 120 million people in the United States.

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 reimbursement programs and patient appeals support, including the Eversense Bridge Program, are key initiatives to expanding payor policy and acceptance through case by case review and eventual denial overturn. 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 agencies. 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. We expect all other CGM companies besides Dexcom to pursue an iCGM indication including Abbott and 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.

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 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, 2019, we held a total of approximately 579 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 73 issued United States patents, 290 patents issued in countries outside the United States and 216 pending patent applications worldwide. Our patents expire between 2020 and 2036, 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 2021 to 2039.

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 no pending U.S. trademark applications and 26 pending foreign trademark applications, as well as 14 U.S. trademark registrations and 103 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 Commission, 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, such as ISO 13485, ISO 14971, FDA's Quality System Regulation, or QSR, contained in 21 CFR Part 820, and Directive 90/385/EEC concerning active implantable 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.

The European Union, or EU, has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives, or Essential Requirements, and, accordingly, can be commercially distributed throughout the EU. To assist manufacturers in satisfying the Essential Requirements, the European standards organizations have prepared European standards applicable to medical devices. These include harmonized international quality standards aimed at ensuring that medical devices are correctly designed and manufactured. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." Notified Bodies are entities licensed ('notified') by the individual European member states to provide independent certification of certain classes of medical device. They apply for and are designated to carry out this function by the relevant national competent authorities, which carry out periodic assessment audits to determine whether the Notified Bodies continue to satisfy the necessary requirements. A conformity assessment conducted by a Notified Body may consist of an audit of the medical device manufacturer's quality system and specific testing of the manufacturer's product to ensure that the medical device complies with the Essential Requirements. Once the appropriate conformity assessment procedure has been completed, the manufacturer must draw up a written declaration of conformity and affix the CE mark to the device. The device can then be marketed throughout the European Economic Area (being the EU, Norway, Iceland and Liechtenstein) or EEA. Notified Bodies perform surveillance and unannounced audits at the manufacturer and critical suppliers with respect to the devices covered by the certificates issued by them. If non-conformities raised during the audits are not timely remedied by the manufacturer, the Notified Body may (partially or wholly) suspend or withdraw the certificate concerned. Additional local requirements may apply on a country-by-country basis. Outside of the

European Union, regulatory approval would need to be sought on a country-by-country basis in order for us to market our products.

All manufacturers placing medical devices into the market in the EEA must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the Member States of the EEA, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

In May 2017, the European Commission finalized and adopted the text of the Medical Device Regulation (EU) 2017/745, or the EU Medical Device Regulation, which will repeal and replace both Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC concerning active implantable medical devices. The majority of the provisions in the EU Medical Device Regulation apply from Spring 2020. The current CE certificate will continue to be in effect, while the Company works to ensure compliance with the EU Medical Device Regulation and transitions the CE certificate from current 90/385/EEC Directive to MDR.

Other Regulatory Requirements

Even after a device receives clearance or approval and is placed in commercial distribution, numerous regulatory requirements apply. These include:

- 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 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 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 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 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 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 European Union, member states 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. They 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 any 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. 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.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable (i.e., without the need for adoption of EEA member State laws implementing them) in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will however only become applicable three years after publication in May 2020. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an impact on the way we design and manufacture products and the way we conduct our business in the EEA.

In the European Union (and, specifically the European Economic Area) (EU/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. Additionally, in January 2020, the United Kingdom withdrew from the European Union, commonly referred to as “Brexit”. The implications of Brexit and the future trading relationship between the United Kingdom and the EU are still uncertain and could lead to further legislative and regulatory changes. In March 2017, the United Kingdom began the process to leave the EU by April 2019. While the Data Protection Act of 2018, that “implements” and complements the GDPR has achieved Royal Assent on May 23, 2018 is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. We may incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

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 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.

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 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, and continue to be, 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 eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

Brexit and the Regulatory Framework in the United Kingdom

On January 31, 2020, the United Kingdom, or UK, formally withdrew from the EU, commonly referred to as "Brexit". The United Kingdom and the EU are currently in a transition period during which the United Kingdom and the EU are negotiating additional arrangements, including their future trading arrangement. The United Kingdom has stated that it wants the transition period to expire, and the future trading terms to be agreed, by December 31, 2020. During the transition period, the UK and the EU will negotiate their future relationship, including the terms of trade. The effects of Brexit will depend on any agreements the UK makes to retain access to EU markets, either during the transitional period or more permanently. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. 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. In the longer term, Brexit could materially impact the future regulatory regime which applies to medical devices and their approval in the UK.

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 ant-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

As of December 31, 2019, we had 191 employees, all of whom are located in the United States. 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.

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. Our website and information included in or linked to our website are not part of this Annual Report.

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.

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 $115.5 million, $94.0 million, and $59.1 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $473.3 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 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 in the foreseeable future. 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 significant 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.

We have limited commercialization experience in the United States and Europe. If we are unable to successfully expand our commercialization of Eversense in the United States and Europe, 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 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;
- 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 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, 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.

Approval in the United States by the FDA or by a regulatory agency in another country does not guarantee approval by the regulatory authorities in other countries or jurisdictions or ensure approval 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 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 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 corresponding Notified Body in the European Union and 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, the corresponding Notified Body in the European Union and EEA 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 or cancel our marketing authorizations, 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 of an existing regulatory clearance for Eversense. The FDA, the corresponding Notified Body in the European Union and EEA or comparable foreign 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 and achieving and maintaining market acceptance. In order for us to sell Eversense to people with diabetes, we 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 for Eversense, adverse publicity or other adverse events including any product liability lawsuits.

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, 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. We may not be successful in developing, obtaining regulatory approval 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 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 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 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 and commercial launch, including during research and development, 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 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 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 by the FDA, the corresponding Notified Body in the European Union and 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.

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 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 may be unable to sell Eversense or future versions of Eversense profitably and our business would be adversely impacted.

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 provide financial assistance to eligible patients purchasing Eversense, which may be substantial depending on a patient’s insurance coverage. We also assist patients in their appeal of adverse coverage decisions made by insurance providers. We may not be able to recognize a substantial portion of the revenue related to Eversense insertions for the patients participating in this access 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.

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. We expect all other CGM companies besides Dexcom to pursue an iCGM indication including Abbott and 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.

In addition to CGM providers, we also compete with providers of traditional SMBG systems, including 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.

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 distribution agreements to market Eversense may not be successful.

We have entered into distribution agreements with strategic fulfillment partners in the United States and with distributors in our overseas markets, including our distribution agreement with Roche, to market Eversense in Europe, the Middle East, Africa (EMEA), excluding Scandinavia and Israel, and 17 additional countries, including Brazil, Russia, India and China. Under these agreements, the distributors are generally responsible for the promotion, sale and distribution of Eversense in the specified countries or territories at such prices as they determine in their sole discretion. The agreements do not require our distributors to sell our products exclusively, and therefore they are free to sell products of our competitors. Additionally, if any of our distributors fail to perform satisfactorily under the agreements, our commercialization efforts would be adversely affected.

Net revenue from our distribution arrangement with Roche accounted for 77% of our total net revenues for the year ended December 31, 2019. Net revenue from our distribution arrangement with Advanced Diabetes Supply, a strategic fulfillment partner and supplier of CGM systems to diabetic patients in the United States, accounted for 12% of our total net revenues for the year ended December 31, 2019. We cannot guarantee these relationships, or any of our distribution agreements, will continue or that we will be able to maintain or increase the volume of sales from these relationships in the future. A substantial decrease or loss of sales from our distributors, including Roche and Advanced Diabetes Supply, could materially impact future operating results.

Our sales and marketing infrastructure may not be successful in commercializing Eversense in the United States.

To achieve commercial success in the United States for Eversense, we will need to rely on and expand our sales and marketing infrastructure to further drive adoption of our products and market penetration. If we are unable to attract and retain sufficient, and skilled, sales and marketing representatives, our sales could be adversely affected. If one of our sales or marketing representatives were to depart and be retained by one of our competitors, they could help competitors solicit business from our existing customers, which could further harm our sales. In addition, if our sales and marketing representatives or field clinical managers fail to achieve their objectives we may not be able to successfully train healthcare providers and people with diabetes on the use of Eversense, which could delay new sales and harm our reputation.

As we commercialize Eversense or future versions of Eversense, we will need to hire, train, retain and motivate skilled sales and marketing representatives with significant industry-specific knowledge in various areas, such as diabetes treatment techniques and technologies and reimbursement practices. Our success will depend largely on the competitive landscape for our products and the ability of our personnel to obtain access to healthcare providers, educate those healthcare providers on the benefits of Eversense with the hope that they will recommend Eversense to people who intensively manage their diabetes, and navigate commercial third-party payor policies.

We anticipate that we will derive nearly all of our U.S. revenue from the sales of Eversense or future versions of Eversense and that this will continue for the next several years. As a result, our financial condition and operating results will be highly dependent on the ability of our sales representatives and marketing initiatives to adequately promote, market and sell Eversense. If we are unable to establish and expand our sales and marketing capabilities, or if our marketing programs are not successful, we may not be able to effectively commercialize our existing or planned products, or enhance the strength of our brand, either of which could 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. We intend 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, 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 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 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;
- 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.

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 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 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. 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 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 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 expanded commercialization of Eversense, growth of our sales and marketing infrastructure and programs, our ongoing research and development activities, 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 future capital needs are uncertain and we may need to raise substantial additional funds in the future, and these funds may not be available on acceptable terms or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, scale back or cease some or all operations. As a result, our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited consolidated financial statements included in this Annual Report.

At the time of issuance of our consolidated financial statements for the year ended December 31, 2019 in this Annual Report on Form 10-K, we did not have sufficient cash to fund our operations through the next twelve months without additional financing and, therefore, we concluded there was substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph regarding this uncertainty in its report on those consolidated financial statements. At December 31, 2019, we had approximately $95.9 million in cash and cash equivalents, and we have insufficient committed sources of additional capital to fund our operations as described in this Annual Report for more than a limited period of time. We do not expect our existing cash and cash equivalents will be sufficient to fund our operations through the first quarter of 2021.

The continued growth of our business, including the commercialization of our CGM systems, potential regulatory submission to the FDA for Eversense XL in the United States, product development and product upgrades, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our expectations. As a result, we may be required to seek substantial additional funds in the future. Our future capital requirements will depend on many factors, including:

- the cost of obtaining and maintaining regulatory clearance or approval for Eversense or future versions of Eversense;
- the costs associated with developing and commercializing our products;
- any change in our development priorities regarding our future versions of Eversense;
- the revenue generated by sales of Eversense or future versions of Eversense;
- the costs associated with expanding our sales and marketing infrastructure;
- any change in our plans regarding the manner in which we choose to commercialize our products in the United States;
- the cost of ongoing compliance with regulatory requirements;
- expenses we incur in connection with potential litigation or governmental investigations;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these and other factors, we do not know whether and the extent to which we may raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under credit lines or other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to

relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

If we are unable to raise additional capital in the near team, we may not be able to successfully expand the commercialization of our Eversense CGM systems, enhance Eversense or develop future versions of Eversense, take advantage of future opportunities, or respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Moreover, we may be unable to meet our obligations, or obtain a waiver for noncompliance with our obligations, under the convertible senior subordinated notes due 2023, or the 2023 Notes, and the convertible senior subordinated notes due 2025, or the 2025 Notes, and our a Loan and Security Agreement, or the Solar Loan Agreement, with Solar Capital, Ltd., or Solar, or other agreements, which could result in an acceleration of our obligation to repay all amounts owed thereunder, and we may be forced to liquidate our assets. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. Any of these events could adversely affect our ability to achieve our strategic objectives, which could negatively effect on our business, financial condition and operating results.

Our operating results may fluctuate significantly 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 or approvals affecting our products or those of our competitors;
- our ability to increase sales of Eversense and to commercialize and sell our future products, and the number of our products sold in each quarter;
- our 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; 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 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 or clearance and import licenses before we can sell such products and given that the timing of such approvals, 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, clearances or licenses are obtained. In addition, we will be significantly 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 Solar Loan 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 Solar Loan Agreement has specified financial covenants related to our liquidity and trailing six-month revenues and the Solar Term Loan and other obligations under the Solar Loan Agreement are secured by substantially all of our assets. Although we were in compliance with the financial covenants as of January 31, 2020 (the last month end for which we have completed our procedures to confirm covenant compliance as of the date of this filing),, based upon our current expectations for the remainder of the first quarter of 2020, we expect that we will not be in compliance with the trailing six-month revenue covenant as of March 31, 2020 and that, absent a waiver or amendment to the terms of the Solar Loan Agreement, we would likely remain in noncompliance with the trailing six-month revenue covenant for the foreseeable future thereafter. Therefore, if we are not able to obtain a waiver of such default by Solar, it is possible that our outstanding indebtedness under the Solar Loan Agreement and the 2025 Notes could be accelerated and become immediately due and payable. If this were to occur, based on our current capital resources, we would not be able to satisfy such indebtedness without raising additional capital from other sources, which may not be available on commercially reasonable terms or at all. If we were unable to raise such capital to satisfy these obligations, we could be required to sell assets, potentially liquidate our business or be forced into bankruptcy, any of which would have a material adverse effect on the value of our common stock.

In addition, the indentures related to the 2023 Notes and the 2025 Notes and the Solar Loan Agreement 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.

The Solar Term Loan bears interest at variable interest rates based on USD London Inter-bank Offered Rate, or LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Financial Conduct Authority, the authority that regulates the London Inter-bank Offered Rate, or LIBOR, announced that it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021. The Solar Term Loan bears interest based on USD LIBOR. As a result, changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness. Any transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that rely on LIBOR, reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent

processes. The transition away from LIBOR may result in increased expenses, may impair our ability to refinance our indebtedness or hedge our exposure to floating rate instruments, or may result in difficulties, complications or delays in connection with future financing efforts, any of which could adversely affect our financial condition and results of operations.

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

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 FDA-approved product, we may need to seek additional approvals, 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. We may not be able to obtain additional regulatory approvals 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 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. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. 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. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system.

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 our initial 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, in December 2018 we initiated the PROMISE pivotal trial to support a future PMA supplement for 180-day use of the Eversense sensor in the U.S. 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, Fran Kaufman, our Chief Medical Officer, and Mirasol Panlilio, our Vice President and General Manager, Global Commercial Operations, 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 sales, 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, 2019, we had 191 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, regulatory affairs and sales, marketing and distribution. 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, 2019, we held a total of approximately 579 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 73 issued United States patents, 290 patents issued in countries outside the United States, and 216 pending patent applications worldwide. Our patents expire between 2020 and 2036, 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 2021 to 2040. 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 no pending U.S. trademark applications and 26 pending foreign trademark applications, as well as 14 U.S. trademark registrations and 103 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 and the European Commission and corresponding Notified Body in the European Union and 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 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 to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by such regulatory agencies. 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 is expensive, time-consuming and uncertain, and the failure to obtain and maintain required regulatory clearances 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. The process of obtaining regulatory approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these approvals 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 can delay, limit or deny approval 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; and
- the manufacturing process or facilities we use may not meet applicable requirements.

