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, 2018 _____

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 29, 2018, 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 $432.0 million based on the closing price of the registrant's common stock, as reported by the NYSE American on such date.

As of March 14, 2019, 176,958,387 shares of common stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2019 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;
- 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 CGM 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 design, development and commercialization of glucose monitoring products to improve the lives of people with diabetes by enhancing their ability to manage their disease with relative ease and accuracy. Our continuous glucose monitoring, or CGM, systems, Eversense and Eversense XL, are reliable, long-term, implantable CGM systems that we have designed to continually and accurately measure glucose levels in people with diabetes for a period of up to 90 and 180 days, respectively, as compared to six to fourteen days for currently available CGM systems. We believe Eversense and Eversense XL will provide people with diabetes with a more convenient method to monitor their glucose levels in comparison to the traditional method of self-monitoring of blood glucose, or SMBG, as well as currently available CGM systems. In our U.S. pivotal clinical trial, we observed that Eversense measured glucose levels over 90 days with a degree of accuracy superior to that of other currently available CGM systems. On June 21, 2018, the U.S. Food and Drug Administration, or FDA, approved our Eversense system for marketing in the United States and we began distributing Eversense in the United States through our direct sales force and a network of strategic fulfillment partners in July 2018. Eversense received a CE mark in June 2016, which marked the first approval for the product to be sold within the European Economic Area. Eversense and Eversense XL are currently available in select markets in Europe, the Middle East, and Africa (EMEA).

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 2017 International Diabetes Federation, or IDF, Atlas, an estimated 425 million people worldwide had diabetes as of the date of the report. The number of people with diabetes worldwide is estimated to grow to 629 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 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. Since CGM measurements from interstitial tissue are inherently less accurate than test-strip measurements made directly from the blood, the FDA and other device regulators historically have 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. Recent improvements in the accuracy of CGM systems have led to the FDA issuing the first “non-adjunctive” label in 2016. The approval of the Eversense pre-market application, or PMA, was issued with an “adjunctive” label. We have filed a PMA supplement seeking approval for a “non-adjunctive” label. We also recently received approval in the United States and Europe to expand the Eversense certification to nurse practitioners and physician assistants, expanding the number of professionals who can perform Eversense insertions.

We have designed Eversense and Eversense XL to continually and accurately measure glucose levels under the skin for up to 90 and 180 days, respectively, as compared to six to fourteen days for currently available CGM systems. Eversense also includes additional safety features that warn the user before the occurrence of adverse events and provide distinct on-body vibrations in a number of situations, such as when low or high glucose levels are reached. We believe that Eversense provides a more convenient method of continuous glucose monitoring by providing longer duration, equal or superior accuracy, state of the art communications and analytical capabilities, on-body alarms and alerts and the convenience of being able to take the transmitter on and off with no loss of the sensor.

According to the National Diabetes Statistics Report, as of the end of 2015, there are approximately 23 million patients diagnosed with diabetes in the United States. We estimate that 6.9 million of these diabetes patients take insulin.

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, TheraSense, and Medtronic.

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

Clinical Development and Regulatory Pathway

Overview

In support of our regulatory submissions, we have expended considerable resources designing, developing and refining a glucose monitoring system. We have completed both our European and U.S. pivotal trials. The Eversense and Eversense XL systems have received a CE mark in Europe and are currently being sold commercially. Our PRECISE II U.S. pivotal trial was completed during 2016 and we received PMA approval from the FDA for the Eversense system on June 21, 2018.

We have initiated a clinical trial in the United States for the purpose of submitting a PMA supplement to the FDA for Eversense XL, an extended version of the Eversense system extending its use for a period of up to 180 days. We are also continuing to conduct a number of feasibility studies in which we are evaluating various configurations of our CGM system. These studies are intended to assess the performance of different system configurations in a small population of subjects before enrolling a large clinical trial.

United States Pivotal Trials

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 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 mean absolute relative difference, or MARD, of 8.4% 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, 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 have begun 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 and intend to pursue a Category I CPT code in the future.

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. Approximately 180 subjects will be enrolled in up to 15 centers across the United States. We expect that enrollment will be completed in the third quarter of 2019 and we expect to report data through 180 days in the first half of 2020. The clinical trial population will consist 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 are excluded from participation in the clinical trial. After screening, sensor(s) will be inserted and accuracy measurements will be 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. Further, upon receiving an alert from the CGM, a patient should confirm CGM measurements with test-strip measurements prior to self-medicating, as noted in the CGM's label and instructions.

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Sensor

The sensor is designed to be inserted under the skin, either in the back of the upper arm or in the abdomen, 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 (approved for 90 days in the U.S.), as compared to other currently available CGM sensors labeled for use for between six and fourteen 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 entire capsule is coated by a glucose-permeable membrane for biocompatibility.

The sensor does not use a battery or other stored power source. Instead, 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. Between readings every five minutes, the sensor remains electrically dormant and fully powered down.

Smart Transmitter

The removable smart transmitter is a rechargeable, external device that is worn over the sensor implantation site using a daily adhesive patch or band, such as an armband or waistband. 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 on-body vibration. The information from the transmitter is also transmitted for display to the user's mobile device via Low-Energy Bluetooth, or BLE. Our transmitter is functional for at least 36 hours without recharging and can be fully charged in fifteen minutes.

Mobile App

Our mobile app is a software application that runs on both 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, trends, graphs and alarms. Within the mobile app, users can set alarms based on, among other things, glucose levels. The mobile app also allows for cloud-based storage.

Future Product Development

Following the potential approval of Eversense XL in the United States, we intend to continue to expand our line of product offerings to benefit both 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 people with diabetes and healthcare providers.

Future developments include the submission of a PMA-supplement application for a “non-adjunctive” dosing claim, which would permit users to dose with insulin without first confirming the blood glucose measure via a fingerstick, submitting an IDE for a pediatric trial in the United States, submitting a PMA-supplement application for a one calibration per day calibration scheme following the review of our PMA-supplement application for the “non-adjunctive” dosing claim, potential further reductions of significantly reducing calibration requirements, continuing to improve accuracy, and initiating clinical trials for On-Demand, or “swipe”, and technology for both type 1 and type 2

users. Through our collaboration with Roche, and separately with BetaBionics, we are working on a closed loop diabetes management system that would allow users to automatically and sustainably maintain tight glucose control while avoiding hypoglycemia.

Sales and Marketing

We are utilizing third-party distributors for our commercial activities in Europe. We currently market Eversense in 15 European countries where there is an understanding and market acceptance of CGM. We have an exclusive arrangement with Rubin Medical for sales in Scandinavia. We have an exclusive arrangement with Roche Diabetes Care for sales in the rest of Europe, the Middle East and Africa, excluding Israel and Finland, and in 17 additional countries, including Brazil, Russia, India, and China, as well as select markets in the Asia Pacific and Latin American regions.

Based on the size and maturity of the U.S. market, we are investing in developing a direct sales team consisting regional and district managers, medical educators, and a customer care organization to support the continued commercialization of the product in the United States in order to target what we estimate to be approximately 2,100 endocrinologists in the United States who are clinically active and diabetes-focused. We utilize a network of strategic fulfillment partners in the United States who resell the products to health care providers and patients.

We recently announced that we would be launching a patient access program, the Eversense Bridge Program, in March 2019 to assist those patients who do not have insurance coverage for Eversense, or whose insurance is denied or insufficient. Pursuant to this program, we will provide financial assistance to eligible patients purchasing Eversense, which may be substantial depending on a patient's insurance coverage. The program establishes maximum limits per patient in the program and excludes certain patients as ineligible, including government-insured patients and residents of certain states. We believe this patient access program will enable more patients to utilize the Eversense system.

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 initial feedback in the United States indicates healthcare providers highly valued the accuracy and sensor duration of our 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.

Distribution Agreement with Rubin Medical

In September 2015, we entered into a distribution agreement with Rubin Medical, or Rubin, pursuant to which we granted Rubin the exclusive right to market, sell and distribute Eversense in Sweden, Norway and Denmark. Pursuant to the agreement, Rubin is obligated to purchase from us specified minimum volumes of Eversense components at pre-determined prices, which are subject to potential amendment upon the occurrence of specified events. Rubin is responsible for the promotion, sale and distribution of Eversense in Sweden, Norway and Denmark at such prices as Rubin determines in its sole discretion, subject to specified exceptions.

The distribution agreement has an initial term of five years and is subject to renewal for up to two additional five year periods if, at least 180 days prior to the expiration of a term, we and Rubin agree to minimum purchase requirements for the additional term and we do not increase the purchase price of Eversense components that are subject to existing publicly procured contracts unless Rubin can pass through the price increase to the customer.

The distribution agreement is terminable by us upon 30 days' notice under a number of circumstances, including if Rubin fails to make required payments, Rubin competes with us or Rubin seeks to distribute Eversense outside of Sweden, Norway or Denmark. The agreement is terminable by Rubin upon 30 days' notice under a number of circumstances, including if we breach the warranties of the agreement, fail to obtain marketing approval or fail to satisfy our supply obligations. The agreement is terminable by either party if the other party fails to comply with marketing laws, violates the confidentiality or intellectual property protection provisions of the agreement, becomes insolvent, or becomes subject to specified convictions, injections or enforcement actions. The termination rights contained in the

agreement generally are subject to an opportunity to cure. Further, we may terminate the agreement upon a change of control of our company, subject to us providing 180 days' written notice and paying a specified termination fee to Rubin.