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

Any delay in, or failure to receive or maintain, approval for our products could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some people with diabetes from using our products and adversely affect our reputation and the perceived accuracy and safety of our products.

If we or our third-party suppliers fail to comply with the FDA's 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.

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, 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. 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 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, with 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, as defined by such law, and teaching hospitals. 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.

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 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 determines 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 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 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 and comply with extensive safety and quality regulations in other countries.

In the EEA, our devices are required to comply with the essential requirements set out in Annex I of the EU Active Implantable Medical Device Directive (Council Directive 90/385/EEC) in order to be placed on the market. Provided that our devices successfully complete a conformity assessment under Council Directive 90/385/EEC demonstrating compliance with these essential requirements, we may affix the CE conformity mark to our devices, without which they cannot be commercialized in the EEA.

The advertising and promotion of our products is subject to the laws of EEA Member States implementing Directive 2006/114/EC concerning misleading and comparative advertising, Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State laws or codes of practice governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare providers, 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 or other 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 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, the EU Medical Device Regulation will repeal and replace both Directive 93/42/EEC concerning medical devices and Directive 90/385/EEC concerning active implantable medical devices, and therefore will materially change the regulatory environment in which we operate in Europe. The majority of the provisions in the EU Medical Device Regulation apply from spring 2020. The Company will need to ensure compliance with the EU Medical Device Regulation in the future if it is to place a medical device on the EU market after this regulation comes into force and this may take time and require additional resources to ensure compliance.

Regulations of the FDA and other regulatory agencies 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, EU member states 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 any 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 remain judicial and Congressional challenges to certain aspects of the PPACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part 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. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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 eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because

the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

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 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business, which could adversely affect our revenue and results of operations.

After significant negotiation between the United Kingdom and the EU, the United Kingdom withdrew from the EU on January 31, 2020 and there is currently a transition period during which the United Kingdom and EU negotiate additional arrangements, including their future trading terms. The United Kingdom has stated that it wants the transition period to expire, and the future trading terms to be agreed, by December 31, 2020.

The uncertainties regarding the United Kingdom's future relationship with the EU, have had and may continue to have an adverse effect on global economic conditions and the stability of global financial markets. In particular, depending on what terms are agreed between the United Kingdom and the EU, if any, it could lead to a period of considerable uncertainty in relation to global financial and banking markets, as well as on regulatory processes in Europe and the EEA. Lack of clarity about future United Kingdom laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could decrease foreign direct investment in all markets, increase costs, depress economic activity and restrict access to capital.

If the United Kingdom and the EU are unable to negotiate acceptable future trading terms or if other EU countries pursue withdrawal, barrier-free access between the United Kingdom and other EU or EEA countries could be diminished or eliminated, which could make our doing business in the EU more difficult. As a result of Brexit, we may face disruptions in our supply chain, inventory management, manufacturing process and product distribution network, which could adversely affect our business and results of operations. Moreover, Brexit may also lead to new regulatory costs and challenges that could have a material adverse effect on our operations.

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 January 1, 2019 through December 31, 2019, the closing sale price of our common stock has been as low as $0.83 per share and as high as $3.27 per share. The market price of our common stock may be influenced by many 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;
- 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;
- 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 actions;
- litigation;
- public concern as to the safety of our products or recalls; and
- the other factors described in this Risk Factors section.

The issuance of additional stock in connection with financings, acquisitions, investments, our stock incentive plan, upon the conversion of our convertible senior subordinated notes or otherwise will dilute our existing stockholders.

Our certificate of incorporation authorizes us to issue up to 450,000,000 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 by conversion of our convertible notes in certain circumstances, 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.

Our GAAP operating results could fluctuate substantially due to the accounting for the embedded conversion option, interest make-whole provision and make-whole fundamental change provision features of the notes.

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 notes and the associated fluctuations in the fair value of the embedded features 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.

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.

Our financial results may be adversely affected by changes in accounting principles applicable to us.

U.S. GAAP are subject to interpretation by the FASB, the SEC, and other bodies formed to promulgate and interpret appropriate accounting principles. For example, in May 2014, the FASB issued accounting standards update No. 2014-09 (Topic 606), *Revenue from Contracts with Customers*, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. We adopted this guidance as of January 1, 2018. Any difficulties in implementing these pronouncements or adequately accounting after adoption could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us.

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 provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by 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. The choice of forum provision 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 such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management

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. 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 identified a material weakness in our internal control over financing reporting during the fourth quarter of 2019 related to inventory controls. This was successfully remediated during the same quarter of 2019. As a result, we have

no material weaknesses in our internal control over financial reporting at December 31, 2019, which aligns with our independent registered public accounting firm's attestation report included elsewhere in this Annual Report on Form 10-K, which is required to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting that existed at the reporting date. 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, 2019, we had federal and state net operating loss, or NOL, carryforwards of $419.2 million and had research and experimental credit carryforwards of $9.4 million. NOL carryforwards in the amount of $199.5 million will expire in varying amounts between 2020 and 2038. 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, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses may be limited. 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.

We will incur increased costs and demands upon management as a result of being a public company.

As a public company in the United States, we have incurred, and will continue to incur, significant additional legal, accounting and other costs, particularly now that we have ceased to be an "emerging growth company." These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the NYSE American, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities.

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 commencing on September 2, 2019, and expiring in 2023. 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. 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 March 10, 2020, we had 204,113,102 shares of common stock outstanding held by 185 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 performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under the Securities Act or the Exchange Act.

Recent Sales of Unregistered Securities

None.

Item 6. Selected Consolidated Financial Data

The following tables set forth selected financial data for each of the years in the five-year period ended December 31, 2019 and is derived from our audited financial statements. Our historical results are not necessarily indicative of the results to be expected in the future. The selected financial data should be read together with Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in conjunction with the consolidated financial statements, related notes, and other financial information included elsewhere in this Annual Report.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Revenue, net	$ 4,924	$ 2,039	$ 529	$ —	$ —
Revenue, net - related parties	16,377	16,874	5,844	332	38
Total revenue	21,301	18,913	6,373	332	38
Cost of sales	40,749	27,059	9,758	660	—
Gross profit	(19,448)	(8,146)	(3,385)	(328)	38
Expenses:					
Sales and marketing expenses	49,555	27,730	6,857	2,736	792
Research and development expenses	38,430	31,863	30,735	26,347	18,251
General and administrative expenses	23,229	19,839	15,336	13,022	9,807
Operating loss	(130,662)	(87,578)	(56,313)	(42,433)	(28,812)
Other income (expense), net:					
Interest income	1,933	2,001	135	80	9
Loss on extinguishment of debt	(398)	—	—	—	—
Interest expense	(11,799)	(8,282)	(3,099)	(1,602)	(1,100)
Debt issuance costs	(3,344)	—	—	—	—
Change in fair value of derivative liabilities	29,232	209	—	—	—
Other (expense) income	(511)	(321)	176	25	26
Net loss	(115,549)	(93,971)	(59,101)	(43,930)	(29,877)
Deemed dividend as a result of Series E preferred stock beneficial conversion feature	—	—	—	—	(407)
Net loss available to common stockholders	(115,549)	(93,971)	(59,101)	(43,930)	(30,284)
Basic and diluted net loss per common share	$ (0.61)	$ (0.60)	$ (0.51)	$ (0.49)	$ (4.32)
Basic and diluted weighted-average shares outstanding	188,754,160	157,429,145	115,975,402	89,243,853	7,002,317

	December 31,				
	2019	2018	2017	2016	2015
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 95,938	$ 136,793	$ 16,150	$ 13,047	$ 3,939
Working capital	1,050	129,220	21,775	9,806	(2,371)
Marketable securities	—	—	20,300	7,291	—
Total assets	132,801	159,973	45,944	22,271	5,423
Term loan, net of discount, including current portion	43,434	14,783	24,414	19,066	9,819
Convertible notes, net of discount and derivative liabilities, including current portion	46,610	36,103	—	—	—
Derivative liabilities	26,207	17,091			
Total liabilities	141,450	88,712	38,677	27,148	15,120
Additional paid-in capital	464,491	428,878	270,953	199,751	151,019
Accumulated deficit	(473,343)	(357,794)	(263,823)	(204,722)	(160,792)
Total stockholders' (deficit) equity	(8,649)	71,261	7,267	(4,877)	(9,697)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis together with "Selected Financial Data" in Part II, Item 6 and 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 commercialization of a long-term, implantable continuous glucose monitoring, or CGM, system to improve the lives of people with diabetes by enhancing their ability to manage their disease with relative ease and accuracy. Our Eversense and Eversense XL 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 90 and 180 days, respectively, as compared to seven to 14 days for non-implantable CGM systems. The original Eversense CGM system received a CE mark in June 2016, which marked the first approval for the product to be sold within the European Economic Area. Subsequently, the extended life Eversense XL CGM system received its CE mark in September 2017 and is currently available in select markets in Europe, the Middle East, and Africa, or EMEA. 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.

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.

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 the United States, we have a 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 our overseas markets, we 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.

European Commercialization of Eversense

In September 2017, we received the CE mark for Eversense XL, which is indicated for a sensor life of up to 180 days. Eversense XL began commercialization in Europe 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 have granted Roche the exclusive right to market, sell and distribute Eversense in the EMEA, excluding Scandinavia and Israel. In addition, Roche has 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. The distribution agreement has a term through January 31, 2021. Roche is 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.

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 180 days in the United States. In September 30, 2019, we completed enrollment of the PROMISE trial. We expect to report topline data from the PROMISE trial in the second quarter of 2020. If the data from the PROMISE trial is positive, we intend to use the data in a regulatory submission to the FDA to expand the Eversense system use for up to 180 days in the United States and expect approval by the end of 2020. We also intend to use data from the first 90 days of the PROMISE trial, if positive, to support a regulatory submission to the FDA for an integrated, or iCGM, designation for our current Eversense 90-day system, which the FDA could potentially approve in the second half of 2020.

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 are providing financial assistance to eligible patients purchasing Eversense to enable more patients to access the Eversense system. The amount of assistance that we provide depends on a patient's insurance coverage. The program establishes maximum limits per patient and excludes certain patients as ineligible, including government-insured patients and residents of certain states. We continue to experience increasing interest and activity across patients and providers. The program provides opportunities to engage both regional and national payors, which we expect will lead to additional positive payor coverage decisions for the Eversense system.

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.

Critical Accounting Policies and Use of 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 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 at a fixed price to third-party distributors in the European Union and to a network of 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. Under the terms of our distribution agreement with Roche, Roche is contractually obligated to make certain minimum purchases of Eversense systems from us and, accordingly, the revenue we recognize for any given period is not necessarily indicative of the level of sales to end users for that, or any other, period.

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.

We recognize revenue only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in a future period. Our contracts may contain some form of variable consideration such as prompt-pay discounts or tier-volume price discounts. Variable consideration, including reimbursements paid by us to our Customers in accordance with the Eversense Bridge Program initiated in March 2019 and to a lesser extent, other discounts, is treated as a reduction in revenue when the product sale is recognized. Depending on the variable consideration, we develop estimates for the expected value based on the terms of the agreements, historical data, third-party payor mix, reimbursement rates, and market conditions. In connection with the Eversense Bridge Program, we reimburse participating Customers an amount up to a fixed maximum for the difference in the cost of the Eversense System and what they collect from insurance payors and the patient's fee of $99. Our Customers are responsible for confirming patient insurance coverage, obtaining pre-authorizations, determining eligibility, and continuously provide us with data regarding which patient orders are under the program and which are not. We use this data, along with actual reimbursements that have been validated to patient claims, to support our expected reimbursement estimates. Estimated reimbursement payments for product shipped to our Customers but not provided to a patient within the same reporting period are recorded within accrued expenses and other current liabilities in our accompanying consolidated balance sheets. Because of the limited experience with the Eversense Bridge Program, our estimates could change in future periods, and such changes could be material.

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, 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 Accounting Standards Codification, or 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, 2019 and 2018

The following table sets forth our results of operations for the years ended December 31, 2019 and 2018.

	Year Ended December 31,		Period-to-Period Change
	2019	2018	
	(in thousands)		
Revenue, net	$ 4,924	$ 2,039	$ 2,885
Revenue, net - related parties	16,377	16,874	(497)
Total revenue	21,301	18,913	2,388
Cost of sales	40,749	27,059	13,690
Gross profit	(19,448)	(8,146)	(11,302)
Expenses:			
Sales and marketing expenses	49,555	27,730	21,825
Research and development expenses	38,430	31,863	6,567
General and administrative expenses	23,229	19,839	3,390
Operating loss	(130,662)	(87,578)	(43,084)
Other income (expense), net:			
Interest income	1,933	2,001	(68)
Loss on extinguishment of debt	(398)	—	(398)
Interest expense	(11,799)	(8,282)	(3,517)
Debt issuance costs	(3,344)	—	(3,344)
Change in fair value of derivative liabilities	29,232	209	29,023
Other (expense) income	(511)	(321)	(190)
Total other income (expense), net	15,113	(6,393)	21,506
Net loss	$ (115,549)	$ (93,971)	$ (21,578)

Revenue, net

Our total net revenue increased to $21.3 million for the year ended December 31, 2019, compared to $18.9 million for the year ended December 31, 2018, an increase of $2.4 million. This increase was primarily due to increased U.S. sales of Eversense, net of reimbursements in connection with the Eversense Bridge Program.

Cost of sales

Our cost of sales increased to $40.7 million for the year ended December 31, 2019, compared to $27.1 million for the year ended December 31, 2018, an increase of $13.7 million. This increase was primarily attributable to increased impairment charges of $5.3 million due to obsolete inventory and product enhancements, $3.3 million for scrap and costs to streamline our sensor supply chain, $3.0 million for warranty expenses, $1.0 million for product back-ups and replacements associated with the recall of 844 uninserted sensors in the third quarter of 2019 and a net increase of $1.1 million for packaging, warehousing and logistics related costs

Gross profit was $(19.4) million and $(8.1) million for the years ended December 31, 2019 and 2018, respectively. Gross profit as a percentage of revenue, or gross margin, was (91.3)% and (43.1)% for the years ended December 31, 2019 and 2018, respectively.

Sales and marketing expenses

Sales and marketing expenses were $49.6 million for the year ended December 31, 2019, compared to $27.7 million for the year ended December 31, 2018, an increase of $21.8 million. The increase was primarily due to increased commercialization efforts in the United States during 2019, including a $13.0 million increase in salaries, commissions and payroll related costs for additional headcount, an increase in marketing costs of $6.4 million mainly related to consultants and travel, and an increase of $2.4 million for marketing programs, customer support services and software.

Research and development expenses

Research and development expenses were $38.4 million for the year ended December 31, 2019, compared to $31.9 million for the year ended December 31, 2018, an increase of $6.6 million. The increase was primarily due to a $7.9 million increase related to the PROMISE clinical trial and other post-approval and feasibility studies, a $0.8 million increase in salaries, bonuses and payroll related costs for additional headcount, partially offset by a decrease in contractual services of $2.1 million due to the FDA approval of Eversense in the United States in July 2018.

General and administrative expenses

General and administrative expenses were $23.2 million for the year ended December 31, 2019, compared to $19.8 million for the year ended December 31, 2018, an increase of $3.4 million. The increase was primarily due to a $1.3 million increase in salaries, bonuses and payroll related costs for additional headcount, a $1.3 million increase in other general and administrative costs to support our operations, and a $1.1 million increase for legal, audit and consulting fees.

Total other income (expense), net

Total other income (expense), net, was $15.1 million for the year ended December 31, 2019, compared to $(6.4) million for the year ended December 31, 2018, an increase of $21.5 million. The increase was primarily due to a $29.2 million change in fair value on our derivative liabilities in connection with the 2023 and 2025 Notes in 2019, offset by a $7.3 million increase in interest expense, debt issuance costs, and loss on the extinguishment of debt associated with the modification of the 2023 Notes and issuance of the 2025 Notes in July 2019.

Comparison of the Years Ended December 31, 2018 and 2017

The following table sets forth our results of operations for the years ended December 31, 2018 and 2017.

	Year Ended December 31,		Period-to-Period Change
	2018	2017	
	(in thousands)		
Revenue, net	$ 2,039	$ 529	$ 1,510
Revenue, net - related parties	16,874	5,844	11,030
Total revenue	18,913	6,373	12,540
Cost of sales	27,059	9,758	17,301
Gross profit	(8,146)	(3,385)	(4,761)
Expenses:			
Sales and marketing expense	27,730	6,857	20,873
Research and development expenses	31,863	30,735	1,128
General and administrative expenses	19,839	15,336	4,503
Operating loss	(87,578)	(56,313)	(31,265)
Other income (expense):			
Interest income	2,001	135	1,866
Interest expense	(8,282)	(3,099)	(5,183)
Change in fair value of derivative liabilities	209	—	209
Other (expense) income	(321)	176	(497)
Total other expense, net	(6,393)	(2,788)	(3,605)
Net loss	$ (93,971)	$ (59,101)	$ (34,870)

Revenue

Our revenue increased to $18.9 million for the year ended December 31, 2018, compared to $6.4 million for the year ended December 31, 2017. This increase was due to increased demand of Eversense primarily from Roche for distribution in Europe, as well as $1.4 million in revenue related to U.S. sales of Eversense.

Cost of sales

Our cost of sales increased to $27.1 million for the year ended December 31, 2018, compared to $9.8 million for the year ended December 31, 2017. This increase was due to increased sales of Eversense primarily from Roche for distribution in Europe, as well as costs related to U.S. sales of Eversense.

Gross profit was $(8.1) million and $(3.4) million for the years ended December 31, 2018 and 2017, respectively. Gross profit as a percentage of revenue, or gross margin, was (43.1)% and (53.1)% for the years ended December 31, 2018 and 2017, respectively.

Sales and marketing expenses

Sales and marketing expenses were $27.7 million for the year ended December 31, 2018, compared to $6.9 million for the year ended December 31, 2017, an increase of $20.9 million. The increase was primarily due to a $13.0 million increase in salaries, bonuses and payroll related costs for additional headcount, an increase in market research and marketing costs of $6.9 million in connection with the U.S. launch of Eversense, and an increase of $1.0 million in other sales and general marketing expenses to support our European distribution of Eversense as well as in connection with our U.S. launch of Eversense.

Research and development expenses

Research and development expenses were $31.9 million for the year ended December 31, 2018, compared to $30.7 million for the year ended December 31, 2017, an increase of $1.1 million. The increase was primarily due to a $2.8 million increase in salaries, bonuses and payroll related costs for additional headcount, partially offset by a decrease in clinical trial expenses of $1.7 million.

General and administrative expenses

General and administrative expenses were $19.8 million for the year ended December 31, 2018, compared to $15.3 million for the year ended December 31, 2017, an increase of $4.5 million. The increase was primarily due to a $2.8 million increase in salaries, bonuses and payroll related costs for additional headcount, and an increase of $1.7 million in other general and administrative costs to support our operations.

Total other expense, net

Total other expense, net, was $6.4 million for the year ended December 31, 2018, compared to $2.8 million for the year ended December 31, 2017, an increase of $3.6 million. The increase was primarily due to an increase of $5.2 million in interest expense on our Oxford/SVB Term Loans and 2023 Notes and an increase of $0.1 million in other expenses, partially offset by an increase in interest income earned on cash equivalents of $1.7 million.

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 $115.5 million, $94.0 million, and $59.1 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $473.3 million.

To date, we have funded our operations principally through the issuance of preferred stock, common stock and debt. As of December 31, 2019, we had cash and cash equivalents of $95.9 million.

Common Stock

On June 28, 2018, pursuant to an underwriting agreement with BTIG, LLC, we closed an underwritten offering of 38,076,561 shares of our common stock, including BTIG, LLC's exercise in full of its option to purchase additional shares, at a price of $3.93 per share, or the June 2018 Offering. We received aggregate net proceeds of $149.0 million from the June 2018 Offering.

In July 2019, pursuant to an underwriting agreement with Jefferies LLC, we closed a follow-on public offering of 26,136,363 shares of our common stock at a price of $1.10 per share, which included the exercise in full by Jefferies LLC of its option to purchase up to 3,409,090 additional shares. We received net proceeds of $26.8 million from the offering, after deducting underwriting discounts and offering expenses.

In November 2019, we entered into an Open Market Sale Agreement with Jefferies LLC which allows us to issue and sell up to $50 million in gross proceeds of our common stock. There have been no sales under this agreement as of December 31, 2019.

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. The proceeds from the Solar Term Loan were allocated between the debt and the Solar Warrants based on their respective fair value of $0.7 million, and were recorded within equity resulting in a debt discount that is being amortized as additional interest expense over the term of the Solar Term Loan using the effective interest method

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. Interest on the Solar Term Loan is payable monthly at a floating annual rate of 6.50% plus the greater of (i) the rate per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. and (ii) 2.48%, provided that the minimum floor interest rate is 8.98%. The maturity date for the Solar Term Loan will be July 1, 2024, or the Solar Maturity Date. Commencing on August 1, 2021, we will be required to make monthly principal amortization payments in the amount of $1.3 million; provided that the interest only period may be extended to (i) August 1, 2022 if our product revenue is greater than or equal to $40.0 million on a trailing six-month basis prior to the second anniversary of the effective date and (ii) August 1, 2023 if our product revenue is greater than or equal to $75.0 million on a trailing six-month basis after the achievement of the first extension. We may elect to prepay the Solar Term Loan prior to the Solar Maturity Date subject to a prepayment fee equal to 3.00% if the prepayment occurs within one year of the effective date, 2.00% if the prepayment occurs during the second year following the effective date, and 1.00% if the prepayment occurs more than two years after the effective date and prior to the Solar Maturity Date.

As of December 31, 2019, we were subject to the following financial covenants and in compliance:

- minimum liquidity at the end of the prior month, cash to be less than the positive value of two multiplied by the monthly cash burn plus the amount of accounts payable aged greater than 120 days;
- minimum product revenue on a trailing six-month basis at the end of the prior month to be lower than the schedule provided pursuant the Solar Loan Agreement; and
- redemption of permitted convertible debt.

If an event of default arises, and we are not able to obtain a waiver, all amounts owed by us would begin to bear interest at a rate that is 5.00% above the rate effective immediately before such event of default, and may be declared immediately due and payable by the Lenders. In addition, such a default would trigger a cross-default under the 2025 Notes, which would also result in the acceleration of the indebtedness under the 2025 Notes.

Although we were in compliance with the above financial covenants as of January 31, 2020 (the last month end for which we have completed our procedures to confirm covenant compliance as of the date of this filing),, based upon our current expectations for the remainder of the first quarter of 2020, we expect that we will be in noncompliance with the trailing six-month revenue covenant as March 31, 2020 and that, absent a waiver or amendment to the terms of the Solar Loan Agreement, we would likely remain in noncompliance with the trailing six-month revenue covenant for the foreseeable future thereafter. Therefore, if we are not able to obtain a waiver of such default by Solar, it is possible that our outstanding indebtedness under the Solar Loan Agreement and the 2025 Notes could be accelerated and become immediately due and payable. As a result, we have classified the outstanding indebtedness on the Solar Loan and 2025 Notes, net of discounts, as short-term liabilities in our consolidated balance sheet as of December 31, 2019. If this were to occur, based on our current capital resources, we would not be able to satisfy such indebtedness without raising additional capital from other sources, which may not be available on commercially reasonable terms or at all. If we were unable to raise such capital to satisfy these obligations, we could be required to sell assets, potentially liquidate our business or be forced into bankruptcy, any of which would have a material adverse effect on the value of our common stock.

The Solar Term Loan contains various non-financial covenants, including covenants that limit 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.

Convertible Notes

The following table summarizes our outstanding senior convertible note obligations at December 31, 2019:

Convertible Note	Issuance Date	Coupon	Aggregate Principal (in millions)	Maturity Date	Initial Conversion Rate per Share of Common Stock	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%	82.0	January 15, 2025	757.5758	1.32
Total			$ 97.7			

See Note 10 in the accompanying notes to our consolidated financial statements included elsewhere in this Annual Report for further discussion of the Term Loan, 2023 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, and post-approval requirements. These activities, including our ongoing focus to grow covered lives through positive insurance payor policy decisions and obtain approval for Eversense XL in the United States, will require significant uses of working capital through 2020 and beyond.

Given our current cash position and our current operating plans, and our expected noncompliance with covenants under the Solar Loan Agreement, we had a working capital deficiency as of December 31, 2019. As a result of these circumstances, there is substantial doubt about our ability to continue as a going concern through one year after the filing of our consolidated financial statements included in this Annual Report, without obtaining additional financing, securing a waiver from Solar Capital for expected covenant noncompliance, or entering into another form of non-equity or debt arrangement.

On November 7, 2019, we implemented a restructuring designed to meet the following objectives:

- reset strategic goals based on learnings from the Company’s first year of U.S. commercial launch;
- enhance the customer experience with the Company’s Eversense CGM system, including outcomes, longevity, reliability, access, support, and training;
- focus on executing pathways to successful launch of the 180-day product in the United States; and
- reduce cash burn to support these activities while minimizing near-term dilution and ensuring the best allocation of capital.

Pursuant to the restructuring, we also immediately reduced our current, open and planned workforce by approximately 30%. We incurred one-time restructuring costs related to severance expenses of approximately $0.8 million in the fourth quarter of 2019.

Our ability to fund our operations is dependent upon the effectiveness of our November 2019 restructuring, raising additional capital in the near term, strategic alliances and successful marketing efforts, and distribution or other collaborative arrangements. Our existing debt and covenants could also impact our ability to raise additional funds. Subject to obtainment of a waiver, we expect to be in noncompliance with certain covenants under the Solar Loan as of March 31, 2020 and for the foreseeable periods thereafter. To the extent that we raise additional capital through debt or the sale of equity, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds, we may have to relinquish valuable rights to our technologies, future revenue streams or grant terms that may not be favorable to us. If we are unable to raise additional funds through equity, debt financings, or strategic alliances when needed, we may be required to delay, limit, reduce or terminate some of our operating plans.

Cash Flows

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

	Year Ended December 31,		
	2019	**2018**	**2017**
Net cash used in operating activities	$ (136,047)	$ (90,771)	$ (55,739)
Net cash (used in) provided by investing activities	(1,045)	19,426	(13,226)
Net cash provided by financing activities	96,237	191,988	72,068
Net (decrease) increase in cash and cash equivalents	$ (40,855)	$ 120,643	$ 3,103

Net cash used in operating activities

Net cash used in operating activities was $136.0 million for the year ended December 31, 2019, and consisted of a net loss of $115.5 million and a net change in operating assets and liabilities of $(13.5) million, a change in the fair value of derivative liabilities of $(29.2) million, stock-based compensation expense of $8.1 million, non-cash interest expense of $8.5 million, loss on extinguishment of debt in the amount of $0.4 million and other non-cash charges of $5.2 million.

Net cash used in operating activities was $90.8 million for the year ended December 31, 2018, and consisted of a net loss of $94.0 million and a net change in operating assets and liabilities of $(6.7) million, partially offset by stock-based compensation expense of $6.4 million, non-cash interest expense of $3.3 million, and other non-cash charges of $0.2 million.

Net cash used in operating activities was $55.7 million for the year ended December 31, 2017, and consisted primarily of a net loss of $59.1 million, partially offset by stock-based compensation expense of $4.0 million, other non-cash expenses of $0.8 million, and a net change in assets and liabilities of $1.4 million.

Net cash provided by (used in) investing activities

Net used in investing activities was $1.0 million for the year ended December 31, 2019, and consisted of $1.0 million of capital expenditures, primarily for production equipment.

Net cash provided by investing activities was $19.4 million for the year ended December 31, 2018, and consisted of $28.4 million from the sale of marketable securities, partially offset by $1.0 million of capital expenditures for laboratory equipment, and $8.0 million for the purchase of marketable securities.

Net cash used in investing activities was $13.2 million for the year ended December 31, 2017, and consisted of $33.2 million for the purchase of marketable securities and $0.3 million of capital expenditures for laboratory equipment, partially offset by $20.3 million for the sale of marketable securities.

Net cash provided by financing activities

Net cash provided by financing activities was $96.2 million for the year ended December 31, 2019, and consisted primarily of $26.8 million from the issuance of common stock in our July 2019 offering, net of costs, $77.7 million from the issuance of the 2025 Notes, net of costs, and $43.0 million from the Solar Term Loan, net of cost, partially offset by $15.0 million for the repayment of the Oxford/SVB Term Loans and the repurchase of $37.0 million of 2023 Notes.

Net cash provided by financing activities was $192.0 million for the year ended December 31, 2018, and consisted primarily of $149.0 million from the issuance of common stock in our June 2018 Offering, $50.7 million from the issuance of the 2023 Notes, and $2.3 million from the exercise of stock options, partially offset by aggregate principal payments on our Solar Term Loan and Oxford/SVB Term Loans of $10.0 million.

Net cash provided by financing activities was $72.1 million for the year ended December 31, 2017, and consisted primarily of the net proceeds of $66.9 million from the issuance of common stock, $5.0 million from notes payable and the issuance of warrants and $0.2 million from the exercise of stock options.

Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2019.

	Payment due by period				
Contractual Obligations	**Total**	**2020**	**2021-2023**	**2024-2025**	**After 2025**
Operating lease obligations	$ 3,509	$ 938	$ 2,571	$ -	$ -
Principal payments under Solar Term Loan (1)	45,000	-	36,250	8,750	-
Interest payments under Solar Term Loan (1)	15,716	4,108	8,439	3,169	-
Principal payment under 2023 Notes (1)	15,700	-	15,700	-	-
Interest payments under 2023 Notes (1)	2,541	824	1,717	-	-
Principal payment under 2025 Notes (1)	82,000	-	-	82,000	-
Interest payments under 2025 Notes (1)	22,227	4,372	13,116	4,739	
Other commitments (2)	1,500	1,500	-	-	-
Total contractual obligations	$ 188,193	$ 11,742	$ 77,793	$ 98,658	$ -

(1) Represents the principal and interest payment schedule for the Solar Term Loan, 2023 Notes and 2025 Notes. For additional information, see "Liquidity and Capital Resources – Indebtedness." The Solar Term Loan interest payments include the $2.9 million payoff fee at the term of the loan.