Distribution Agreement with Roche Diabetes Care

On May 24, 2016, we entered into an exclusive distribution agreement with Roche Diagnostics International AG, Basel Branch Diabetes Care, and Roche Diabetes Care GmbH, or collectively, Roche, pursuant to which we granted Roche the exclusive right to market, sell and distribute Eversense in Germany, Italy and the Netherlands. On November 28, 2016, we amended the distribution agreement to also grant Roche the exclusive right to market, sell and distribute Eversense in Europe, the Middle East, and Africa, excluding Sweden, Norway, Denmark, Finland and Israel.

On January 31, 2019, we further amended the distribution agreement. As amended, the distribution agreement has a term through January 31, 2021. Under the terms of the extended agreement, Roche will continue its role as our exclusive distributor in EMEA excluding Scandinavia and Israel. In addition, under the extended agreement, 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. Roche is obligated to purchase from us specified minimum volumes of Eversense components at pre-determined prices.

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.

Reimbursement

Coverage in the United States

In the U.S. market, it is critical to maintain third-party payor coverage policies, coding mechanisms, and adequate payment for medical technology to obtain 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. Given Eversense currently does not possess a "therapeutic label," Medicare coverage is not available. Moreover, it is unclear how the Centers for Medicare & Medicaid Services, or CMS, will allow for access to Eversense at the Medicare Administrative Contractor level since it is supported by a Category III CPT code and a procedure-based technology. At present, the dominant target market for CGM resides in the commercial sector. While obtaining Medicare coverage in the future is important, gaining coverage with, and adequate reimbursement from, U.S. commercial third-party payors is paramount to gaining and maintaining market adoption of Eversense.

Currently, we have approached large national U.S. commercial third-party payors, as well as regional commercial payors, in an effort to establish coverage for Eversense. To date, we have received positive reimbursement decisions from U.S. third-party payors that cover approximately 60 million people in the United States. We have been met with mixed results seeing some commercial payors establishing a clear coverage position for Eversense and the CPT codes that support it. However, other commercial payors have either remained silent or have denied coverage by explicitly deeming Eversense as an "experimental and investigational" technology. Our experience shows us that policy silence notwithstanding, Eversense is being paid for consistently through the existing HCPCS codes for CGM technology. Additionally, we have experienced payment for Eversense through various Pharmacy Benefit Managers as Eversense maintains "NDC codes" that allow for pharmacy adjudication to take place.

For the established Category III CPT procedure codes we have also observed mixed results where some commercial third-party payors have set payment in their claims system for these unique codes, while other commercial

payors have not set standard payment in their systems, thus requiring claims re-submission by the HCP's staff. As commercial third-party payors gain more experience with claims that are being submitted for the Eversense procedure, we are confident that over time, the existing code will be accepted and paid for more consistently through the patient's health plan benefit. 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 HCP. As a result some patients and their HCPs may choose not to use Eversense on a widespread basis. We intend to seek a Category I CPT code for the placement of Eversense in the future, but the timing of filing the Category I CPT code is contingent on product iteration and other factors in the reimbursement environment.

Where commercial payors have determined that Eversense is "experimental and investigational," we believe the reasoning of many of these payors largely rests on their view that additional larger, randomized, well controlled clinical trials are needed to demonstrate the impact of Eversense on health outcomes. 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. We do not believe running a redundant clinical trial materially adds to the body of evidence supporting CGM. Additionally, some commercial third-party payors believe that the nature of implantation adds to the overall CGM cost, which we believe is incorrect based on our budget impact models and how we have priced Eversense in the U.S. market. We believe as the market gets more experience with Eversense and the deeper understanding of its overall price profile, more U.S. commercial third-party payors will provide coverage. However, the reimbursement market is still focused on containing healthcare costs and lack of visibility into the exact impacts may stall commercial third-party payor adoption until that understanding is realized. Accordingly, unless CMS and other third-party payors provide coverage and adequate reimbursement for Eversense and the related insertion and removal procedures, market adoption and our financial performance may be limited.

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 our system. 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 and are able to scale up their capacity relatively quickly with minimal capital investment. 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.

Our suppliers are managed through our supplier management program that is focused on reducing supply chain risk. Key aspects of this program include managing component inventory at the supplier, contractual requirements for last time buy opportunities and second sourcing approaches for specific suppliers. 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.

Competition

The market for CGM systems is developing and competitive, subject to rapid change and significantly affected by new product introductions. We expect to 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 Bluetooth-enabled CGM system is designed to be integrated with smartphones. 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.

As the industry evolves, we anticipate encountering increasing competition from companies that integrate CGM with insulin pumps. We are aware of two companies, Medtronic and Tandem Diabetes Care, Inc., which have received FDA approval for CGM-integrated insulin pumps.

In addition to CGM providers, we will also compete with providers of traditional 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, including Abbott, developing next generation real-time CGM or sensing devices and technologies, as well as several other companies that are evaluating non-invasive CGM products to measure a user's blood glucose level. For example, Abbott has commercialized its FreeStyle Libre Flash Glucose Monitoring System, which eliminates the need for routine fingersticks by reading glucose levels through a transcutaneous sensor that can be worn for up to 14 days in the United States and Europe. There are also a number of academic and other institutions involved in various phases of our industry's technology development.

Although we will face potential competition from many different sources, we believe that our technology, knowledge, experience and scientific resources will provide us with competitive advantages. The key competitive factors affecting the success of Eversense are likely to be: the accuracy, sensor duration, safety, convenience, adherence and price of treatment; the availability of coverage and reimbursement from government and other third-party payors; effective sales, marketing and distribution; brand awareness and acceptance by healthcare providers and people with diabetes; customer service and support and comprehensive education for people with diabetes and their healthcare providers; and rapid product innovation, including insulin pump integration.

Many of the companies against which we may compete in the future 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, 2018, we held a total of approximately 503 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 51 issued United States patents, 226 patents issued in countries outside the United States and 226 pending patent applications worldwide. Our patents expire between 2019 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 2020 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 29 pending foreign trademark applications, as well as 14 U.S. trademark registrations and 65 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

Eversense 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 operations, 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. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are subject to general controls such as labeling, pre-market notification and adherence to the FDA's QSR, which cover manufacturers' methods and documentation of the design, testing, production, quality assurance, labeling, packaging, sterilization, storage and shipping of products, but are usually exempt from premarket notification requirements. Class II devices are subject to the same general controls, may be subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling, and may also require clinical testing prior to clearance or approval. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, including devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Some Class I and Class II devices are exempted by regulation from the pre-market notification requirement under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, and the requirement of compliance with substantially all of the QSR. However, a PMA application is required for devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or those that are "not substantially equivalent" either to a device previously cleared through the 510(k) process or to a "preamendment" Class III device in commercial distribution before May 28, 1976 when PMA applications were not required. Unless an exemption applies, each new or significantly modified CGM system we seek to commercially distribute in the United States will require either 510(k) clearance or approval from the FDA through the PMA process.

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.

During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA.

The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be safe, effective, reliable or accurate to the FDA's satisfaction;
- the data from preclinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

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.

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.

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 to address 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.

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 June 2016, United Kingdom voters approved an exit from the EU, commonly referred to as "Brexit," which could also 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 and 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 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. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new causes of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. 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 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.

We are providing the initial training to patients necessary for appropriate use of our products both by utilizing our own diabetes educators and by contracting with outside diabetes educators that have completed an appropriate training course.

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. 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. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

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 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.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom, or UK, voted in favor of leaving the EU, commonly referred to as "Brexit". Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the UK from the EU is expected to take effect on March 29, 2019 unless this is postponed or an agreement that the UK remain in the EU is reached. Since the regulatory framework for medical devices in the UK covering quality, safety and efficacy, clinical trials, CE marking, commercial sales and distribution is derived from EU directives and regulations, immediately following Brexit, it is expected that the UK's regulatory regime will remain aligned to European regulations. The guidance provided by the UK confirms that, for an unspecified time-limited period, medical devices approved for the EU market and appropriately CE marked will be recognized by the UK, should the UK leave the EU without an agreement in place. Any medical devices which have been certified by UK-based Notified Bodies will need to be re-certified in the EU as UK-based Notified Bodies will not be recognized by the EU after March 29, 2019, unless an agreement to the contrary is reached between the UK and the EU. The UK has also confirmed that it will comply with all key elements of the EU Medical Device Regulation when they apply in the EU and, subject to parliamentary approval, is proposing to introduce a UK equivalent to the CE mark, to be known as the UKCA (UK Conformity Assessed) mark. However, it remains to be seen exactly how Brexit will impact regulatory requirements for medical devices in the UK. 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, 2018, we had 192 employees, all of whom are located in the United States. None of our employees is 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 $94.0 million, $59.1 million, and $43.9 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $357.8 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.

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.

We plan to seek private third-party payor reimbursement for Eversense and specific reimbursement code recognition for the insertion and removal procedures with national and regional third-party payors in the United States. While we also anticipate entering into contracts with third-party payors, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis. In addition, contracts with third-party payors generally can be modified or terminated by the third-party payor without cause and with little or no notice to us. Moreover, compliance with the administrative procedures or requirements of third-party payors may result in delays in processing approvals by those third-party payors for people with diabetes to obtain coverage and reimbursement for Eversense. Failure to secure or retain coverage or adequate reimbursement for Eversense by third-party payors, or delays in processing approvals by those payors, 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.

We recently announced that we would be launching a patient access program, the Eversense Bridge Program, in March 2019 to assist those patients who do not have insurance coverage for Eversense, or whose insurance is denied or insufficient. Pursuant to this program, we will provide financial assistance to eligible patients purchasing Eversense, which may be substantial depending on a patient’s insurance coverage. We will 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 very competitive, subject to rapid change and significantly affected by new product introductions. We believe competitors have historically dedicated and will continue to dedicate significant resources to promote their products or develop new products or methods to manage diabetes. We expect to compete with well-capitalized companies, some of which are publicly-traded, that manufacture CGM systems including Medtronic, Inc., or Medtronic, Dexcom, Inc., or Dexcom, and Abbott Diabetes Care, a division of Abbott Laboratories, or Abbott.

As the industry evolves, we anticipate encountering increasing competition from companies that integrate CGM with insulin pumps. We are aware of two companies, Medtronic and Tandem Diabetes Care, Inc., which have received FDA approval for CGM-integrated insulin pumps.

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

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

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

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 with Rubin and Roche to market Eversense may not be successful.

We have entered into a distribution agreement with Rubin to market Eversense in Sweden, Norway and Denmark and a distribution agreement with Roche to market Eversense in the rest of Europe, the Middle East, Africa

(EMEA), excluding Scandinavia and Israel, and 17 additional countries, including Brazil, Russia, India and China. Under these agreements, Rubin and Roche are generally responsible for the promotion, sale and distribution of Eversense in the specified countries at such prices as they determine in their sole discretion. Although Rubin and Roche have the exclusive right to distribute Eversense in the covered countries, the agreements do not require Rubin or Roche to sell our products exclusively, and therefore, Rubin and Roche are free to sell products of our competitors. Because we are still relatively early in our European launch, we are not yet able to fully assess Rubin's and Roche's performance in distributing Eversense in the covered countries, and it may take an extended period of time for us to accurately assess their performance under the agreements. Additionally, because the agreements with Rubin and Roche are exclusive, we will have limited ability to terminate the agreements or to contract with any other distributor for Europe, the Middle East, Africa and in 17 other countries, and therefore we may be entirely dependent on Rubin and Roche for sales in these countries. If Rubin or Roche fails to perform satisfactorily under the agreements, our ability to commercialize in these territories could be adversely affected.

If we are unable to establish a sales and marketing infrastructure, we 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 expand our sales and marketing infrastructure to drive adoption of our products. We expect that we will face significant challenges as we recruit and subsequently grow our sales and marketing infrastructure. 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 increase our sales and marketing expenditures with respect to 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. Our success will depend largely on the competitive landscape for our products and the ability of our sales personnel to obtain access to healthcare providers and educate those healthcare providers on the benefits of Eversense, with the hope that they will recommend Eversense to people who intensively manage their diabetes. Recently hired sales representatives require training and take time to achieve full productivity. We cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. In addition, the expansion of our sales and marketing personnel will place significant burdens on our management team.

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 to adequately promote, market and sell Eversense. If we are unable to establish and expand our sales and marketing capabilities, 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 for clinical testing and expect to continue to do so for commercialization. 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 clinical testing, as well as for commercial manufacture. 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. In addition, although we expect some of our future versions of Eversense to share product features and components with our first generation Eversense, 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, 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, and 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 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 marketing data, accounting and financial functions, inventory management, product development tasks, research and development data, and technical support functions. 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 substantially in connection with the expanded commercialization of Eversense, establishment of our sales and marketing infrastructure, 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 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 that the audit of our consolidated financial statements for the year ended December 31, 2018 was completed, we did not have sufficient cash to fund our operations through March 2020 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, 2018, we had approximately $136.8 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 2020. The continued growth of our business, including the establishment of our sales and marketing infrastructure, and research and development activities 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 be required to 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, we may not be able to establish and expand our sales and marketing infrastructure, enhance Eversense or 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 under our convertible senior subordinated notes, the Loan and Security Agreement 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.

We may not be able to generate sufficient cash to service our indebtedness.

Following our convertible senior subordinated notes offering, the principal amount of our total consolidated indebtedness is $67.7 million. Our obligations under the Amended and Restated Loan and Security Agreement with

Oxford and SVB are secured by a first priority security interest in substantially all of our assets. Our Amended and Restated Loan and Security Agreement with Oxford and SVB also contains certain restrictive covenants that limit our 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. We were in compliance with the affirmative and restrictive covenants as of December 31, 2018. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to 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.

The indenture governing our convertible senior subordinated notes contains restrictions that limit our ability to incur additional indebtedness.

The indenture governing our convertible senior subordinated notes provides that, so long as at least 25% of the initial aggregate principal amount of the notes (including any notes issuable upon exercise of the underwriter's overallotment option), remain outstanding, we shall not incur indebtedness in excess of $35 million, other than certain permitted indebtedness, and, that we shall not consolidate with or merge with or into, or sell, convey, transfer or lease all or substantially all of our consolidated properties and assets to, another person, unless (i) the resulting, surviving or transferee person is a corporation organized and existing under the laws of the United States, any state thereof or the District of Columbia, and such corporation expressly assumes by supplemental indenture all of our obligations under the notes and the indenture; and (ii) immediately after giving effect to such transaction, no default or event of default has occurred and is continuing under the indenture. This covenant limits our operational flexibility and could prevent us from taking advantage of business opportunities as they arise, growing our business or competing effectively.

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 may in the future derive revenues, 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. 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, Jon Isaacson, our Chief Financial Officer, Mukul Jain, our Chief Operating Officer, Mirasol Panlilio, our Vice President and General Manager, Global Commercial Operations, and Mike Gill, our Vice President and General Manager, U.S. Region, 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, 2018, we had 192 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.

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, 2018, we held a total of approximately 503 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 51 issued United States patents, 226 patents issued in countries outside the United States, and 226 pending patent applications worldwide. Our patents expire between 2019 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 2020 to 2039. 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 29 pending foreign trademark applications, as well as 14 U.S. trademark registrations and 65 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. Any of these 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. 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 will be 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 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 healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could

adversely impact our business. Healthcare fraud and abuse and health information privacy and security 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, and their implementing regulations, which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of 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 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; 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.

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, 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 adjunctive to SMBG, which means that our system is not intended to provide definitive data regarding a patient's blood glucose levels for purposes of self-medication with insulin. Rather, patients are instructed to obtain confirmation of blood glucose levels, by means of a real-time test-strip reading using blood obtained by means of a fingerstick, prior to administering insulin. We have no control over whether patients adhere to labeling instructions and confirm blood glucose levels prior to administering insulin. 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 the 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).

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent 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 July 2018, CMS published a 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. 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. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, 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 2027 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.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The PPACA imposes, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013 , which, due to subsequent legislative amendments, including the continuing resolution on appropriations for fiscal year 2018, signed by President Trump on January 22, 2018, has been suspended thorough December 31, 2019 . We do not believe that Eversense is currently subject to this tax based on the retail exemption under applicable Treasury Regulations. However, the availability of this exemption is subject to interpretation by the Internal Revenue Service, or IRS, and the IRS may disagree with our analysis. In addition, future products that we manufacture, produce or import may be subject to this tax. The financial impact this tax may have on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it.

Recent developments relating to the United Kingdom's referendum vote in favor of withdrawal from the European Union could adversely affect us.

The UK held a referendum on June 23, 2016, in which a majority voted for the UK's withdrawal from the EU, commonly known as 'Brexit'. As a result of this vote, on March 29, 2017, the UK officially started the separation process and commenced negotiations to determine the terms of the UK's withdrawal from the EU. The UK is currently scheduled to leave the EU at 11:00p.m. GMT on March 29, 2019. If the UK and the EU are unable to negotiate acceptable withdrawal terms, barrier-free access between the UK and other European Member States or among the EEA overall could be diminished or eliminated. The effects of Brexit is expected to be far-reaching and will depend on any agreements (or lack thereof) between the UK and the EU and, in particular, any arrangements for the UK to retain access to EU markets either during a transitional period or more permanently. Given the level of uncertainty, Brexit, and the perceptions as to its impact, may adversely affect business activity and economic conditions in the UK, Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets, asset valuations and credit ratings. Brexit could also have the effect of disrupting and potentially ending the free movement of goods, services and people between the UK and the EU, which may negatively affect our operations together with those of our customers and suppliers, particularly those which are based in the UK or the EEA.

In addition, we expect that Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replicate or replace. If the UK were to significantly alter its regulations affecting the medical device industry, we could face significant new costs. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations and our products which are currently approved for sale across the EEA, may need to undergo a registration process in the UK in the future. Altered or divergent regulations could also add time and expense to the process by which our devices receive and maintain regulatory approval in the UK and EU.

Similarly, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining, maintaining, defending and enforcing such rights. For example, whilst current guidance provided by the UK's government suggests that trademarks granted by the EU, known as EU registered trademarks or EUTMs, will be continue to be protected in the UK after Brexit, it is unclear whether we will be required to refile our trademarks and other intellectual property applications domestically in the UK and whether any other steps will be required for us to protect our trade marks in the UK in the future. As a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership in the EU. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, we cannot be certain of the full extent to which Brexit could adversely affect our business, results of operations and financial condition.

Risks Related to our Common Stock

An active trading market for our common stock may not continue to develop or be sustained.

Prior to our public offering in March 2016, there was no liquid market for our common stock. Although our common stock is listed on The NYSE American, we cannot assure you that an active trading market for our shares will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all.

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 or securities convertible into our common stock from time to time 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.