(2) Other commitments include, among other things, minimum payment obligations and other obligations in the ordinary course of business that we cannot cancel or where we would be required to pay a fee for termination before the contractual period ended.

As described above, in light of the expected noncompliance with a financial covenant under the Solar Loan Agreement as of March 31, 2020, we have classified the outstanding indebtedness under the Solar Loan and 2025 Notes as short-term liabilities in our consolidated balance sheet as of December 31, 2019.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

Recently Adopted

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-02, Leases (Topic 842), or ASC 842. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. In July 2018, the FASB issued ASU 2018-11 to provide another transition method, allowing a cumulative effect adjustment to the opening balance of retained earnings during the period of adoption. The guidance is effective for annual reporting periods beginning after December 15, 2018, subject to early adoption. We adopted the new standard effective January 1, 2019 using the modified retrospective approach. . We did not elect the transition option, but elected the package of practical expedients permitted under the transition guidance, which allowed us to carryforward our historical lease classification, our assessment of whether a contract is or contains a lease and our initial direct costs for any leases that existed prior to adoption of the standard. We also elected to combine lease and non-lease components for our facility leases and to exclude leases with an initial term of 12 months or less from our consolidated balance sheet and recognize the associated lease payments in our consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. Our equipment leases had a remaining term of 12 months or less at the adoption date. The impact of adopting ASC 842 on our consolidated balance sheet as of January 1, 2019 is shown in the table below. The adoption of ASC 842 did not materially affect our consolidated net loss or cash flows.

Impact of Adopting ASC 842 on the Financial Statements.

	January 1, 2019 *Prior to ASC 842 Adoption*	*ASC 842 Adoption*	**January 1, 2019** *As Adjusted*
Consolidated Balance Sheet Data (in thousands)			
Operating lease assets [1]	$ —	$ 2,235	$ 2,235
Deferred rent non-current [2]	$ 84	$ (84)	$ —
Operating lease liabilities [3]	$ —	$ 417	$ 417
Non-current operating lease liabilities [3]	$ —	$ 1,902	$ 1,902

1. Represents capitalization of operating lease assets, including reclassification of deferred rent to operating lease assets.
2. As of December 31, 2018, the deferred rent balance was $84.
3. Represents recognition of operating lease liabilities.

In June 2018, the FASB issued ASU 2018-07*, Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments made to nonemployees so the accounting for such payments is substantially the same as those made to employees. Under the guidance, share based awards to nonemployees are measured at fair value on the grant date of the awards, entities will need to assess the probability of satisfying performance conditions if any are present, and awards are classified according to ASC 718 upon vesting which eliminates the need to reassess classification upon vesting, consistent with awards granted to employees. We adopted this guidance on January 1, 2019 and there was no significant impact on our consolidated financial statements.

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. We do not currently hold or plan to invest in available-for-sale securities, and we have not historically experienced collection issues or bad debts with our trade receivables. Accordingly, we do not expect this to have a significant impact on our consolidated financial statements and related disclosures at this time. We will adopt this guidance on its effective date for smaller reporting companies, January 1, 2023.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates, adds and modifies certain disclosure requirements on fair value measurements. The new standard includes additional disclosure requirements regarding the range and weighted average to develop significant unobservable inputs within Level 3 fair value measurements and became effective for us on January 1, 2020. We have evaluated the standard and do not expect this guidance to have a significant impact on our consolidated financial statements and related disclosures.

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

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, 2019 and 2018, we had cash and cash equivalents of $95.9 million and $136.8 million, respectively. 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 on the Solar Loan bears a floating annual rate of 6.50% plus the greater of (i) the rate per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. and (ii) 2.48%, provided that the minimum floor interest rate is 8.98%. Since execution of the Solar Term Loan, the rate has not changed from 8.98%. The interest rate on our 2023 and 2035 Notes is 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.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and 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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 16, 2020 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has a projected working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

/s/ Ernst & Young LLP

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

Tysons, VA
March 16, 2020

Report of Independent Registered Public Accounting Firm

To the Shareholders and 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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated March 16, 2020 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 16, 2020

Senseonics Holdings, Inc.

Consolidated Balance Sheets

(in thousands, except for share and per share data)

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 95,938	$ 136,793
Accounts receivable	3,239	830
Accounts receivable - related parties	7,140	6,267
Inventory, net	16,929	10,231
Prepaid expenses and other current assets	4,512	3,985
Total current assets	127,758	158,106
Deposits and other assets	3,042	117
Property and equipment, net	2,001	1,750
Total assets	$ 132,801	$ 159,973
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,285	$ 4,407
Accrued expenses and other current liabilities	18,636	13,851
Deferred revenue	—	628
Term Loans, net of discount	43,434	10,000
2025 Notes, net of discount	60,353	—
Total current liabilities	126,708	28,886
Term Loans, net of discount and current portion	—	4,783
2023 Notes, net of discount	12,464	53,194
Other liabilities	2,278	1,849
Total liabilities	141,450	88,712
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.001 par value per share; 450,000,000 shares authorized; 203,452,812 and 176,918,381 shares issued and outstanding as of December 31, 2019 and 2018	203	177
Additional paid-in capital	464,491	428,878
Accumulated deficit	(473,343)	(357,794)
Total stockholders' (deficit) equity	(8,649)	71,261
Total liabilities and stockholders' equity (deficit)	$ 132,801	$ 159,973

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,		
	2019	**2018**	**2017**
Revenue, net	$ 4,924	$ 2,039	$ 529
Revenue, net - related parties	16,377	16,874	5,844
Total revenue	21,301	18,913	6,373
Cost of sales	40,749	27,059	9,758
Gross profit	(19,448)	(8,146)	(3,385)
Expenses:			
Sales and marketing expenses	49,555	27,730	6,857
Research and development expenses	38,430	31,863	30,735
General and administrative expenses	23,229	19,839	15,336
Operating loss	(130,662)	(87,578)	(56,313)
Other income (expense), net:			
Interest income	1,933	2,001	135
Loss on extinguishment of debt	(398)	—	—
Interest expense	(11,799)	(8,282)	(3,099)
Debt issuance costs	(3,344)	—	—
Change in fair value of derivative liabilities	29,232	209	—
Other (expense) income	(511)	(321)	176
Total other income (expense), net	15,113	(6,393)	(2,788)
Net loss	(115,549)	(93,971)	(59,101)
Total comprehensive loss	$ (115,549)	$ (93,971)	$ (59,101)
Basic and diluted net loss per common share	$ (0.61)	$ (0.60)	$ (0.51)
Basic and diluted weighted-average shares outstanding	188,754,160	157,429,145	115,975,402

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 Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2016	93,569	$ 94	$ 199,751	$ (204,722)	$ (4,877)
Issues shares of common stock	42,461	42	66,819	—	66,861
Exercise of stock options and warrants	853	1	286	—	287
Stock-based compensation expense and vesting of RSUs	—	—	3,993	—	3,993
Issuance of warrants related to debt	—	—	104	—	104
Net loss	—	—	—	(59,101)	(59,101)
Balance, December 31, 2017	136,883	$ 137	$ 270,953	$ (263,823)	$ 7,267
Issued shares of common stock	38,077	38	149,006	—	149,044
Exercise of stock options for cash and warrants	1,873	2	2,257	—	2,259
Conversion of 2023 Notes	85	—	250	—	250
Stock-based compensation expense and vesting of RSUs	—	—	6,412	—	6,412
Net loss	—	—	—	(93,971)	(93,971)
Balance, December 31, 2018	176,918	$ 177	$ 428,878	$ (357,794)	$ 71,261
Issued shares of common stock	26,136	26	26,731	—	26,757
Exercise of stock options and warrants	256	—	108	—	108
Stock-based compensation expense and vesting of RSUs	143	—	8,052	—	8,052
Issuance of warrants related to debt, net of issuance costs	—	—	722	—	722
Net loss	—	—	—	(115,549)	(115,549)
Balance, December 31, 2019	203,453	$ 203	$ 464,491	$ (473,343)	$ (8,649)

Senseonics Holdings, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	2019	2018	2017
Cash flows from operating activities			
Net loss	$ (115,549)	$ (93,971)	$ (59,101)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	1,001	270	227
Non-cash interest expense (debt discount and deferred costs)	8,457	3,317	453
Loss on extinguishment of debt	398	—	—
Change in fair value of derivative liabilities	(29,232)	(209)	—
Stock-based compensation expense	8,052	6,412	3,993
Provision for inventory obsolescence and net realizable value	3,970	201	226
Net realized gain on marketable securities	—	(115)	(128)
Loss on disposal of assets	310	—	—
Changes in assets and liabilities:			
Accounts receivable	(3,282)	(3,715)	(3,131)
Prepaid expenses and other current assets	(527)	(1,893)	(1,727)
Inventory	(10,668)	(7,441)	(2,741)
Deposits and other assets	(3,442)	59	(71)
Accounts payable	(122)	(3,395)	4,642
Accrued expenses and other liabilities	4,827	8,355	823
Deferred revenue	(628)	628	—
Accrued interest	388	710	781
Other	—	16	15
Net cash used in operating activities	(136,047)	(90,771)	(55,739)
Cash flows from investing activities			
Capital expenditures	(1,045)	(989)	(345)
Purchases of marketable securities	—	(7,935)	(33,181)
Sales and maturities of marketable securities	—	28,350	20,300
Net cash (used in) provided by investing activities	(1,045)	19,426	(13,226)
Cash flows from financing activities			
Proceeds from issuance of common stock	28,750	149,502	67,556
Common stock issuance costs	(1,993)	(458)	(695)
Proceeds from exercise of stock options and stock warrants	108	2,259	287
Proceeds from issuance of warrants	722	—	104
Proceeds from issuance of notes	82,000	52,950	5,000
Notes issuance costs	(4,301)	(2,245)	(104)
Proceeds from issuance of term loans	45,000	—	—
Term loans issuance costs	(2,049)	—	—
Repayment of Oxford and SVB Term Loan	(15,000)	(10,000)	—
Repurchase of 2023 notes	(37,000)	—	—
Principal payments under capital lease obligations	—	(20)	(80)
Net cash provided by financing activities	96,237	191,988	72,068
Net (decrease) increase in cash and cash equivalents	(40,855)	120,643	3,103
Cash and cash equivalents, at beginning of year	136,793	16,150	13,047
Cash and cash equivalents, at ending of year	$ 95,938	$ 136,793	$ 16,150
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	$ 5,233	$ 3,136	$ 1,830
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	$ 32	$ 178	$ —

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

Senseonics Holdings, Inc.

Notes to Consolidated Financial Statements

1. Organization

Senseonics Holdings, Inc., a Delaware corporation, is a medical technology company focused on the development and commercialization 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. Going Concern

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 Eversense in the United States and Eversense and Eversense XL 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 for the sale of those products, including approval by the FDA for the extended Eversense XL CGM system in the United States. These activities will require significant uses of working capital through 2020 and beyond.

In 2019, the Company generated a net loss of $(115.5) million and had an accumulated deficit of $(473.3) million at December 31, 2019. At December 31, 2019, the Company had $95.9 million in cash and cash equivalents. The Company's ability to meet its obligations as they become due in the ordinary course of business for the next twelve months from the date of this Annual Report filed on Form 10-K will depend on its ability to achieve forecasted results, its ability to raise additional funds, and to obtain a waiver or amend its Loan and Security Agreement with Solar Capital, Ltd. ("Solar"), which the Company expects to be in noncompliance with as of March 31, 2020 and for the foreseeable periods thereafter. As a result of these factors and the projected working capital deficiency, the Company has substantial doubt about its ability to continue as a going concern through one year from the date that the consolidated financial statements included in this Annual Report were issued.

The Company is in discussions with Solar to procure a waiver for the expected covenant noncompliance. Because those discussions have not been finalized, under cross-default provisions in the Loan and Security Agreement with Solar, the Solar Loan and the Company's convertible senior subordinated notes due in 2025, may be callable at the time of noncompliance. The Company intends to raise additional capital in the near term through future sales of its common stock, debt financings, collaborations, strategic alliances and partnerships, distribution or licensing arrangements and in the longer term, from revenue related to product sales to the extent the Company is able to expand commercialization of Eversense. New financings may not be available to the Company on commercially acceptable terms, or at all, and may be impacted by the current debt covenants. The Company's plans to alleviate its substantial doubt about its ability to continue as a going concern assume that there will be no material adverse development in its business, liquidity, or capital requirements. If the Company is unable to obtain additional capital when required, or is unable to obtain a waiver from Solar, the Company may be required to reduce or delay management's strategic plans for commercializing Eversense and Eversense XL, developing future products or product upgrades, reduce, delay or eliminate one or more of its research and development programs or studies, and/or downsize the organization.

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.

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 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. 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 loss comprises net loss and other changes in equity that are excluded from net loss. For the years ended December 31, 2019, 2018 and 2017, 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 and cash equivalents consisted of the following as of December 31 (in thousands).

	2019	2018
Cash (1)	$ 38,043	$ 13,934
Money market funds	37,769	122,859
Commercial paper	13,870	
Corporate bonds	6,256	—
Cash and cash equivalents	$ 95,938	$ 136,793

(1)Includes overnight repurchase agreements.

Concentration of Revenues and Customers

During the year ended December 31, 2019 the Company derived 77% of its total net revenue from Roche Diabetes Care GmbH, a related party, and 12% from Advanced Diabetes Supply, one of the Company's strategic fulfillment partners and a supplier of CGM products to diabetic patients in the United States. During the years ended December 2018 and December 2017, the Company derived 86% and 93%, respectively, from one customer, Roche Diabetes Care GmbH.

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, 2019, 2018, and 2017:

	December 31, 2019		December 31, 2018		December 31, 2017	
(Dollars in thousands)	Amount	% of Total	Amount	% of Total	Amount	% of Total
Revenue, net:						
Outside of the United States	$ 18,054	84.8 %	$ 17,498	92.5 %	$ 6,373	100.0 %
United States	3,247	15.2	1,415	7.5	—	0.0
Total	$ 21,301	100.0 %	$ 18,913	100.0 %	$ 6,373	100.0 %

Marketable Securities

Marketable securities consist of government and agency securities and corporate debt securities and are typically 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. The Company classifies all available-for-sale marketable securities with maturities greater than one year from the balance sheet date as non-current assets. As of December 31, 2019 and 2018, the Company did not have any marketable securities.

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. As of December 31, 2019 and 2018, the Company did not have any allowances for doubtful accounts, as there are no collectability concerns.

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 did not identify any indicators of impairment in 2019, 2018, and 2017.

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*.

The two 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, 2019 and December 31, 2018, the warranty reserve was $2.2 million and $0.8 million, respectively. The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2019 and 2018:

	December 31,	
(Dollars in thousands)	**2019**	**2018**
Balance at beginning of the year	$ 816	$ 813
Provision for warranties during the period	3,296	1,119
Settlements made during the period	(1,915)	(1,116)
Balance at end of the year	$ 2,197	$ 816

Revenue Recognition

The Company recognizes revenue in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company generates revenue from sales of the Eversense CGM system and related components at a fixed price to third-party distributors in the European Union and to a network of strategic fulfillment partners in the United States (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 is recognized, at a point in time, when the Customers obtain control of the product based upon the delivery terms as defined in the contract at an amount that reflects the consideration which is expected to be received in exchange for the product. Contracts with the Customers include performance obligations for supply of goods and the performance obligation is typically satisfied upon transfer of control of the product. Distribution contracts may also contain requirements for training and customer service support, however these are not assessed as performance obligations given the activities are considered immaterial in the context of the contract. The payment terms and conditions of the Customers vary, but the Company is typically paid within 60 days of invoicing subsequent to the Customers obtaining control of the Company's product.

Revenue is recognized only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur in a future period. The Company's contracts may contain variable consideration such as prompt-pay discounts or tier-volume price discounts. Variable consideration, including the reimbursements paid by the Company to its Customers in accordance with the Eversense Bridge Program initiated in March 2019 and to a lesser extent, other discounts and prompt-pay incentives, is treated as a reduction in revenue when the product sale is recognized. Depending on the variable consideration, the Company estimates the expected value based on the terms of the agreements, historical data, third-party payor mix, reimbursement rates, and market conditions. In connection with the Eversense Bridge Program, the Company reimburses participating Customers an amount up to a fixed maximum for the difference in the cost of the Eversense System and what they collect from insurance payors and the patient's fee of $99. The Customers are responsible for confirming patient insurance coverage, obtaining pre-authorizations, determining eligibility, and continuously provide the Company with data regarding which patient orders are under the program and which are not. Customer supplied data, along with actual reimbursements that have been validated to patient claims, are used to support expected reimbursement estimates. Estimated reimbursement payments for product shipped to Customers but not provided to a patient within the same reporting period are recorded within accrued expenses and other current liabilities in the accompanying consolidated balance sheets. Because of the limited experience with the Eversense Bridge Program, the estimates used in determining the variable consideration on a sale transaction could change in future periods, and such changes could be material.

Contract assets consist of trade receivables from Customers and contract liabilities consist of amounts due to the Customers in connection with the Eversense Bridge Program, incentive programs, or prompt-pay discounts, classified as patient access and incentive programs within accrued liabilities on the accompanying consolidated balance sheets. The Company's contracts provide for a one-year warranty on transmitters to Customers. Customer contracts do not include the right to return.

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 marketing programs, website design and advertising, educational and promotional materials, consultants, and tradeshow expenses.

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 and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The Company's term loan under the Solar Loan Agreement, 2025 Notes and 2023 Notes 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 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, 2019, 2018 and 2017, consisting of common stock options and stock purchase warrants, which have been excluded from the computation of diluted loss per share, was as follows:

	2019	2018	2017
Stock-based awards	24,218,612	21,457,946	16,413,840
2023 Notes	6,672,500	20,480,638	—
2025 Notes	63,565,883	—	—
Warrants	5,196,581	4,071,581	4,427,086
Total anti-dilutive shares outstanding	99,653,576	46,010,165	20,840,926

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 February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASC 842"). The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. In July 2018, the FASB issued ASU 2018-11 to provide another transition method, allowing a cumulative effect adjustment to the opening balance of retained earnings during the period of adoption. The guidance is effective for annual reporting periods beginning after December 15, 2018, subject to early adoption. The Company adopted the new standard effective January 1, 2019 using the modified retrospective approach. The Company did not elect the transition option, but elected the package of practical expedients permitted under the transition guidance, which allowed the Company to carryforward its historical lease classification, its assessment of whether a contract is or contains a lease and its initial direct costs for any leases that existed prior to adoption of the standard. The Company also elected to combine lease and non-lease components for its facility leases and to exclude leases with an initial term of 12 months or less from its consolidated balance sheet and recognize the associated lease payments in its consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. The Company's equipment leases had a remaining term of 12 months or less at the adoption date.. The impact of adopting ASC 842 on the Company's consolidated balance sheet as of January 1, 2019 is shown in the table below. The standard did not materially affect the Company's consolidated net loss or cash flow.

Impact of Adopting ASC 842 on the Financial Statements

	January 1, 2019 *Prior to ASC 842 Adoption*	*ASC 842 Adoption*	**January 1, 2019** *As Adjusted*
Consolidated Balance Sheet Data (in thousands)			
Operating lease assets [(1)]	$ —	$ 2,235	$ 2,235
Deferred rent non-current [(2)]	$ 84	$ (84)	$ —
Operating lease liabilities [(3)]	$ —	$ 417	$ 417
Non-current operating lease liabilities [(3)]	$ —	$ 1,902	$ 1,902

(1) Represents capitalization of operating lease assets, including reclassification of deferred rent to operating lease assets.
(2) As of December 31, 2018, the deferred rent balance was $84.
(3) Represents recognition of operating lease liabilities

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments made to nonemployees so the accounting for such payments is substantially the same as those made to employees. Under the guidance, share based awards to nonemployees will be measured at fair value on the grant date of the awards, entities will need to assess the probability of satisfying performance conditions if any are present, and awards will continue to be classified according to ASC 718 upon vesting which eliminates the need to reassess classification upon vesting, consistent with awards granted to employees. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. The Company adopted the guidance on January 1, 2019. The standard did not materially affect the Company's consolidated net loss or cash flows.

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 does not currently hold or plan to invest in available-for-sale securities, and 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. The Company will adopt this guidance on its effective date for smaller reporting companies, January 1, 2023.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates, adds and modifies certain disclosure requirements on fair value measurements. The new standard includes additional disclosure requirements regarding the range and weighted average to develop significant unobservable inputs within Level 3 fair value measurements and became effective for the Company on January 1, 2020. The Company has evaluated the standard and does not expect this to have a significant impact on the consolidated financial statements and related disclosures.

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. Inventory, net

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

	December 31,	
	2019	2018
Finished goods	$ 3,944	$ 1,457
Work-in-process	10,938	7,211
Raw materials	2,047	1,563
Total	$ 16,929	$ 10,231

The Company recorded $5.3 million and $0.2 million in cost of sales for the years ended December 31, 2019 and 2018, 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.

5. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
Contract manufacturing	$ 3,043	$ 2,962
Clinical and preclinical	240	111
Marketing and sales	605	287
IT and software	294	244
Interest receivable	107	239
Other	223	142
Total prepaid expenses and other current assets	$ 4,512	$ 3,985

6. Property and Equipment, net

Property and equipment, net consisted of the following as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
Machinery and laboratory equipment	$ 2,272	$ 2,132
Office furniture and equipment	371	281
Leasehold improvements	112	647
	2,755	3,060
Less: Accumulated depreciation	(754)	(1,310)
Property and equipment, net	$ 2,001	$ 1,750

Depreciation expense for the years ended December 31, 2019, 2018, and 2017 was $0.5 million, $0.3 million, and $0.2 million, respectively. The Company disposed of $1.4 million of property and equipment in 2019, resulting in a loss of $0.3 million recorded within other income (expense) in the consolidated statements of operations and comprehensive loss, and primarily related to machinery and laboratory equipment, including machinery at contract manufacturers determined to be impaired or obsoleted. The Company did not dispose of any property or equipment in 2018 or 2017.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
Contract manufacturing	$ 2,452	$ 6,068
Compensation and benefits	5,630	3,685
Sales and marketing services	553	738
Professional & administration services	1,384	727
Interest on notes payable	2,153	1,268
Research and development	1,956	147
Product warranty and replacement obligations	2,197	816
Patient access and incentive programs	1,578	—
Operating lease	696	—
Other	37	402
Total accrued expenses and other current liabilities	$ 18,636	$ 13,851

8. 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 new 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. The Company recorded $2.8 million of associated ROU assets and lease liabilities in its consolidated balance sheet at December 31, 2019.

Operating lease expense for the year ended December 31, 2019, 2018 and 2017 was $0.7 million, $0.7 million and $0.6 million, respectively. Short-term lease expense is included in operating lease expense and was $0.2 million for the year ended December 31, 2019.

The following table summarizes the lease assets and liabilities as of December 31, 2019 (in thousands):

Operating Lease Assets and Liabilities	Balance Sheet Classification	Amount
Assets		
Operating lease ROU assets	Deposits and other assets	$ 2,822
Liabilities		
Current operating lease liabilities	Accrued expenses and other current liabilities	$ 696
Non-current operating lease liabilities	Other non-current liabilities	2,278
Total operating lease liabilities		$ 2,974

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, 2019 (in thousands):

2020	$ 938
2021	969
2022	1,002
2023	600
2024	—
Total operating lease payments	3,509
Less: imputed interest	(535)
Total operating lease liability	$ 2,974

The following table summarizes the weighted-average lease term and weighted-average discount rate as of December 31, 2019:

Remaining lease term (years)	
Operating leases	3.6
Discount rate	
Operating leases	9.1 %

During the year ended December 31, 2019, the Company made cash payments of $0.7 million included in the measurement of its operating lease liabilities.

9. 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, 2019 and 2018 were $0.2 million and $0.2 million, respectively. There was no employer match expense during the year ended December 31, 2017. Administrative expenses for the plan, which are paid by the Company, were not material in 2019, 2018 or 2017.

10. Notes Payable and Stock Purchase Warrants

Term Loans

Solar Loan Agreement

On July 16, 2019, the Company entered into a Loan and Security Agreement (the "Solar Loan Agreement"), with Solar. Pursuant to the Solar Loan Agreement, on July 25, 2019 ("the effective date"), the Company borrowed term loans in an aggregate principal amount of $45.0 million (the "Solar Term Loan"), of which the Company used $11.6 million to repay in full the Oxford/SVB Term Loans and terminate the Amended and Restated Loan and Security Agreement with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") described below.

Interest on the Solar Term Loan is payable monthly at a floating annual rate of 6.50% plus the greater of (i) the rate per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. and (ii) 2.48%, provided that the minimum floor interest rate is 8.98%. The maturity date for the Solar Term Loan is July 1, 2024 (the "Solar Maturity Date"). Commencing on August 1, 2021, the Company will be required to make monthly principal amortization payments of $1.3 million; provided that the interest only period may be extended to (i) August 1, 2022 if the Company's product revenue is greater than or equal to $40.0 million on a trailing six-month basis prior to the second anniversary of the effective date and (ii) August 1, 2023 if the Company's product revenue is greater than or equal to $75.0 million on a trailing six-month basis after the achievement of the first extension.

The Company may elect to prepay the Solar Term Loan prior to the Solar Maturity Date subject to a prepayment fee equal to 3.00% if the prepayment occurs within one year of the effective date, 2.00% if the prepayment occurs during the second year following the effective date, and 1.00% if the prepayment occurs more than two years after the effective date and prior to the Solar Maturity Date.

The Solar Loan Agreement contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on the Solar Lenders' security interest over the collateral, a material adverse change, the occurrence of a default under certain other agreements entered into by the Company and its subsidiaries, the rendering of certain types of judgments against the Company and its subsidiaries, the revocation of certain government approvals, violation of covenants, and incorrectness of representations and warranties in any material respect. Upon the occurrence of an event of default, subject to specified cure periods, all amounts owed by the Company would begin to bear interest at a rate that is 5.00% above the rate effective immediately before the event of default, and may be declared immediately due and payable by the Solar Lenders.

Although the Company was in compliance with the financial covenants as of December 31, 2019, it is expected that the Company will not be in compliance with the trailing six-month revenue covenant as of March 31, 2020 and that, absent a waiver or amendment to the terms of the Solar Loan Agreement, the Company would likely remain in noncompliance with the trailing six-month revenue covenant for the foreseeable future thereafter. Therefore, if the Company is not able to obtain a waiver of such default by Solar, it is possible that the outstanding indebtedness under the Solar Loan Agreement and the 2025 Notes could be accelerated and become immediately due and payable in 2020. As a result, the Company has classified the outstanding indebtedness on the Solar Loan and 2025 Notes, net of discounts, as of December 31, 2019 in short-term liabilities in its consolidated statement of operations.

The Solar Term Loan is secured by substantially all of the Company and its subsidiaries' assets. The Solar Loan Agreement also contains specified financial covenants related to the Company's liquidity and trailing six-month revenue.

The Solar Loan Agreement also contains certain restrictive covenants that limit the Company's ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions, as well as financial reporting requirements.

A final fee ("Final Fee"), which is equal to $2.9 million (6.45% of the Solar Term Loan), is due and payable on the earliest to occur of (i) Solar Maturity Date, (ii) the acceleration of the Solar Term Loan including, upon the occurrence of a bankruptcy or insolvency event, or (iii) prepayment, refinancing, substitution or replacement of the Solar Term Loan. The fee is accreted to interest expense over the term of the loan to the Final Fee amount.

In connection with the Solar Term Loan, the Company incurred issuance costs in the amount of $0.4 million, and paid fees to Lenders (as defined below) in the amount of $0.9 million in connection with the repayment of the Oxford/SVB Term Loans, which are netted against the principal balance of the Solar Term Loan and amortized as additional interest expense over the term of the Solar Term Loan using the effective interest method. Unamortized debt issuance costs and additional prepayment fees in the amount of $0.4 million associated with the repayment of the Oxford/SVB Term Loans were recorded as a loss on the extinguishment of debt in other income (expense) in the Company's consolidated statements of operations and comprehensive loss as of December 31, 2019.

Additionally, the Company 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 (the "Solar Warrants"). The Solar Warrants are exercisable until July 25, 2029. The proceeds from the Solar Term Loan were allocated between the debt and the Solar Warrants based on their respective fair value of $0.7 million, and were recorded within equity resulting in a debt discount that is being amortized as additional interest expense over the term of the Solar Term Loan using the effective interest method.

Oxford and Silicon Valley Bank Term Loans

On June 30, 2016, the Company entered into an Amended and Restated Loan and Security Agreement with Oxford and SVB (together, the "Lenders"). Pursuant to the Amended and Restated Loan and Security Agreement, the Company borrowed an aggregate principal amount of $25.0 million in the following three tranches: $15.0 million (the "Tranche 1 Term Loan"); $5.0 million (the "Tranche 2 Term Loan"); and $5.0 million (the "Tranche 3 Term Loan" and together with the Tranche 1 Term Loan and the Tranche 2 Term Loan, the "Oxford/SVB Term Loans"). The funding conditions for the Tranche 1 Term Loan were satisfied as of June 30, 2016. Therefore, the Company issued secured notes to the Lenders for aggregate gross proceeds of $15.0 million (the "Oxford/SVB Notes"), on June 30, 2016. The Company used approximately $11.0 million from the proceeds from the Oxford/SVB Notes to repay the outstanding balance under the Company's previously existing Loan and Security Agreement with Oxford. The Company borrowed the Tranche 2 Term Loan and Tranche 3 Term Loan in November 2016 and March 2017, respectively. The maturity date for all the Oxford/SVB Term Loans was June 1, 2020. The Company was also required to make a final payment equal to 9.00% of the aggregate principal balances of the funded Oxford/SVB Term Loans and was being accrued as additional interest expense over the term of the Oxford/SVB Notes using the effective interest method.

Proceeds from the Solar Term Loan were used to repay the remaining balance of the Oxford/SVB Term Loans, which were subject to a prepayment fee equal to $0.1 million.

Convertible Notes

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 are 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.

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, were $53.6 million as of December 31, 2019.

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 September 30, 2019.