In addition, holders of our convertible senior subordinated notes who convert their notes on or after the date that is six months after the last date of original issuance of the notes but prior to February 1, 2021 (other than for a conversion in connection with a make-whole fundamental change), will receive in certain circumstances an interest make-whole payment equal to the sum of the remaining scheduled payments of interest that would have been made on the notes to be converted had such notes remained outstanding from the conversion date through February 1, 2021. Except for conversions occurring following the record date prior to the February 1, 2021 interest payment date, we will pay any interest make-whole payment by delivering shares of our common stock. The number of shares a converting holder will receive will be the number of shares equal to the amount of the interest make-whole payment to be paid to such holder, divided by the product of (x) 95% and (y) the simple average of the daily VWAP (as defined below) of the shares for the ten consecutive trading days ending on and including the trading day immediately preceding the conversion date, which could result in significant dilution to our stockholders.

Our GAAP operating results could fluctuate substantially due to the accounting for the interest make-whole payment features of the notes.

Holders of our convertible senior subordinated notes who convert their notes prior to February 1, 2021 will, in certain circumstances, receive an interest make-whole payment. The interest make-whole payment feature of the notes is expected to be accounted for under Accounting Standards Codification 815, Derivatives and Hedging, or ASC 815, as an embedded derivative.

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 have tentatively determined that we must bifurcate and account for the interest make-whole payment feature of the notes as an embedded derivative in accordance with ASC 815. We tentatively will record this embedded derivative liability as a non-current liability on our consolidated balance sheet with a corresponding debt discount at the date of issuance that is netted against the principal amount of the notes. The derivative liability is expected to be 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 liability being recorded in other income and loss. We expect we will estimate the fair value of these liabilities using a Monte Carlo simulation model.

We cannot predict the effect that the accounting for the notes will have on our future GAAP financial results, the trading of our common stock and the trading price of the notes, which could be material.

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, stock-based compensation and income taxes. Moreover, the revenue recognition guidance, ASC Topic 606 *, Revenue from Contracts with Customers* , requires more judgment than did the prior guidance.

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 the Loan and Security Agreement with Oxford and SVB, 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation, known as the Tax Cuts and Jobs Act of 2017, that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate

from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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.

As of December 31, 2018, we had federal and state net operating loss, or NOL, carryforwards of $291.4 million, which, if not utilized, will have begun to expire at various dates starting in 2018. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, 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 is limited. It is uncertain how various states will respond to the newly enacted federal tax law. 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 after we cease 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.

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.

We may in the future discover areas of our internal financial, accounting, and operational controls and procedures that need improvement. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are unable to maintain proper and effective internal controls in the future, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal controls over financial reporting are not effective. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the NYSE American, the SEC or other regulatory authorities.

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 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 (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. 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.

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, we lease approximately 12,000 square feet of office space under a cancelable operating lease expiring in April 2019. We can terminate this lease upon 60 days' prior written notice and have an option to renew this lease for one additional two-month term. 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 Equit y, 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 14, 2019, we had 176,958,387 shares of common stock outstanding held by 184 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 selected statement of operations data for the years ended December 31, 2018, 2017 and 2016, and balance sheet data as of December 31, 2018 and 2017 is derived from our audited financial statements included within this Annual Report. The balance sheet data as of December 31, 2016, 2015, and 2014,and the statement of operations data for the years ended December 31, 2015 and 2014 have been derived from our audited financial statements which are not included herein. 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,				
	2018	2017	2016	2015	2014
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Revenue, primarily from a related party	$ 18,913	$ 6,373	$ 332	$ 38	$ —
Cost of sales	27,059	9,758	660	—	—
Gross profit	(8,146)	(3,385)	(328)	38	—
Expenses:					
Sales and marketing expenses	27,730	6,857	2,736	792	95
Research and development expenses	31,863	30,735	26,347	18,251	12,881
General and administrative expenses	19,839	15,336	13,022	9,807	5,726
Operating loss	(87,578)	(56,313)	(42,433)	(28,812)	(18,702)
Other income (expense), net:					
Interest income	2,001	135	80	9	—
Interest expense	(8,282)	(3,099)	(1,602)	(1,100)	(191)
Change in fair value of derivative liability	209	—	—	—	—
Other (expense) income	(321)	176	25	26	8
Net loss	(93,971)	(59,101)	(43,930)	(29,877)	(18,885)
Deemed dividend as a result of Series E preferred stock beneficial conversion feature	—	—	—	(407)	—
Net loss available to common stockholders	(93,971)	(59,101)	(43,930)	(30,284)	(18,885)
Basic and diluted net loss per common share	$ (0.60)	$ (0.51)	$ (0.49)	$ (4.32)	$ (9.89)
Basic and diluted weighted-average shares outstanding	157,429,145	115,975,402	89,243,853	7,002,317	1,908,587

	December 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 136,793	$ 16,150	$ 13,047	$ 3,939	$ 18,923
Working capital	129,220	21,775	9,806	(2,371)	17,593
Marketable securities	—	20,300	7,291	—	—
Total assets	159,973	45,944	22,271	5,423	19,995
Notes payable, net of discount, including current portion	14,783	24,414	19,066	9,819	9,815
Total liabilities	88,712	38,677	27,148	15,120	12,082
Additional paid-in capital	428,878	270,953	199,751	151,019	138,673
Accumulated deficit	(357,794)	(263,823)	(204,722)	(160,792)	(130,915)
Total stockholders' equity (deficit)	71,261	7,267	(4,877)	(9,697)	7,913

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in 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 design, development and commercialization of glucose monitoring products to improve the lives of people with diabetes by enhancing their ability to manage their disease with relative ease and accuracy. Our continuous glucose monitoring, or CGM, systems, Eversense and Eversense XL, are reliable, long-term, implantable CGM systems that we have designed to continually and accurately measure glucose levels in people with diabetes for a period of up to 90 and 180 days, respectively, as compared to six to fourteen days for currently available CGM systems. We believe Eversense and Eversense XL will provide people with diabetes with a more convenient method to monitor their glucose levels in comparison with the traditional method of self-monitoring of blood glucose, or SMBG, as well as currently available CGM systems. In our U.S. pivotal clinical trial, we observed that Eversense measured glucose levels over 90 days with a degree of accuracy superior to that of other currently available CGM systems. Our Eversense and Eversense XL systems are currently approved for sale in Europe, the Middle East and Africa (EMEA) and our Eversense system is currently approved for sale in the United States.

Corporate History

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 designing, developing and refining a commercially viable glucose monitoring system. On May 10, 2016, we received regulatory approval to commercialize Eversense in Europe. In June 2016, we made our first product shipment of Eversense through our distribution agreement with Rubin Medical, or Rubin. In September 2016, we made our first product shipment of Eversense through our distribution agreement with Roche Diagnostics International AG and Roche Diabetes Care GmbH, together referred to as Roche. Since our inception, we have funded our activities primarily through equity and debt financings. On June 21, 2018 we received PMA approval from the FDA and in July 2018 we made our first product shipment in the United States.

In March 2016, we completed a public offering of our common stock, or the March 2016 Offering, selling 15,800,000 shares of common stock at a price to the public of $2.85 per share, for aggregate gross proceeds of $45.0 million. Net proceeds from the March 2016 Offering were approximately $40.9 million, after deducting underwriting discounts and commissions and estimated offering-related transaction costs payable by us. In April 2016, the underwriters for the March 2016 Offering partially exercised their option to purchase additional shares of common stock, purchasing an additional 1,439,143 shares, from which we received additional net proceeds of approximately $3.9 million, after deducting underwriting discounts and commissions and estimated offering-related transaction costs payable by us.

On June 30, 2016 we entered into an Amended and Restated Loan and Security Agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, pursuant to which we have borrowed an aggregate principal amount of $25.0 million. Under the terms of the agreement, we initially borrowed an aggregate of $15 million from Oxford and SVB on June 30, 2016. We used $11 million of the $15 million to retire existing loans with Oxford, including a final payment fee of $1 million. In November 2016, we borrowed an additional $5 million upon the confirmation from Oxford and SVB that we received positive data in its U.S. pivotal trial of Eversense, and we submitted a PMA application for Eversense in the United States with the FDA. In March 2017, we borrowed an additional $5 million upon completion of the first commercial sale of our second-generation transmitter in the European Union . The agreement provides for monthly payments of interest only through December 31, 2017, followed by an amortization period of 30 months.

In June 2017, we completed an underwritten offering of our common stock, or the May 2017 Offering, selling 29,078,014 shares of common stock at a price of $1.41 per share, for aggregate gross proceeds of $41.0 million. Net proceeds from the May 2017 Offering were approximately $40.4 million, after deducting underwriting discounts and commissions and estimated offering-related transaction costs payable by us.

In August 2017, we completed an underwritten offering of our common stock, or the August 2017 Offering, selling 13,383,125 shares of common stock at a price of $2.15 per share, for aggregate gross proceeds of $28.8 million. Net proceeds from the August 2017 Offering were approximately $26.5 million after deducting underwriting discounts and commissions and estimated offering-related transaction costs payable by us.

In January and February 2018, we completed an underwritten offering of an aggregate of $53.0 million of 5.25% convertible senior subordinated notes due 2023, or the 2023 Notes. Net proceeds from the issuance of the 2023 Notes were approximately $50.9 million after deducting underwriting discounts and commissions and estimated offering-related transaction costs payable by us.

On March 30, 2018, we entered into a sales agreement with Cowen and Company LLC, or Cowen, under which we may offer and sell, from time to time at our sole discretion and pursuant to an at-the-market facility, shares of our common stock having an aggregate offering price of up to $50.0 million through Cowen acting as our sales agent. As of the date of this report, we have not sold any shares of our common stock under the at-the-market facility.

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.

We have never been profitable and our net losses were $94.0 million, $59.1 million, and $43.9 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, our accumulated deficit totaled $357.8 million, primarily as a result of expenses incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. We expect to continue to incur significant expenses and increasing operations and net losses for the foreseeable future.