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 would 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 $11.9 million as of December 31, 2019 and $41 million at December 31, 2018.

In the year ended December 31, 2018, the Company issued 85,007 shares of common stock upon the conversion of $250,000 in aggregate principal amount of the 2023 Notes. There were no conversions of 2023 Notes in the year ended December 31, 2019.

The following carrying amounts are outstanding under the Company's notes payable as of December 31, 2019 and December 31, 2018 (in thousands):

	December 31, 2019			
	Principal ($)	Debt Discount ($)	Issuance Costs ($)	Carrying Amount ($)
Solar Term Loan	45,000	(1,466)	(100)	43,434
2023 Notes	15,700	(3,900)	-	11,800
2025 Notes	82,000	(46,482)	(708)	34,810

	December 31, 2018			
	Principal ($)	Debt Discount ($)	Issuance Costs ($)	Carrying Amount ($)
Oxford / SVB Term	15,000	(114)	(103)	14,783
2023 Notes	52,700	(16,597)	-	36,103

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

	Year ended December 31, 2019				
	Effective Interest Rate	Interest ($)	Debt Discount & Fees ($)	Loss on Extinguishment of Debt ($)	Total Interest Expense ($)
Solar Term Loan	8.98%	1,759	60	-	1,819
Oxford / SVB Term	7.37%	900	56	-	956
2023 Notes	5.25%	2,130	2,500	398	5,028
2025 Notes	5.25%	2,034	2,360	-	4,394
Total		6,823	4,976	398	12,197

Interest expense related to notes payable was $8.3 million, including $2.9 million for amortization of issuance fees and discounts on the 2023 Notes, and $3.1 million for the years ended December 31, 2018 and 2017, respectively.

The following are the scheduled maturities of the Solar Term Loan, 2025 Notes and 2023 Notes as of December 31, 2019:

2020	$ —
2021	6,250
2022	15,000
2023	30,700
Thereafter	90,750
Total	$ 142,700

11. Stockholders' Equity (Deficit)

In connection with our 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, 2019 and December 31, 2018, the Company's authorized capital stock included 450,000,000 shares of common stock, par value $0.001 per share. The Company had 203,452,812 and 176,918,381 shares of common stock issued and outstanding at December 31, 2019 and December 31, 2018, respectively.

Preferred Stock

As of December 31, 2019 and 2018, the Company's authorized capital stock included 5,000,000 shares and 0 shares of undesignated preferred stock, par value $0.001 per share, respectively. No shares of preferred stock were outstanding as of December 31, 2019 or 2018.

Stock Purchase Warrants

The Company issued the 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. The Solar Warrants are exercisable until July 25, 2029. The proceeds from the Solar Term Loan were allocated between the debt and the Solar Warrants based on their fair value of $0.7 million, and were recorded within equity resulting in a discount to the Solar Term Loan.

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.

The unamortized deferred financing fees and debt discount related to the notes rollover amount was being amortized along with the deferred financing costs and the discount created by the new issuance of the Solar Warrants over the term of the loan using the effective interest method. In connection with the repayment of the Term Loans, the unamortized discount and additional prepayment fee of $0.4 million was recorded as a loss on extinguishment of debt in other income (expense) in the Company's consolidated statements of operations and comprehensive loss.

12. 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, 2019, 4,852,081 shares remained available for grant under the amended and restated 2015 Plan. Effective January 1, 2020, 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 11,972,929 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 nonstatutory options, restricted stock unit awards and other equity incentive awards. As of December 31, 2019, 901,697 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, 2019 there were 4,873,706 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, 2020, there were 566,573 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 6,253,301 shares of the Company's common stock underlying options have vested or are expected to vest under the 1997 Plan. Upon the effectiveness of the 2015 Plan, the Company no longer grants any awards under the 1997 Plan.

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, 2019, 2018 and 2017 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, 2016	11,389	$ 1.26	
Granted	5,674	$ 2.24	
Exercised	(509)	$ 0.64	
Cancelled/forfeited	(159)	$ 2.47	
Options outstanding as of December 31, 2017	16,395	$ 1.61	7.20
Granted	7,533	$ 3.03	
Exercised	(1,439)	$ 1.20	
Cancelled/forfeited	(1,031)	$ 2.43	
Options outstanding as of December 31, 2018	21,458	1.61	6.68
Granted	9,294	$ 2.54	
Exercised	(88)	$ 1.26	
Cancelled/forfeited	(6,446)	$ 2.48	
Options outstanding as of December 31, 2019	24,218		6.64
Options vested and expected to vest as of December 31, 2019	24,218	$ 2.16	
Options exercisable as of December 31, 2019	14,346	$ 1.85	5.37

The weighted average grant-date fair value of stock option awards granted in 2019, 2018 and 2017 was $1.60, $1.91, and $1.36 per share, respectively.

For the years ended December 31, 2019 and 2018 and 2017, 87,591, 1,438,671, and 508,625 options were exercised, respectively, with an aggregate intrinsic value at the time of exercise of $0.2 million, $3.7 million, and $1.0 million, respectively.

The total fair value of options that vested during 2019 and 2018 were approximately $8.2 million and $5.4 million, respectively.

The aggregate intrinsic value of the options currently exercisable at December 31, 2019 was $2.0 million. The aggregate intrinsic value of stock options outstanding at December 31, 2019 was $2.0 million, which approximated the aggregate intrinsic value of options vested and expected to vest as of December 31, 2019.

The weighted average grant date fair value of the unvested stock option awards outstanding at December 31, 2019 and 2018 was $1.64 and $1.76 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, 2019 were $1.72, $1.50 and $1.71 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,		
	2019	2018	2017
Expected term of options (in years)	6.5	6.5	6.5
Expected volatility rate	64.49 -67.16 %	63.52 -66.95 %	60.66 -75.43 %
Risk-free interest rate	1.60 -2.64 %	2.45 -3.08 %	1.90 -2.30 %
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 life 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 $8.1 million, $6.4 million, and $4.1 million for the years ended December 31, 2019 and 2018 and 2017, respectively, classified as follows (in thousands):

	December 31,		
	2019	2018	2017
Cost of sales	$ 153	$ —	
Sales and marketing	3,001	1,685	$ 509
Research and development	1,600	1,364	930
General and administrative	3,298	3,326	2,659
Total stock-based compensation	$ 8,052	$ 6,375	$ 4,098

As of December 31, 2019, there was $14.8 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 2.64 years. There was no unrecognized compensation cost related to non-vested restricted stock awards as of December 31, 2019.

Restricted Stock Units

The Company issued 142,600 and 91,786 shares of restricted stock units in lieu of cash payment to members of the Board of Directors during 2019 and 2018, respectively. The restricted stock units immediately vest upon issuance. The weighted average share price on date of exercise for restricted stock awards was $1.72 and $3.40 for the years ended December 31, 2019 and 2018, respectively.

Stock-based compensation expense for restricted stock awards was $0.3 million, $0.3 million, and $0.3 million for the years ended December 31, 2019, 2018 and 2017 respectively, all of which was classified as general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss.

13. 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, 2019 and 2018 is as follows (in thousands):

Deferred income tax assets (liabilities)	December 31, 2019	December 31, 2018
Deferred Tax Assets:		
Net operating loss carryforwards	$ 94,630	$ 67,823
Capitalized start-up costs	9,353	10,487
R&E credit carryforwards	9,405	7,875
Stock-based compensation	2,978	2,024
Change in fair value of derivative liability	5,916	3,978
Other	2,495	355
Total deferred tax asset	124,777	92,542
Valuation allowance	(113,169)	(89,123)
Net deferred tax assets	$ 11,608	$ 3,419
Deferred tax liabilities:		
ROU amortization	(637)	—
Amortization of debt discount	(10,971)	(3,419)
Total deferred tax liability	(11,608)	(3,419)
Net deferred tax assets	$ —	$ —

The net change in valuation allowance for the years ended December 31, 2019 and 2018 was a net increase of $24 million and a net increase of $12.7 million, respectively.

The increase in valuation allowance is primarily due to net losses and credits incurred in 2019. 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, 2019, the Company had federal and state net operating loss (“NOL”) carryforwards of $419.2 million and had research and experimental credit carryforwards of $9.4 million. NOL carryforwards in the amount of 199.5 million will expire in varying amounts between 2020 and 2038. 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 consolidated statement of operations and comprehensive loss 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, 2019, 2018 and 2017 is as follows:

	Year Ended December 31,		
	2019	2018	2017
Tax at U.S. Federal Statutory rate	21.00 %	21.00 %	34.00 %
State taxes, net	1.57	2.27	5.15
Research and development credit	1.32	1.27	1.79
Tax reform	—	—	(52.54)
State tax rates changes	(2.17)	(10.64)	—
Other non-deductible items	(0.91)	(0.39)	(0.86)
Increase (decrease) in valuation allowance	(20.81)	(13.51)	12.46
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 used to calculate deferred tax liabilities and assets as of December 31, 2017 was 34%. The Tax Cuts and Jobs (the "Act") was enacted into law as of December 22, 2017. Among other provisions, the Act reduced the federal tax rate to 21% effective for the Company as of January 1, 2018. The Company measures deferred tax assets and liabilities using enacted tax rates that will apply in the years in which the temporary differences are expected to be recovered or paid. Accordingly, the Company's deferred tax assets and liabilities were remeasured to reflect the reduction in the U.S. corporate income tax rate. As a result of the tax rate, the Company's deferred tax assets were decreased by $30.8 million and the valuation allowance was decreased by the same amount, resulting in no net tax expense. The federal tax rate remained unchanged at 21% for the 2019 tax year. The change in the state tax rate from 2018 to 2019, and 2017 to 2018, respectively, is primarily due to changes in applicable state apportionment factors and additional jurisdictions.

The Company recognized the income tax effects of the Act in its financial statements for the year ended December 31, 2017 in accordance with Staff Accounting Bulletin No. 118, which provides SEC staff guidance for the application of ASC Topic 740, Income Taxes, in the reporting period in which the Act was signed into law. In accordance with Staff Accounting Bulletin No. 118, as of December 31, 2018, the Company completed its accounting for the tax effects of enactment of the Act and no adjustments to the provisional income tax effects were required.

A breakdown of the Company's uncertain tax position during 2019, 2018 and 2017 is as follows (in thousands):

	2019	2018	2017
Gross unrecognized tax benefit at beginning of year	$ 1,969	$ 1,670	$ 1,383
Increase from tax positions taken in prior years	—	—	22
Increase from tax positions in current year	396	323	265
Lapse of statute of limitations / expiration	(14)	(24)	—
Gross unrecognized tax benefit at end of year	$ 2,351	$ 1,969	$ 1,670

The Company did not incur any penalties or interest payable to taxing authorities in 2019, 2018 and 2017.

The Company's U.S. Federal and state income tax returns from 2000 to 2018 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.

14. Related Party Transactions

Roche Holding A.G, through their ownership interests in Roche Finance Ltd, has a noncontrolling ownership interest in the Company. For the years ended December 31, 2019 and 2018, revenues from Roche were $16.4 million and $16.2 million, respectively, and amounts due from them were $7.1 million and $6.3 million, respectively. At December 31, 2019, the Company had committed replacement obligations under warranties in the amount of $0.6 million. At December 31, 2018. the Company had deferred revenue of $0.6 million related to Roche, which was earned and recognized during 2019.

15. 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 debt instruments is based on the binomial option pricing model 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, 2019 and 2018 (in thousands):

	December 31, 2019			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets				
Money market funds	$ 37,769	$ 37,769	$ —	$ —
Commercial	13,870	—	13,870	—
Corporate bonds	6,256	—	6,256	—
Liabilities				
Embedded features of the 2023 Notes	$ 664	$ —	$ —	$ 664
Embedded features of the 2025 Notes	$ 25,543	$ —	$ 25,543	$ —

	December 31, 2018			
	Total	**Level 1**	**Level 2**	**Level 3**
Liabilities				
Embedded features of the 2023 Notes	$ 17,091	$ —	$ —	$ 17,091

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):

	Embedded Features of the the Notes
December 31, 2018	$ 17,091
Change in derivative liabilities (including the partial settlement of the 2023 Notes)	(16,427)
December 31,2019	$ 664

The recurring Level 3 fair value measurements of the embedded features of the 2023 Notes include the following significant unobservable inputs:

Unobservable Inputs	Assumptions
Risky (bond) rate	16.4 %
Stock price volatility	68 %
Probabilities of make-whole provision	7.8 % - 83.7 %
Time period until maturity (yrs)	3.09
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 years ended December 31, 2019 and 2018. 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**.**

16. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal years 2019 and 2018 is presented in the following table (in thousands, except per share data):

	For the Quarter Ended			
	March 31	June 30	September 30	December 31
2019:				
Revenue, net, primarily from a related party	$ 3,423	$ 4,607	$ 4,319	$ 8,953
Gross profit	$ (3,310)	$ (4,553)	$ (3,340)	$ (8,244)
Operating expenses	$ 26,458	$ 30,100	$ 28,024	$ 26,632
Operating loss	$ (29,768)	$ (34,653)	$ (31,364)	$ (34,877)
Net loss	$ (29,365)	$ (31,074)	$ (19,499)	$ (35,611)
Basic and diluted net loss per share (1)	$ (0.17)	$ (0.17)	$ (0.10)	$ (0.18)
2018:				
Revenue, net, primarily from a related party	$ 2,946	$ 3,623	$ 5,158	$ 7,186
Gross profit	$ (362)	$ (216)	$ (2,584)	$ (4,984)
Operating expenses	$ 15,565	$ 19,848	$ 20,391	$ 23,628
Operating loss	$ 15,927	$ 20,064	$ 22,975	$ 28,612
Net loss	$ 22,273	$ 32,496	$ 31,881	$ 7,321
Basic and diluted net loss per share (1)	$ (0.16)	$ (0.23)	$ (0.18)	$ (0.04)

(1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per-share calculations will not necessarily equal the annual per share calculation.

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, 2019 and 2018 has no such contingencies.

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, 2019, 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, 2019, 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, 2019 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 identified a material weakness in our internal control over financing reporting during the fourth quarter of 2019 related to inventory controls. This was successfully remediated during the same quarter of 2019. As a result, we have no material weaknesses in internal control over financial reporting at December 31, 2019, which aligns with our independent registered public accounting firm's attestation report included elsewhere in this Annual Report on Form 10-K, which is required to include disclosure of any material weaknesses identified by the Company in its internal control over financial reporting that existed at the reporting date.

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, 2019.

The Annual Report on Form 10-K includes an attestation report of our independent registered public accounting firm regarding internal control over financial reporting, which appears in Part II, Item 8 of this Annual Report on Form 10-K.

Item 9B. Other Information

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2020 Annual Meeting of Stockholders, or the 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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 2020 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.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(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

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).
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).
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 27, 2019).
4.6	Form of Note representing the Company's 5.25% Convertible Senior Notes due 2025 (included as Exhibit A to the Indenture filed as Exhibit 4.1), filed with the Commission on July 29, 2019).
4.7	Description of Senseonics Holdings, Inc. Common Stock.
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).

Exhibit Number	Description of Document
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).
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).

Exhibit Number	Description of Document
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#	Distribution Agreement, by and among Senseonics, Incorporated, Roche Diagnostics International AG and Roche Diabetes Care GmbH, dated as of May 24, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed on August 9, 2016).
10.21	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).
10.22#	Amendment to Distribution Agreement, by and among Senseonics, Incorporated, Roche Diagnostics International AG and Roche Diabetes Care GmbH, dated as of November 28, 2016 (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K (File No. 001-37717) filed on February 23, 2017).
10.23	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).
10.24	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).
10.25	Loan and Security Agreement among Solar Capital Ltd., the Lenders, Senseonics, Incorporated and the Company dated as of July 16, 2019 (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 17, 2019).
10.26	Form of Warrant issued pursuant to the Solar Loan Agreement (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on July 17, 2019).
10.27+	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).
10.28	Fourth Amendment to Distribution Agreement, dated as of January 31, 2019, by and among Senseonics, Incorporated, Roche Diagnostics International AG, Basel Branch Diabetes Care and Roche Diabetes Care GmbH (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed with the Commission on May 9, 2019).
10.29#	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).
10.30+	Form of Stock Option Grant Notice and Stock Option Agreement used in connection with the Senseonics Holdings, Inc. Inducement Plan (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37717), filed with the Commission on June 5, 2019).
10.31##*	Fifth Amendment to Distribution Agreement, by and among Senseonics, Incorporated, Roche Diagnostics International AG and Roche Diabetes Care GmbH, dated as of December 12, 2019.
10.32+*	Amended and Restated Employment Agreement, by and between Senseonics, Incorporated and Nick B. Tressler, effective as of November 12, 2019.
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.
24.1*	Power of Attorney (contained on signature page hereto).
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.

Exhibit Number	Description of Document
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

* 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.

\# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and have been separately filed with the Securities and Exchange Commission.

Certain portions of this exhibit, indicated by asterisks, have been omitted pursuant to Item 601(b)(10) of Regulation S-K because they are not material and would likely cause competitive harm to the registrant if publicly disclosed.

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 16, 2020

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 16, 2020
/s/ NICK B. TRESSLER Nick Tressler	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 16, 2020
/s/ Stephen P. DeFalco Stephen P. DeFalco	Chairman of the Board of Directors	March 16, 2020
/s/ Steven Edelman, M.D. Steven Edelman, M.D.	Director	March 16, 2020
/s/ Edward J. Fiorentino Edward J. Fiorentino	Director	March 16, 2020
/s/ Peter Justin Klein, M.D., J.D. Peter Justin Klein, M.D., J.D.	Director	March 16, 2020
/s/ Douglas Prince Douglas Prince	Director	March 16, 2020
/s/ DOUGLAS ROEDER Douglas Roeder	Director	March 16, 2020
/s/ FRANCINE KAUFMAN, M.D. Francine Kaufman, M.D.	Director and Chief Medical Officer	March 16, 2020

Exhibit 4.7

DESCRIPTION OF SENSEONICS HOLDINGS, INC. COMMON STOCK

The following description of the common stock of Senseonics Holdings, Inc., or the Company, is a summary and does not purport to be complete. This summary is qualified in its entirety by reference to the provisions of the Delaware General Corporation Law, or the DGCL, and the complete text of the Company's amended and restated certificate of incorporation, or the restated certificate, and amended and restated bylaws, or the bylaws, each as currently in effect, which are incorporated by reference as Exhibits 3.1 and 3.2, respectively, of the Company's Annual Report on Form 10-K, to which this description is also an exhibit. The Company encourages you to read that law and those documents carefully.

Common Stock

Authorized Capital Stock

The restated certificate authorizes the issuance of up to 450,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share. The Company's board of directors may establish the rights and preferences of the preferred stock from time to time.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under the restated certificate and bylaws, common stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of the Company's liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that the Company may designate in the future.

Antitakeover Effects of Provisions of Charter Documents and Delaware Law

Charter Documents

The Company's restated certificate and bylaws, each as amended to date, include a number of provisions that may have the effect of deterring hostile takeovers or delaying or preventing changes in control or management of the Company. First, the Company's board of directors is classified into three classes of directors. Under Delaware law, directors of a corporation with a classified board may be removed only for cause unless the corporation's certificate of incorporation provides otherwise. The restated certificate does not provide otherwise. In addition, the restated certificate provides that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing. Further, the bylaws limit who may call special meetings of the stockholders. The restated certificate does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. Finally, the bylaws establish procedures, including advance notice procedures, with regard to the nomination of candidates for election as directors and stockholder proposals. These and other provisions of the restated certificate and bylaws and Delaware law could discourage potential acquisition proposals and could delay or prevent a change in control or management of the Company.

Delaware Takeover Statute

The Company is subject to Section 203 of the DGCL, which regulates acquisitions of some Delaware corporations. Section 203 generally prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date of the transaction in which the person became an interested stockholder, unless:

- the board of directors of the corporation approved the business combination or the other transaction in which the person became an interested stockholder prior to the date of the business combination or other transaction;

- upon consummation of the transaction that resulted in the person becoming an interested stockholder, the person owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers of the corporation and shares issued under employee stock plans under which employee participants do not have the right to determine

confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date the person became an interested stockholder, the board of directors of the corporation approved the business combination and the stockholders of the corporation authorized the business combination at an annual or special meeting of stockholders by the affirmative vote of at least 66-2/3% of the outstanding stock of the corporation not owned by the interested stockholder.

Section 203 of the DGCL defines a "business combination" to include any of the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the corporation's assets or outstanding stock involving the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any of its stock to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.
- In general, Section 203 defines an "interested stockholder" as any person who, together with the person's affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock.

Section 203 of the DGCL could depress the Company’s stock price and delay, discourage or prohibit transactions not approved in advance by the board of directors, such as takeover attempts that might otherwise involve the payment to the Company’s stockholders of a premium over the market price of the its common stock.

Transfer Agent and Registrar

The transfer agent and registrar for the Company’s common stock is Computershare Trust Company, N.A. The transfer agent's address is 250 Royall Street, Canton, Massachusetts 02021.

Listing on the NYSE American

The Company’s common stock is listed on the NYSE American under the symbol "SENS."

FIFTH AMENDMENT TO DISTRIBUTION AGREEMENT

This Fifth Amendment to Distribution Agreement (the "Fifth Amendment") is effective as of December 12, 2019 (the "Fifth Amendment Effective Date"), by and between Roche Diagnostics International AG, Basel Branch Diabetes Care, with offices located at Peter Merian-Weg 4, 4052 Basel, Switzerland ("Roche Diagnostics") and Roche Diabetes Care GmbH, with offices located at Sandhofer Strasse 116, 68305 Mannheim, Germany ("Roche Diabetes" and collectively with Roche Diagnostics, "ROCHE") and Senseonics, Incorporated, with offices located at 20451 Seneca Meadows Parkway, Germantown, MD 20876-7005, USA ("SENSEONICS"). ROCHE and SENSEONICS are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, ROCHE and SENSEONICS are parties to that certain Distribution Agreement dated May 23, 2016 (as amended, the "Agreement"), as amended from time to time including the Amendments to Distribution Agreement dated as of November 28, 2016 (the "First Amendment"), April 11, 2018 (the "Second Amendment"), December 20, 2018 (the "Third Amendment") and January 31, 2019 (the "Fourth Amendment"); and

WHEREAS, the Parties desire to amend the Agreement in accordance with Section 11.11 thereof in order to reduce the Minimum Requirement for 2020;

NOW THEREFORE, in consideration of the premises and mutual covenants contained in the Fifth Amendment, the Parties agree as follows:

The Parties agree that the table shown on page 7 of the Fourth Amendment, Exhibit 4 regarding the Minimum Requirement for 2019 – 2020 (units) shall be amended as follows:

Minimum Requirement for 2019 – 2020 (units)

	Eversense® XL Sensor Pack	Eversense® XL Smart Transmitter Pack
2019	[***]	[***]
2020	[***]	[***]

Furthermore, the Parties would like to amend Section 1.c of the Fourth Amendment, Exhibit 4 as follows:

1.c 2020 Pricing shall be [***] per Eversense XL Senor Pack.

[Remainder of Page Intentionally Blank]

IN WITNESS WHEREOF, each of the Parties has caused this Fifth Amendment to be executed by its duly authorized representative as of the Fifth Amendment Effective Date.

Senseonics, Incorporated

By: _____/s/ Tim Goodnow_____

Name: _____Tim Goodnow_____

Title: _____President & CEO_____

Roche Diagnostics International AG
Basel Branch Diabetes Care

By: ___/s/ Marcel Gmeunder_____

Name: Marcel Gmeunder

Title: CEO Diabetes Care

By: /s/ Edwin Sonnenschein

Name: Edwin Sonnenschein

Title: Head Legal DC

Roche Diabetes Care GmbH

By: /s/ Edwin Sonnenschein

Name: Edwin Sonnenschein

Title: Head Legal DC

By: /s/ P. Hoffman

Name: P. Hoffman

Title: Head Legal DC

amended and restated Employment Agreement

This **Amended and Restated Employment Agreement** (the "***Agreement***") is entered into as of the 12th day of November, 2019 ("***Effective Date***"), by and between **Nick Bryan Tressler** ("***Employee***") and **Senseonics, Incorporated** ("***Company***").

Whereas, the Company wishes to continue to employ Employee, now in a new role as Chief Financial Officer of the Company, and Employee wishes to serve in such capacity for the Company and continue to be its Employee, subject to the terms and conditions of this Agreement;

Whereas, the Company and Employee entered into a the prior Employment Agreement (the "Prior Agreement"), dated as of March 11, 2019 (the "Start Date") and desire to amend and restate the Prior Agreement; and

Whereas, the Company and Employee desire to set forth their respective rights and obligations in this Agreement;

Now, Therefore, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. Employment by the Company.

1.1 Position. Subject to the terms set forth herein, the Company agrees to continue to employ Employee, in the new position of Chief Financial Officer, and Employee hereby accepts such continued employment on the terms and conditions set forth in this Agreement. Employee will commence work in this new position commencing November 15, 2019 (the "**Transition Date**").

1.2 Duties. Employee will report to the Chief Executive Officer ("CEO") performing such duties as are normally associated with his position and such duties as are assigned to him from time to time, subject to the oversight and direction of the CEO. During the term of Employee's employment with the Company, Employee will work on a full-time basis for the Company and will devote Employee's best efforts and substantially all of Employee's business time and attention to the business of the Company. Employee shall perform Employee's duties under this Agreement principally out of the Company's corporate headquarters. In addition, Employee shall make such business trips to such places as may be necessary or advisable for the efficient operations of the Company.

1.3 Company Policies and Benefits. The employment relationship between the parties shall also be subject to the Company's personnel and other policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. Employee will be eligible to participate on the same basis as similarly situated employees in the Company's benefit plans in effect from time to time during his employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that

the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Salary. From the Transition Date, Employee shall receive for Employee's services to be rendered under this Agreement a base salary of $340,000.00 (Three-hundred forty thousand dollars) on an annualized basis, subject to review and adjustment by the Company in its sole discretion, payable subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices ("***Base Salary***").

2.2 Bonus. During the period Employee is employed with the Company, Employee shall be eligible to earn for Employee's services to be rendered under this Agreement a discretionary annual cash bonus of up to 40% of Base Salary ("***Target Amount***"), subject to review and adjustment by the Company in its sole discretion, payable subject to standard federal and state payroll withholding requirements. Whether or not Employee earns any bonus will be dependent upon (a) Employee's continuous performance of services to the Company through the date any bonus is paid; and (b) the actual achievement by Employee and the Company of the applicable performance targets and goals set by the Board of Directors of the Company ("***Board***"). The annual period over which performance is measured for purposes of this bonus is January 1 through December 31. The Board will determine in its sole discretion the extent to which Employee and the Company have achieved the performance goals upon which the bonus is based and the amount of the bonus, which could be above or below the Target Amount (and may be zero). Any bonus shall be subject to the terms of any applicable incentive compensation plan adopted by the Company. Any bonus, if earned, will be paid to Employee within the time period set forth in the incentive compensation plan. For the 2019 period, Employee's bonus shall be prorated, so that 10.5/12 is payable based on a 25% Target Amount on a $250,000 Base Salary, and 1.5/12 shall be prorated based on the Target Amount and Base Salary in this Section 2.2.

2.3 Sign-on Bonus and Stay Bonus: The Company provided a one-time sign-on bonus payment of $50,000.00 following the Start Date subject to standard federal and state payroll withholding requirements. If Employee resigns from his employment without good reason, or if the Company terminates Employee's employment for Cause, within one year of the Start Date Employee must reimburse the Company the Sign-on Bonus paid to Employee. Employee hereby agrees that any such repayment obligation will be recovered from Employee's final paycheck and any other amounts owed to Employee by the Company payable after his termination date. In order to retain Employee, if Employee remains employed with the Company on January 1, 2021, Employee will be entitled to a Stay Bonus of $85,000, payable with the first regular pay period following January 1, 2021, subject to standard withholdings and deductions. If Employee is not employed by the Company on this date, this Stay Bonus is not payable.

2.4 Stock Options. Employee was granted 200,000 options in conjunction with the Prior Agreement. Subject to approval by the Board and subject to the terms of the 2015 Equity Incentive Plan (the "Plan"), Employee will be granted an option (the "Option") to purchase up to an additional 300,000 shares of the Company's Common Stock pursuant to the Company's standard Qualified Stock Option Agreement (to the extent permitted) and

the terms of the Plan. Twenty-five (25%) percent of the Option Shares will vest on the first anniversary of the Transition Date and the remaining seventy-five percent (75%) shall vest in equal amounts at the end of each calendar month for the 36-month period following the first anniversary of the Transition Date, in each such case subject to Employee's continuous employment through the applicable vesting date. The exercise price of the Option will be equal to the fair market value of the Company's Common Stock on the date of grant of the Option, as determined by the Board in its sole discretion. The Option will be governed by and subject to the terms and conditions of the Plan and other documents issued in connection with the grant.

2.5 Expense Reimbursement. The Company will reimburse Employee for reasonable business expenses in accordance with the Company's standard expense reimbursement policy, as the same may be modified by the Company from time to time. The Company shall reimburse Employee for all customary and appropriate business-related expenses actually incurred and documented in accordance with Company policy, as in effect from time to time. For the avoidance of doubt, to the extent that any reimbursements payable to Employee are subject to the provisions of Section 409A of the Code: (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

3. Ideas, Inventions, Confidentiality, Competition and Confidentiality. As a condition of employment, Employee executed and agreed to abide by, and Employee agrees to continue to abide by, an Ideas, Inventions, Competition and Confidentiality Agreement attached as Exhibit A ("***Proprietary Information Agreement***"), which may be amended by the parties from time to time without regard to this Agreement. The Proprietary Information Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

4. Outside Activities during Employment. Except with the prior written consent of the CEO, including consent given to Employee prior to the signing of this Agreement, Employee will not, while employed by the Company, undertake or engage in any other employment, occupation or business enterprise that would interfere with Employee's responsibilities and the performance of Employee's duties hereunder except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Employee may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Employee's duties; and (iii) such other activities as may be specifically approved by the Board. This restriction shall not, however, preclude Employee (x) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (y) from employment or service in any capacity with Affiliates of the Company. As used in this Agreement, "Affiliates" means an entity under common management or control with the Company.