European Commercialization of Eversense

In September 2015, we entered into a distribution agreement with Rubin Medical, or Rubin, pursuant to which we granted Rubin the exclusive right to market, sell and distribute Eversense in Sweden, Norway and Denmark through September 2020. Rubin markets and sells medical products for diabetes treatment in the Scandinavian region, including as the exclusive Scandinavian distributor for the insulin pump manufacturer Tandem Corporation. Under the agreement, Rubin is obligated to purchase from us specified minimum volumes of Eversense components at pre-determined prices.

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 which we granted Roche the exclusive right to market, sell and distribute Eversense in Germany, Italy and the Netherlands. Roche is a pioneer in the development of blood glucose monitoring systems and a global leader for diabetes management systems and services. Under the agreement, Roche is obligated to purchase from us specified minimum volumes of Eversense components at pre-determined prices. We began distributing Eversense through Roche in Germany in September 2016 and in Italy and the Netherlands in the fourth quarter of 2016. In November 2016, we entered into an amendment to the distribution agreement with Roche granting Roche the exclusive right to market, sell and distribute Eversense in Europe, the Middle East and Africa, excluding Sweden, Norway, Denmark, Finland and Israel. In January 2019, we entered into an additional amendment to the distribution agreement with Roche to extend the agreement through January 31, 2021. Pursuant to the amendment to the agreement, Roche has agreed to certain purchase levels of Eversense systems and pricing terms through the extended term of the agreement. In addition, under the amendment, Roche's role as the exclusive distributor of Eversense was been expanded to provide Roche with 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. To date, we have begun distributing Eversense in an aggregate of 15 European countries through Rubin and Roche.

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.

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 8.4% 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. We also observed a MARD of 9.5% utilizing one calibration point 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. We have begun 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. We intend to pursue a Category I CPT code .

We have incurred and expect to continue to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect to continue incurring expenses associated with the research and development of our other products and maintaining, expanding and protecting our intellectual property portfolio and seeking regulatory approvals in other jurisdictions. Furthermore, we expect to continue to incur, additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. We will need to obtain substantial additional funding in connection with our continuing operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. However, we may be unable to raise additional funds when needed on favorable terms or at all. Our failure to raise such capital as and when needed would have a negative impact on our financial condition and our ability to develop and commercialize Eversense and future products and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Overview

Revenue

During the year ended December 31, 2018, we generated product revenue from sales of the Eversense and Eversense XL systems in Europe pursuant to distribution agreements with Roche and Rubin, and from initial sales in the United States. We recognize revenue upon the sales of Eversense systems and related components and supplies to our distributors for sales outside of the United States and to our fulfillment partners for sales in the United States, regardless of whether these customers resell those products to health care providers and patients. Under the terms of our distribution agreements with Roche and Rubin, these distributors are 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. We expect that our revenue from both European and U.S. product sales will increase for 2019 over 2018 as we continue to ramp up our commercialization efforts. If we fail to successfully commercialize or are otherwise unable to complete the development of Eversense, our ability to generate future revenue, and our results of operations and financial position, will be adversely affected.

Cost of Sales

We utilize contract manufacturers to produce Eversense. Cost of sales consists primarily of the components of Eversense and assembly, as well as reserves for warranty costs. Other cost of sales includes distribution-related expenses such as logistics and shipping costs of Eversense to Roche and Rubin for distribution in various regions in EMEA and costs associated with distribution through our strategic fulfillment partners in the United States. We calculate gross margin as revenue less costs of sales divided by revenue. We expect our overall gross margin to improve over the long

term, as our sales increase and we have more opportunities to leverage our costs over larger production volumes. However, our gross margins may fluctuate from period to period.

Sales and Marketing

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 promotional materials and tradeshow expenses.

We anticipate that our sales and marketing expenses will increase substantially in the future as we continue to expand our commercialization of Eversense both in the United States and Europe.

Research and Development

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

We have incurred significant research and development expenses from inception, with the substantial majority of the expenses spent on the development of Eversense. We expect to continue to commit significant resources to continue to develop Eversense and future product enhancements and to conduct ongoing and future clinical trials. We expect that our overall research and development expenses will continue to increase in absolute dollars, but to decline as a percentage of total expenses as we expand the commercialization of Eversense.

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Clinical development	$ 3,021	$ 4,700	$ 4,242
Contract R&D and consulting	10,073	8,228	8,071
Contract fabrication and manufacturing	3,602	5,495	5,536
Personnel related	11,926	9,112	6,491
Other R&D expenses	3,241	3,200	2,007
Total R&D expenses	$ 31,863	$ 30,735	$ 26,347

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, accounting, business development, and human resources functions. Other significant costs include facility costs, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

Our general and administrative expenses have increased, and we expect them to continue to increase in the future, as a result of operating as a public company. These increases include increased costs related to the hiring of additional personnel and increased fees to outside consultants, lawyers and accountants as well as expenses related to maintaining compliance with NYSE American listing rules and SEC requirements, insurance, and investor relations costs. These expenses may further increase when we no longer qualify as an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, which will require us to comply with certain reporting requirements from which we are currently exempt.

Other Income (Expense), Net

Interest income consists of interest earned on our cash equivalents. Interest expense primarily consists of interest expense on our convertible senior subordinated notes, and our obligations under the Amended and Restated Loan and Security Agreement with Oxford and SVB. This interest expense primarily consists of contractual interest on the outstanding debt balances and amortization of debt discounts. In connection with our issuance of the 2023 Notes in January 2018, we bifurcated the embedded conversion option of the 2023 Notes, 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. This embedded derivate instrument is remeasured at the end of each reporting period with changes in fair value recorded to change in fair value of derivative liability in our consolidated results of operations.

Results of Operations

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, primarily from a related party	$ 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 expenses	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), net:			
Interest income	2,001	135	1,866
Interest expense	(8,282)	(3,099)	(5,183)
Change in fair value of derivative liability	209	—	209
Other expense	(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 from Rubin and 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 to Roche and Rubin 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 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.

Comparison of the Years Ended December 31, 2017 and 2016

The following table sets forth our results of operations for the years ended December 31, 2017 and 2016.

	Year Ended December 31,		Period-to-Period Change
	2017	2016	
	(in thousands)		
Revenue, primarily from a related party	$ 6,373	$ 332	$ 6,041
Cost of sales	9,758	660	9,098
Gross profit	(3,385)	(328)	(3,057)
Expenses:			
Sales and marketing expense	6,857	2,736	4,121
Research and development expenses	30,735	26,347	4,388
General and administrative expenses	15,336	13,022	2,314
Operating loss	(56,313)	(42,433)	(13,880)
Other income (expense):			
Interest expense, net	(2,964)	(1,522)	(1,442)
Other income	176	25	151
Total other expense, net	(2,788)	(1,497)	(1,291)
Net loss	$ (59,101)	$ (43,930)	$ (15,171)

Revenue

Our revenue increased to $6.4 million for the year ended December 31, 2017, compared to $0.3 million for the year ended December 31, 2016. This increase was due to a higher number of shipments of Eversense in 2017 to our distributor partners for distribution in Europe.

Cost of sales

Our cost of sales increased to $9.8 million for the year ended December 31, 2017, compared to $0.7 million for the year ended December 31, 2016. This increase was due to increased manufacturing and distribution of Eversense to our distributor partners for distribution in Europe.

Gross profit was $(3.4) million and $(0.3) million for the years ended December 31, 2017 and 2016, respectively. Gross profit as a percentage of revenue, or gross margin, was (53.1)% and (101)% for the years ended December 31, 2017 and 2016, respectively.

Sales and marketing expenses

Sales and marketing expenses were $6.9 million for the year ended December 31, 2017, compared to $2.7 million for the year ended December 31, 2016, an increase of $4.1 million. The increase was primarily due to an increase in personnel and consulting related expenses of $3.6 million and an increase of $0.5 million of other sales and marketing expenses to support the expanded distribution of Eversense in Europe as well as in preparation for our U.S. launch of Eversense.

Research and development expenses

Research and development expenses were $30.7 million for the year ended December 31, 2017, compared to $26.3 million for the year ended December 31, 2016, an increase of $4.4 million. The increase was primarily due to an increase in contract research and development and other expenses for future versions of Eversense of $1.8 million and a $2.6 million increase in personnel-related expenses.

General and administrative expenses

General and administrative expenses were $15.3 million for the year ended December 31, 2017, compared to $13.0 million for the year ended December 31, 2016, an increase of $2.3 million. The increase was primarily due to a $0.5 million increase in personnel and consulting related expenses, a $0.6 million increase in recruiting and relocation costs, a $0.4 million increase in information and technology spending for services to support our operations, and a $0.8 million increase in general spending.

Total other expense, net

Total other expense, net, for the year ended December 31, 2017 and 2016 was $2.8 million and $1.5 million, respectively, consisting primarily of interest expense on the Oxford and SVB notes.

Liquidity and Capital Resources

Sources of Liquidity

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 designing, 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 $94.0 million, $59.1 million, and $43.9 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $357.8 million.

To date, we have funded our operations principally through the issuance of preferred stock, common stock and debt. As of December 31, 2018, we had cash and cash equivalents of $136.8 million. Under the terms of the Amended and Restated Loan and Security Agreement with the Lenders, we have borrowed an aggregate principal amount of $25.0 million.

In January 2018, we issued $50.0 million in aggregate principal amount of 5.25% convertible senior subordinated notes due 2023, or the 2023 Notes, and in February 2018, we issued an additional $3.0 million in aggregate principal amount of the 2023 Notes.