5. No Conflict with Existing Obligations. Employee represents that Employee's performance of all the terms of this Agreement does not and will not breach any agreement or obligation of any kind made prior to Employee's employment by the Company, including

agreements or obligations Employee may have with prior employers or entities for which Employee has provided services. Employee has not entered into, and Employee agrees that Employee will not enter into, any agreement or obligation, either written or oral, in conflict herewith. As part of this obligation, Employee agrees that he is subject to a duty to maintain the confidentiality of confidential or proprietary information that he has received from third parties, to hold such information in the strictest confidence, and not to disclose it to any person or entity or use it in carrying out Employee's work for the Company, consistent with any agreements between Employee and such third party or third parties.

6. Termination of Employment. The parties acknowledge that Employee's employment relationship with the Company is at-will, meaning either the Company or Employee may terminate Employee's employment at any time, with or without cause or advanced notice, except for the notice from Employee set out in **Section 8.1** below. The provisions in this Section govern the amount of compensation, if any, to be provided to Employee upon termination of employment and do not alter this at-will status.

6.1 Termination by the Company without Cause or for Good Reason.

(a) The Company shall have the right to terminate Employee's employment with the Company pursuant to this **Section 6.1** at any time, in accordance with **Section 6.6**, without "Cause" (as defined in **Section 6.2(b)** below) by giving notice as described in **Section 8.1** of this Agreement. A termination pursuant to **Section 6.5** below is not a termination without "Cause" for purposes of receiving the benefits described in this **Section 6.1**.

(b) If the Company terminates Employee's employment at any time without Cause or Employee terminates his employment with the Company for Good Reason and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), then Employee shall be entitled to receive the Accrued Obligations (defined below). If Employee complies with the obligations in **Section 6.1(c)** below, Employee shall also be eligible to receive the following severance benefits: (1) an amount equal to Employee's then current Base Salary for twelve (12) months, less all applicable withholdings and deductions ("***Severance***"), paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date (as defined in **Section 6.1(c)** below), with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter and (2) a pro rata portion of Employee's Target Amount for the performance year in which Employee's termination occurs, with such pro rata portion calculated based upon the number of days that Executive was employed during such performanc year divided by the total number of days in such performance year, payable as a lump sum payment on the Release Effective Date (as defined below) (**"Severance Bonus"**).

(c) Employee will be paid all of the Accrued Obligations on the Company's first payroll date after Employee's date of termination from employment or earlier if required by law. Employee shall receive the Severance pursuant to **Section 6.1(b)** of this Agreement and the payments pursuant to **Section 6.1(d)** if: (i) by the 60th day following the date of Employee's Separation from Service, he has signed and delivered to the Company a separation agreement containing an effective, general release of claims in favor of the Company

and its affiliates and representatives, in a form acceptable to the Company (the "***Release***"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "***Release Effective Date***"); and (ii) if he holds any other positions with the Company, he resigns such position(s) to be effective no later than the date of Employee's termination date (or such other date as requested by the Board); (iii) he returns all Company property; (iv) he complies with his post-termination obligations under this Agreement and the Proprietary Information Agreement; and (v) he complies with the terms of the Release, including without limitation any non-disparagement and confidentiality provisions contained in Release. To the extent that any severance payments are deferred compensation under Section 409A of the Code, and are not otherwise exempt from the application of Section 409A, then, if the period during which Employee may consider and sign the Release spans two calendar years, the payment of Severance will not be made or begin until the later calendar year.

(d) If Employee timely elects continued coverage under COBRA for himself and his covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Employee's and his covered dependents' health insurance coverage in effect for himself (and his covered dependents) on the termination date until the earliest of: (i) twelve (12) months following the termination date (the "***COBRA Severance Period***"); (ii) the date when Employee becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (iii) the date Employee ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (i)-(iii), (the "***COBRA Payment Period***"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Employee's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Employee on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding (such amount, the "***Special Severance Payment***"), such Special Severance Payment to be made without regard to the COBRA period prior to the end of the COBRA Payment Period. Nothing in this Agreement shall deprive Employee of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company.

(e) For purposes of this Agreement, "***Accrued Obligations***" are (i) Employee's accrued but unpaid salary through the date of termination, (ii) any unreimbursed business expenses incurred by Employee payable in accordance with the Company's standard expense reimbursement policies, and (iii) benefits owed to Employee under any qualified retirement plan or health and welfare benefit plan in which Employee was a participant in accordance with applicable law and the provisions of such plan.

(f) The Severance provided to Employee pursuant to this **Section 6.1** is in lieu of, and not in addition to, any benefits to which Employee may otherwise be entitled under any Company severance plan, policy or program.

(g) Any damages caused by the termination of Employee's employment without Cause would be difficult to ascertain; therefore, the Severance for which Employee is eligible pursuant to **Section 6.1(b)** above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

(h) For purposes of this Agreement, "*Good Reason*" shall mean the occurrence of any of the following events without Employee's consent: (i) a material reduction in Employee's Base Salary of at least 10%; (ii) a material breach of this Agreement by the Company; (iii) any material diminution in Employee's duties, responsibilities, authority, reporting structure, status or title, unless approved in writing by Employee; or (iv) the relocation of Employee's principal place of employment, without Employee's consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation; *provided, however,* that, any such termination by Employee shall only be deemed for Good Reason pursuant to this definition if: (1) Employee gives the Company written notice of his intent to terminate for Good Reason within thirty (30) days following the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the "***Cure Period***"); and (3) Employee voluntarily terminates his employment within thirty (30) days following the end of the Cure Period.

(i) Any damages caused by the termination of Employee's employment without Cause or for Good Reason would be difficult to ascertain; therefore, the payments for which Employee is eligible pursuant to this Section 6.1 above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

6.2 Termination by the Company without Cause or for Good Reason Following a Change in Control.

(a) If Employee's employment by the Company is terminated by the Company without "Cause" (and not due to Disability or death) or by Employee for Good Reason coincident with a Change in Control (as defined below), then the Company shall pay or provide Employee with the Accrued Obligations and all of the benefits described in **Section 6.1** above, subject to compliance with **Section 6.1(c)**; *provided that:* if Employee's employment by the Company or any successor entity is terminated by the Company or the successor entity without "Cause" (and not due to Disability or death) within twelve (12) months following a Change in Control, 100% of the then unvested portion of the equity awards granted to Employee shall become fully vested.

(b) For purposes of this Agreement, a "***Change in Control***" means (a) any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, continue to hold a majority of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization; (b) any transaction or series of related

transactions to which the Company is a party in which in excess of fifty percent (50%) of the Company's voting power is transferred; provided that the foregoing shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or indebtedness of the Company is cancelled or converted or a combination thereof; or (c) a sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company. In the event of any interpretation of this definition, the Board of Directors of the Company, upon advice of legal counsel, shall have final and conclusive authority, so long as such authority is exercised in good faith. Notwithstanding the foregoing, a Change in Control will only be deemed to occur for purposes of this Agreement it is also meets the definition used for purposes of Treasury Regulation Section 1.409A-3(a)(5), that is, as defined under Treasury Regulation Section 1.409A-3(i)(5).

(c) Any damages caused by the termination of Employee's employment without Cause or for Good Reason following a Change in Control would be difficult to ascertain; therefore, the payments for which Employee is eligible pursuant to Section 6.2 above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

6.3 Termination by the Company for Cause.

(a) The Company shall have the right to terminate Employee's employment with the Company at any time, in accordance with **Section 6.6**, for Cause by giving notice as described in **Section 8.1** of this Agreement. In the event Employee's employment is terminated at any time for Cause, Employee will not receive Severance, a Severance Bonus or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

(b) ***"Cause"*** for termination shall mean that the Company has determined in its sole discretion that Employee has engaged in any of the following: (i) a material breach of any covenant or condition under this Agreement or any other agreement between the parties; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) violation of any written Company policy or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive of the Company; (vi) negligence or incompetence in the performance of Employee's duties or failure to perform such duties in a manner satisfactory to the Company after the expiration of ten (10) days without cure after written notice of such failure; or (vii) breach of fiduciary duty.

6.4 Resignation by Employee.

(a) Employee may resign from Employee's employment with the Company at any time, in accordance with **Section 6.6**, by giving notice as described in **Section 8.1**.

(b) In the event Employee resigns from Employee's employment with the Company for any reason, Employee will not receive Severance, a Severance Bonus or any

other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.5 Termination by Virtue of Death or Disability of Employee.

(a) In the event of Employee's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, in accordance with **Section 6.6**, and the Company shall, pursuant to the Company's standard payroll policies, pay to Employee's legal representatives all Accrued Obligations.

(b) Subject to applicable state and federal law, the Company shall at all times have the right, upon written notice to Employee, and in accordance with **Section 6.6**, to terminate this Agreement based on Employee's Disability. Termination by the Company of Employee's employment based on "***Disability***" shall mean termination because Employee is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for 180 days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In the event Employee's employment is terminated based on Employee's Disability, Employee will not receive Severance, a Severance Bonus or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.6 Notice; Effective Date of Termination.

(a) Termination of Employee's employment pursuant to this Agreement shall be effective on the earliest of:

(i) immediately after the Company gives notice to Employee of Employee's termination, with or without Cause, unless pursuant to Section 6.3(b)(vi) in which case ten (10) days after notice if not cured or unless the Company specifies a later date, in which case, termination shall be effective as of such later date;

(ii) immediately upon the Employee's death;

(iii) ten (10) days after the Company gives notice to Employee of Employee's termination on account of Employee's Disability, unless the Company specifies a later date, in which case, termination shall be effective as of such later date, *provided* that Employee has not returned to the full-time performance of Employee's duties prior to such date;

(iv) thirty (30) days after the Employee gives written notice to the Company of Employee's resignation, *provided* that the Company may set a termination date at any time between the date of notice and the date of resignation, in which case the Employee's resignation shall be effective as of such other date. Employee will receive compensation through any notice period required by Company; or

(v) for a termination for Good Reason, immediately upon Employee's full satisfaction of the requirements of Section 6.1(h).

(b) In the event notice of a termination under subsections (a)(i), (iii), (iv) and (iv) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five (5) business days of the request in compliance with the requirement of Section 8.1 below. In the event of a termination for Cause or Good Reason, written confirmation shall specify the subsection(s) of the definition of Cause or Good Reason relied on to support the decision to terminate.

6.7 Cooperation with Company after Termination of Employment. Following termination of Employee's employment for any reason, Employee agrees to cooperate fully with the Company in connection with its actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters arising from events, acts, or failures to act that occurred during the period of Employee's employment by the Company. Such cooperation includes, without limitation, making Employee available to the Company upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions and trial testimony. In addition, for six months after Employee's employment with the Company ends for any reason, Employee agrees to cooperate fully with the Company in all matters relating to the transition of Employee's work and responsibilities on behalf of the Company, including, but not limited to, any present, prior or subsequent relationships and the orderly transfer of any such work and institutional knowledge to such other persons as may be designated by the Company. The Company will reimburse Employee for reasonable out-of-pocket expenses Employee incurs in connection with any such cooperation (excluding forgone wages, salary, or other compensation) and will make reasonable efforts to accommodate Employee's scheduling needs.

6.8 Application of Section 409A. It is intended that all of the severance payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively, "***Section 409A***") provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9), and this Agreement will be construed in a manner that complies with Section 409A. If not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A, and incorporates by reference all required definitions and payment terms. No severance payments will be made under this Agreement unless Employee's termination of employment constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h)). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Employee's right to receive any installment payments under this Agreement (whether severance payments or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. If the Company determines that the severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A and if Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i) of the Code at the time of Employee's Separation from Service, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance will be delayed as follows: on

the earlier to occur of (a) the date that is six months and one day after Employee's Separation from Service, and (b) the date of Employee's death (such earlier date, the "***Delayed Initial Payment Date***"), the Company will (i) pay to Employee a lump sum amount equal to the sum of the severance benefits that Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the severance benefits had not been delayed pursuant to this Section 6.8 and (ii) commence paying the balance of the severance benefits in accordance with the applicable payment schedule set forth in Section 6. No interest shall be due on any amounts deferred pursuant to this Section 6.8.

7. Section 280G.

7.1 Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "***Aggregate Payments***"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in Employee receiving a higher After Tax Amount (as defined below) than Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

7.2 For purposes of this Section 5, the "***After Tax Amount***" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on Employee as a result of Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes

8. General Provisions.

8.1 Notices. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or

certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company to the Attention of the Chief Executive Officer, with a copy to the General Counsel, at its primary office location and to Employee at either Employee's address as listed on the Company payroll, or Company-issued email address, or at such other address as the Company or Employee may designate by ten (10) days advance written notice to the other.

8.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

8.3 Survival. Provisions of this Agreement which by their terms must survive the termination of this Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the term, termination of Employee's employment, or otherwise, for such period as may be appropriate under the circumstances.

8.4 Waiver. If either party should waive any breach of any provisions of this Agreement, it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

8.5 Complete Agreement. This Agreement constitutes the entire agreement between Employee and the Company with regard to the subject matter hereof. This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by Employee and an authorized officer of the Company. The parties have entered into a separate Ideas, Inventions, Competition and Confidential Information Agreement and an Indemnification Agreement, and have or may enter into separate agreements related to equity. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of Employee's employment under this Agreement, may be amended or superseded by the parties without regard to this Agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

8.6 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement. The parties agree that facsimile and scanned image copies of signatures will suffice as original signatures.

8.7 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

8.8 Successors and Assigns. The Company shall assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any Company or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said Company or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. Employee may not assign or transfer this Agreement or any rights or obligations hereunder, other than to his estate upon his death.

8.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of Maryland.

8.10 Dispute Resolution. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Employee's employment with the Company or out of this Agreement, or the Employee's termination of employment or termination of this Agreement, may not be in the best interests of either the Employee or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or the Employee's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Employee Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided however,* that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the Washington, DC metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the Company; *provided however*, that at the Employee's option, Employee may voluntarily pay up to one-half the costs and fees. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Employee and the Company. The parties each further agree that the arbitration provisions of this Agreement shall provide each party with its **exclusive remedy**, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.**

[signatures to follow on next page]

13.

In Witness Whereof, the parties have duly executed this Agreement as of the date first above written.

Senseonics, Incorporated

By:/s/ Tim Goodnow
Tim Goodnow
President & Chief Executive Officer

Employee

/s/ Nick Bryan Tressler
Nick Bryan Tressler

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-3 No. 333-233656) of Senseonics Holdings, Inc.,
(5) Registration statement (Form S-8 No. 333-232486) pertaining to the equity incentive plans and employee stock purchase plan of Senseonics Holdings, Inc., and
(6) Registration statement (Form S-3 No. 333-235297) of Senseonics Holdings, Inc.,

of our reports dated March 16, 2020, with respect to the consolidated financial statements and 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, 2019, filed with the U.S. Securities and Exchange Commission.

/s/ Ernst & Young, LLP

Tysons, VA

March 16, 2020

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 16, 2020

/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 16, 2020

/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, 2019 (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 16th day of March, 2020.

/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.