On March 30, 2018, we entered into a sales agreement with Cowen and Company LLC, or Cowen, under which we may offer and sell, from time to time at our sole discretion and pursuant to an at-the-market facility, shares of our common stock having an aggregate offering price of up to $50.0 million through Cowen acting as our sales agent. As of the date of this report, we have not sold any shares of our common stock under the at-the-market facility.

On June 28, 2018, pursuant to an underwriting agreement with BTIG, LLC, we closed the June 2018 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. We received aggregate net proceeds of $149.0 million from the June 2018 Offering.

Our ability to generate revenue and achieve profitability depends on our completion of the development of Eversense and future product candidates and obtaining of necessary regulatory approvals for the manufacture, marketing and sales of those products. These activities, including our planned significant research and development efforts, will require significant uses of working capital through 2019 and beyond. Upon the completion of the audit of our consolidated financial statements for the year ended December 31, 2018, we did not have sufficient cash to fund our operations through the first quarter of 2020 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. The financial information throughout this Annual Report and the consolidated financial statements included elsewhere in this Annual Report have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of

business. This financial information and these statements do not include any adjustments that may result from the outcome of this uncertainty.

We do not expect our existing cash and cash equivalents will be sufficient to fund our operations through the first quarter of 2020. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect. Additionally, the process of clinical and regulatory development of medical devices is costly, and the timing of progress of these efforts is uncertain.

We anticipate that we will continue to incur losses for the foreseeable future. We expect that our sales and marketing, research and development, and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations. Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, which may include additional follow-on offerings or through our at-the-market facility, debt financings and revenue from potential research and development and other collaboration agreements. To the extent that we raise additional capital through the future sale of equity or debt, 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 in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant licenses to develop and market products that we would otherwise prefer to develop and market ourselves.

Indebtedness

On June 30, 2016, we entered into an Amended and Restated Loan and Security Agreement with the Lenders. Pursuant to the Amended and Restated Loan and Security Agreement, we have borrowed an aggregate principal amount of $25.0 million in the following three tranches: $15.0 million, or the Tranche 1 Term Loan; $5.0 million, or the Tranche 2 Term Loan; and $5.0 million, or the Tranche 3 Term Loan. We refer to each of the tranches as a Term Loan, and collectively, the Term Loans. The funding conditions for the Tranche 1 Term Loan were satisfied as of June 30, 2016. Therefore, we issued secured notes to the Lenders for aggregate gross proceeds of $15.0 million, or the Notes, on June 30, 2016. We used approximately $11.0 million from the proceeds from the Notes to repay the outstanding balance under our previously existing Loan and Security Agreement with Oxford, dated as of July 31, 2014, including the applicable final payment fee due thereunder of $1 million. On November 22, 2016, the funding conditions for the Tranche 2 Term Loan were satisfied; therefore we issued secured notes to the Lenders for aggregate gross proceeds of $5.0 million. On March 29, 2017, the funding conditions for the Tranche 3 Term Loan were satisfied; therefore we issued secured notes to the Lenders for aggregate gross proceeds of $5.0 million. The maturity date for all Term Loans is June 1, 2020, or the Maturity Date.

The Term Loans bear interest at a floating annual rate of 6.31% plus the greater of (i) 90-day U.S. Dollar LIBOR reported in the Wall Street Journal or (ii) 0.64%, provided that the minimum floor interest rate is 6.95%, and require monthly payments. The monthly payments through December 31, 2017 consisted only of interest. In January 2018, we began to make monthly principal payments that will continue until the Maturity Date.

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

The Amended and Restated Loan and Security Agreement contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on the Lenders' security interest over the collateral, a material adverse change, the occurrence of a default under certain other agreements entered into by us, the rendering of certain types of judgments against us, the revocation of certain of our 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 us 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 Lenders.

Pursuant to the Amended and Restated Loan and Security Agreement, we also 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 with exercise prices of $3.86, $2.38, and $1.86 per share, respectively.

The Notes are collateralized by all of our consolidated assets. The Notes also contain certain restrictive covenants that limit our 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. We incurred issuance costs related to the Notes of approximately $0.6 million that are being amortized as additional interest expense over the term of the Notes using the effective interest method. The fair value of the stock purchase warrants, which was estimated to be $0.5 million, was recorded as a discount to the Notes, which is also being amortized as additional interest expense over the term of the Notes using the effective interest method.

At maturity (or earlier prepayment), we are also required to make a final payment equal to 9.00% of the aggregate principal balances of the funded Term Loans. This fee is being accrued as additional interest expense over the term of the Notes using the effective interest method.

In January 2018, we issued $50.0 million in aggregate principal amount of 2023 Notes, and in February 2018, we issued an additional $3.0 million in aggregate principal amount of 2023 Notes. 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, beginning on August 1, 2018. The 2023 Notes will mature on February 1, 2023, unless earlier repurchased or converted. Payment of the principal of, and accrued and unpaid interest, if any, on the maturity date, and the fundamental change repurchase price of (excluding cash payable in lieu of delivering fractional shares of our common stock), the 2023 Notes is subordinated to the prior payment in full in cash or other payment satisfactory to the holders of senior debt, of all existing and future senior debt, which includes our indebtedness under the Amended and Restated Loan and Security Agreement with the Lenders and any refinancing thereof.

The 2023 Notes are convertible into shares of our common stock at the option of the holders at any time prior to the close of business on the business day immediately preceding the maturity date. The conversion rate is initially 294.1176 shares of common stock per $1,000 principal amount of 2023 Notes (equivalent to an initial conversion price of approximately $3.40 per share of common stock), subject to customary adjustments. 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 our common stock. In addition, following certain corporate events that occur prior to the maturity date, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its 2023 Notes in connection with such a corporate event.

In the second quarter of 2018, we issued 85,007 shares of common stock upon the conversion of $250,000 in aggregate principal amount of the 2023 Notes. As of December 31, 2018, the aggregate outstanding principal amount of the 2023 Notes was $52.7 million.

Funding Requirements and Outlook

Our primary uses of capital are, and we expect will continue to be, costs associated with commercialization of Eversense in the United States, establishment of a direct sales force in the United States, research and development, compensation and related expenses, costs related to clinical trials, laboratory and related supplies, supplies and materials used in manufacturing, legal and other regulatory expenses and general overhead costs.

We do not expect our existing cash and cash equivalents to be sufficient to fund our operations through the first quarter of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Additionally, the process of clinical and regulatory development of medical devices is costly, and the timing of progress of these efforts is uncertain.

Cash Flows

The following is a summary of cash flows for each of the periods set forth below.

	Year Ended December 31,		
	2018	2017	2016
		(in thousands)	
Net cash used in operating activities	$ (90,771)	$ (55,739)	$ (38,016)
Net cash provided by (used in) investing activities	19,426	(13,226)	(7,770)
Net cash provided by financing activities	191,988	72,068	54,894
Net increase in cash and cash equivalents	$ 120,643	$ 3,103	$ 9,108

Net cash used in operating activities

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 (consisting of a net increase in accounts receivable, prepaid expenses and other current assets, inventory, and deposits and other assets of $13.0 million, net of an increase in accounts payable, accrued expenses and other current liabilities, deferred revenue, accrued interest, and deferred rent of $6.3 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 (consisting primarily of an increase in accounts payable, accrued expenses, deferred rent and other current liabilities and accrued interest of $6.2 million and decreases in prepaid expenses, deposits and other assets of $1.8 million, inventory of $2.7 million and accounts receivable of $3.1 million).

Net cash used in operating activities was $38.0 million for the year ended December 31, 2016, and consisted primarily of a net loss of $43.9 million, partially offset by stock-based compensation expense of $2.4 million, other non-cash expenses of $0.7 million, and a net change in assets and liabilities of $2.7 million (consisting primarily of an increase in accounts payable and accrued expenses of $2.7 million and a decrease in prepaid expenses, deposits and other assets of $0.7 million, net of an increase in inventory of $0.5 million and an increase in accounts receivable of $0.2 million).

Net cash provided by (used in) investing activities

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 used in investing activities was $7.8 million for the year ended December 31, 2016, and consisted of $7.3 million for the purchase of marketable securities and $0.5 million of capital expenditures for laboratory equipment.

Net cash provided by financing activities

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 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.

Net cash provided by financing activities was $54.9 million for the year ended December 31, 2016, and consisted primarily of the net proceeds of $45.7 million from our public offering of common stock in March 2016, the net proceeds of $9.0 million from the issuance of the Oxford and SVB notes, and $0.2 million from the exercise of stock options.

Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2018.

	Payment due by period				
Contractual Obligations	**Total**	**2019**	**2020-2021**	**2022-2023**	**After 2023**
Operating lease obligations	$ 2,838	$ 611	$ 1,277	$ 950	$ —
Principal payments under Notes(1)	15,000	10,000	5,000	—	—
Interest payments under Notes(1)	3,344	960	2,384	—	—
Principal payments under 2023 Notes	52,700	—	—	52,700	—
Interest payments under 2023 Notes	12,451	2,767	5,534	4,150	—
Total contractual obligations	$ 86,333	$ 14,338	$ 14,195	$ 57,800	$ —

(1) Represents the principal and interest payment schedule for the $25.0 million principal amount of the Oxford and SVB notes that were outstanding as of December 31, 2018. For additional information, see "—Liquidity and Capital Resources—Indebtedness."

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of revenue and expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our consolidated financial statements prospectively from the date of the change in estimate.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments.

Revenue Recognition

Effective January 1, 2018, we adopted ASC Topic 606, *Revenue from Contracts with Customers* , using the full retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount

that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, 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, once the contract is determined to be within the scope of ASC Topic 606, we assess the goods or services promised within each contract and determines those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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.

Revenues from product sales are recognized when the Customers obtain control of our product, which occurs at a point in time, based upon the delivery terms as defined in the distributor agreement. We are typically paid within 60 days of invoicing subsequent to the Customers obtaining control of our product.

We offer no discounts, rebates, rights of return, or other allowances to the Customers which would result in the establishment of reserves against product revenue. Additionally, to date, we have not incurred incremental costs in obtaining a Customer contract.

Stock-Based Compensation

We issue stock-based compensation awards to our employees and non-employee directors, including stock options. We measure stock-based compensation expense related to these awards based on the fair value of the award on the date of grant and date of any modification, and recognize stock-based compensation expense 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.

We have selected the Black-Scholes option pricing model to determine the fair value of stock option awards, which requires management to apply judgment and make assumptions and estimates, including:

- the fair value of our common stock;
- the expected volatility of the price of our common stock;
- dividend yields;
- future employee turnover rates; and
- future employee stock option exercise behaviors.

Options to purchase 7,532,994 and 5,673,544 shares were granted during the years ended December 31, 2018 and 2017, respectively.

We have assumed no dividend yield because we do not expect to pay dividends in the future, which is consistent with our 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 our 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. We used 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.

The amount of stock-based compensation expense recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. Stock-based compensation expense is recorded monthly and is adjusted periodically for actual forfeitures. Pre-vesting forfeitures are based on our actual forfeitures for the years ended December 31, 2018, 2017 and 2016 and have not been material. Ultimately, the actual expense recognized over the vesting period will only represent those options that vest.

Our assumptions may differ from those used in prior periods, and changes in the assumptions may have a significant impact on the fair value of future equity awards, which could have a material impact on our consolidated financial statements. We grant stock options with exercise prices equal to the estimated fair value of our common stock on the date of grant.

Research and Development Expenses

Research and development costs are expensed as incurred. These costs include compensation and benefits for research and development employees, including stock-based compensation, facilities expenses, depreciation, overhead expenses, cost of laboratory supplies, clinical trial and related clinical manufacturing expenses, costs related to regulatory operations, fees paid to CROs and other consultants, and other outside expenses.

Certain of these costs, such as costs associated with our clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors with respect to their actual costs incurred. We account for the expenses under these agreements according to the progress of the trial or study, as measured by patient enrollment and progression and the timing of various aspects of the trial or study. We determine accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of the applicable clinical trials or feasibility studies. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued expenses, as the case may be. During the course of a clinical trial or feasibility study, we adjust the rate of clinical trial expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at the time. Although we do not expect that our estimates will be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period. As of December 31, 2018, we had not made any material adjustments to our prior period estimates of accrued expenses for clinical trials. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status of our clinical trials.

Derivative Financial Instruments

In connection with our issuance of the 2023 Notes in January 2018, we bifurcated the embedded conversion option, along with the interest make-whole provision and make-whole fundamental change provision, and recorded the embedded conversion option as a derivative liability in our consolidated balance sheets in accordance with ASC Topic 815, *Derivatives and Hedging* . The financial instrument is remeasured at the end of each reporting period with changes in fair value recorded in the consolidated statements of operations in other income (expense) as change in fair value of 2023 derivative.

Recent Accounting Pronouncements

Recently Adopted

In May 2014, the Financial Accounting Standards Board, or FASB, issued ASU 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition

requirements in ASC Topic 605, Revenue Recognition, and creates a new ASC Topic 606, Revenue from Contracts with Customers. In 2015 and 2016, the FASB issued additional ASUs related to ASC Topic 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. We adopted this new standard on January 1, 2018 using the full retrospective transition method. The adoption of the new standard did not materially impact the amounts reported in our consolidated financial statements and there were no other significant changes impacting the timing or measurement of revenues or our business process and controls.

In January 2016, the FASB issued ASU 2016-01, guidance on the classification and measurement of financial instruments. This ASU was further amended in February 2018 by ASU 2018-03. The guidance requires entities to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income. The guidance also amends certain disclosure requirements associated with the fair value of financial instruments. We adopted this new standard on January 1, 2018. The adoption of this guidance did not have a significant impact on our financial statements.

In August 2016, the FASB issued ASU 2016-15, guidance on the classification of certain cash receipts and cash payments in the statements of cash flows, including those related to debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance, and distributions received from equity method investees. We adopted this new standard on January 1, 2018 on a retrospective basis. The adoption of the new standard did not impact the amounts reported in our consolidated statements of cash flows.

Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, guidance for accounting for leases. 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 reporting periods beginning after December 15, 2018 and early adoption is permitted. We will adopt the guidance on January 1, 2019. We have substantially completed the process of reviewing our lease agreements and evaluating the impact of the lease guidance on the our consolidated financial statements. We are still in the process of reviewing our contract manufacturing agreements for embedded leases. We do not anticipate recording right of use assets and lease liabilities greater than 5% of total assets and total liabilities, respectively, upon adoption of this guidance.

In June 2018, the FASB issued ASU 2018-07, 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 Accounting Standards Codification 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. We will adopt the guidance on January 1, 2019. We have determined that the guidance will not have a significant impact on our consolidated financial statements.

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, balance sheets, or cash flows.

JOBS Act

In April 2012, the JOBS Act was enacted. Section 107(b) of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably

elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We remained an emerging growth company for all of fiscal year 2018. At the end of the 2019 fiscal year, we will no longer be an emerging growth company and we will no longer be exempt from (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or regarding a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

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.

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, 2018, 2017 and 2016, we had cash and cash equivalents of $136.8 million, $16.2 million and $13.0 million, respectively. We generally hold our cash in interest-bearing money market accounts. 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. Additionally, the interest rate on our Oxford and SVB notes and on our 2023 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 dollar value of sales is impacted by exchange rates versus the dollar. 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 ERNST & YOUNG LLP, 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, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion..

/s/ Ernst & Young LLP

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

Tysons, VA
March 15, 2019

Senseonics Holdings, Inc.

Consolidated Balance Sheets

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 136,793	$ 16,150
Marketable securities	—	20,300
Accounts receivable, primarily from a related party	7,097	3,382
Inventory, net	10,231	2,991
Prepaid expenses and other current assets	3,985	2,092
Total current assets	158,106	44,915
Deposits and other assets	117	176
Property and equipment, net	1,750	853
Total assets	$ 159,973	$ 45,944
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,407	$ 7,712
Accrued expenses and other current liabilities	13,851	5,428
Deferred revenue	628	—
Notes payable, current portion	10,000	10,000
Total current liabilities	28,886	23,140
Notes payable, net of discount	4,783	14,414
Convertible senior notes, net of discount	36,103	—
Derivative liability	17,091	—
Notes payable, accrued interest	1,764	1,054
Other liabilities	85	69
Total liabilities	88,712	38,677
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value per share; 450,000,000 and 250,000,000 shares authorized as of December 31, 2018 and 2017; 176,918,381 and 136,882,735 shares issued and outstanding as of December 31, 2018 and 2017	177	137
Additional paid-in capital	428,878	270,953
Accumulated deficit	(357,794)	(263,823)
Total stockholders' equity	71,261	7,267
Total liabilities and stockholders' equity	$ 159,973	$ 45,944

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

Senseonics Holdings, Inc.

Consolidated Statements of Operations and Comprehensive Income (Loss)

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

	Years Ended December 31,		
	2018	**2017**	**2016**
Revenue, primarily from a related party	$ 18,913	$ 6,373	$ 332
Cost of sales	27,059	9,758	660
Gross profit	(8,146)	(3,385)	(328)
Expenses:			
Sales and marketing expenses	27,730	6,857	2,736
Research and development expenses	31,863	30,735	26,347
General and administrative expenses	19,839	15,336	13,022
Operating loss	(87,578)	(56,313)	(42,433)
Other income (expense), net:			
Interest income	2,001	135	80
Interest expense	(8,282)	(3,099)	(1,602)
Change in fair value of derivative liability	209	—	—
Other (expense) income	(321)	176	25
Total other expense, net	(6,393)	(2,788)	(1,497)
Net loss	(93,971)	(59,101)	(43,930)
Total comprehensive loss	$ (93,971)	$ (59,101)	$ (43,930)
Basic and diluted net loss per common share	$ (0.60)	$ (0.51)	$ (0.49)
Basic and diluted weighted-average shares outstanding	157,429,145	115,975,402	89,243,853

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

Senseonics Holdings, Inc.

Consolidated Statements of Changes in Stockholders' Equit y (Deficit)

(in thousands)

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance, December 31, 2015	75,760	$ 76	$ 151,019	$ (160,792)	$ (9,697)
Initial Public Offering	17,239	17	44,557	—	44,574
Exercise of stock options and warrants	570	1	1,324	—	1,325
Stock-based compensation expense and vesting of RSUs	—	—	2,421	—	2,421
Issuance of warrants related to debt	—	—	430	—	430
Net loss	—	—	—	(43,930)	(43,930)
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 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

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

Senseonics Holdings, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities			
Net loss	$ (93,971)	$ (59,101)	$ (43,930)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	270	227	155
Non-cash interest expense (debt discount and deferred costs)	3,317	453	252
Change in fair value of warrants		—	430
Change in fair value of derivative liability	(209)	—	—
Stock-based compensation expense	6,412	3,993	2,421
Provision for lower of cost or net realizable value	201	226	—
Net realized gain on marketable securities	(115)	(128)	—
Changes in assets and liabilities:			
Accounts receivable	(3,715)	(3,131)	(250)
Prepaid expenses and other current assets	(1,893)	(1,727)	659
Inventory	(7,441)	(2,741)	(477)
Deposits and other assets	59	(71)	43
Accounts payable	(3,395)	4,642	1,817
Accrued expenses and other current liabilities	8,355	823	893
Deferred revenue	628	—	—
Accrued interest	710	781	(54)
Deferred rent	16	15	25
Net cash used in operating activities	(90,771)	(55,739)	(38,016)
Cash flows from investing activities			
Capital expenditures	(989)	(345)	(479)
Purchases of marketable securities	(7,935)	(33,181)	(7,291)
Sales and maturities of marketable securities	28,350	20,300	—
Net cash provided by (used in) investing activities	19,426	(13,226)	(7,770)
Cash flows from financing activities			
Proceeds from issuance of common stock	149,502	67,556	46,184
Common stock issuance costs	(458)	(695)	(447)
Proceeds from issuance of warrants	—	104	—
Proceeds from exercise of stock options and stock warrants	2,259	287	161
Proceeds from issuance of notes	—	5,000	22,500
Notes issuance costs	—	(104)	—
Proceeds from convertible senior notes	52,950	—	—
Convertible senior notes issuance costs	(2,245)	—	—
Principal payments on notes payable	(10,000)	—	(12,500)
Financing costs of notes	—	—	(1,004)
Principal payments under capital lease obligations	(20)	(80)	—
Net cash provided by financing activities	191,988	72,068	54,894
Net increase in cash and cash equivalents	120,643	3,103	9,108
Cash and cash equivalents, at beginning of period	16,150	13,047	3,939
Cash and cash equivalents, at end of period	$ 136,793	$ 16,150	$ 13,047
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	$ 3,136	$ 1,830	$ 893
Supplemental disclosure of non-cash investing and financing activities			
Capital expenditures not paid	$ 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 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. 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 are hereinafter collectively referred to as the "Company" unless otherwise indicated or the context otherwise requires.

2. Liquidity

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, lack of operating history and uncertainty of future profitability. Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company's research and development programs. The Company has not generated significant revenues from the sale of products and its ability to generate revenue and achieve profitability largely depends on the Company's ability, alone or with others, to complete the development of its products or product candidates, and to obtain necessary regulatory approvals for the manufacture, marketing and sales of those products. These activities, including planned significant research and development and sales and marketing efforts, will require significant uses of working capital throughout 2019 and beyond.

On March 23, 2016, the Company effected the initial closing of its public offering of 15,800,000 shares of its common stock at a price to the public of $2.85 per share (the "March 2016 Offering"). Additionally, the Company closed on the partial exercise of the underwriters' option to purchase additional shares on April 5, 2016. The Company received aggregate net proceeds from the Offering of $44.8 million (after deducting underwriters' discounts and commissions of $2.7 million and additional offering related costs of $1.4 million). On June 30, 2016, the Company entered into Amended and Restated Loan and Security Agreement with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") to potentially borrow up to an aggregate principal amount of $30.0 million. On June 30, 2016, the funding conditions for tranche 1 were satisfied and the Company borrowed $15.0 million. The Company used approximately $11.0 million from the proceeds from tranche 1 to repay the outstanding balance under the Company's previously existing Loan and Security Agreement with Oxford, dated as of July 31, 2014, including the applicable final payment fee due thereunder of $1.0 million. On November 22, 2016, the funding conditions for tranche 2 were satisfied and the Company borrowed $5.0 million. On March 29, 2017, the funding conditions for tranche 3 were satisfied and the Company borrowed $5.0 million. On June 1, 2017, the Company effected the closing of its offering of 29,078,014 shares of its common stock at a price of $1.41 per share (the "May 2017 Offering"). The Company received aggregate net proceeds from the May 2017 Offering of $40.4 million. On August 23, 2017, the Company effected the closing of its offering of 13,383,125 shares of its common stock at a price of $2.15 per share (the "August 2017 Offering"). The Company received aggregate net proceeds from the August 2017 Offering of $26.5 million. In January 2018, the Company issued $50.0 million in aggregate principal amount of convertible senior subordinated notes, and in February 2018, the Company issued an additional $3.0 million in aggregate principal amount of convertible senior subordinated notes (collectively, the "2023 Notes") upon the partial exercise of the underwriters' over-allotment option. On June 28, 2018, pursuant to an underwriting agreement with BTIG, LLC, the Company closed an underwritten offering of 38,076,561 shares of common stock, including BTIG, LLC's exercise in full of its option to purchase additional shares, at a price of $3.93 per share (the "June 2018 Offering").

The Company received aggregate net proceeds from the June 2018 Offering of $149.0 million. M anagement has concluded that, based on the Company's current operating plans, its existing cash and cash equivalents will not be sufficient to meet the Company's anticipated operating needs through the first quarter of 2020. Accordingly, the Company believes that doubt about the Company's ability to continue as a going concern exists.

Historically, the Company has financed its operating activities through the sale of equity and equity-linked securities and the issuance of debt. The Company plans to continue financing its operations with external capital. However, the Company may not be able to raise additional funds on acceptable terms, or at all. If the Company is unable to secure sufficient capital to fund its commercialization, research and development and other operating activities, the Company may be required to delay or suspend operations, enter into collaboration agreements with partners that could require the Company to share commercial rights to its products to a greater extent or at earlier stages in the product development process than is currently intended, merge or consolidate with other entities, or liquidate.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. A portion of the notes payable are classified as long-term in the accompanying consolidated balance sheet as of December 31, 2018 and 2017. The terms of the notes include a subjective acceleration clause which management deems as remote. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet the Company's obligations as they become due.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements reflect the accounts of Senseonics Holdings and its wholly-owned subsidiary Senseonics. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues 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, depreciable lives of property and equipment, and estimated accruals for preclinical study costs, which are accrued based on estimates of work performed under contracts. Actual results could differ from those estimates; however management does not believe that such differences would be material.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources and in assessing performance. 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, 2018, 2017 and 2016, 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 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.

The Company's cash and cash equivalents potentially subject the Company to credit and liquidity risk. The Company maintains cash deposits at major financial institutions with high credit quality and, at times, the balances of those deposits may exceed the Federal Deposit Insurance Corporation limits of $250,000. The Company has not experienced and does not anticipate any losses on deposits with commercial banks and financial institutions that exceed the federally insured amounts.

Concentration of Revenues and Customers

At any given time, the Company's trade receivables are concentrated among a small number of principal customers. If any of the Company's customers fail to perform their obligations under the terms of these financial instruments, the Company's maximum exposure to potential losses would be equal to amounts reported on its consolidated balance sheets.

During the years ended December 2018 and 2017, the Company derived a majority of its total revenue from two customers. During the year ended December 2018, the Company derived 86 percent of its total revenue from one of those two customers. Total revenues from Roche Diabetes Care GmbH were $16.2 million.

Revenues by geographic region

The following table sets forth 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 year ended December 31, 2018. All of the Company's revenues were earned from sales outside of the United States for the years ended December 31, 2017 and 2016.

	Year Ended December 31, 2018	
(Dollars in thousands)	Amount	% of Total
Revenues:		
Outside of the United States	$ 17,498	92.52 %
United States	1,415	7.48
Total	$ 18,913	100.00 %

Marketable Securities

Marketable securities consist of government and agency securities and corporate debt securities. The Company's investments are classified as available for sale. Such securities are carried at fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive income. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in consolidated results of operations. A decline in the market value of any available for sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income is recognized when earned. The cost of securities sold is calculated using the specific identification method. The Company classifies all available-for-sale marketable securities with maturities greater than one year from the balance sheet date as non-current assets.

Inventory

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 periodically reviews inventory to determine if a write down is necessary for inventory that has become obsolete, inventory that has a cost basis less than net realizable value, and inventory in excess of future demand taking into consideration the product shelf life.

Accounts Receivable

The Company grants credit to various customers in the normal course of business. Accounts receivable consist of amounts due from distributors. The Company records 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.

Property and Equipment

Property and equipment are stated at cost. Depreciation is computed by use of the straight-line method over the estimated useful lives of the assets, which is between three to five years for laboratory equipment, between five to seven years for office furniture and equipment, and the shorter of lease term or useful life for leasehold improvements. 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.

Management reviews property and equipment 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 2018, 2017, and 2016.

Derivative Financial Instruments

In connection with the Company's issuance of 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* . The financial instrument is remeasured at the end of each reporting period with changes in fair value recorded in the consolidated statements of operations in other income (expense) as change in fair value of 2023 derivative.

Warranty Reserve

The Company may replace Eversense system components that do not function in accordance with the product specifications. Estimated replacement costs associated with a product are recorded at the time of shipment. The Company estimates future replacement costs by analyzing historical replacement experience for the timing and amount of returned product, and the Company evaluates the reserve quarterly and makes adjustments when appropriate.

At December 31, 2018 and December 31, 2017, the warranty reserve was $0.8 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, 2018 and 2017:

	December 31,	
(Dollars in thousands)	**2018**	**2017**
Balance at beginning of the year	$ 813	$ 67
Provision for warranties during the period	1,119	813
Settlements made during the period	(157)	(20)
Net changes in liability for pre-existing warranties, including expirations and changes in estimate	(959)	(47)
Balance at end of the year	$ 816	$ 813

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC Topic 606, *Revenue from Contracts with Customers* , using the full retrospective transition method. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, 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, once the contract is determined to be within the scope of ASC Topic 606, 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 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 (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.

Revenues from product sales are recognized when the Customers obtain control of the Company’s product, which occurs at a point in time, based upon the delivery terms as defined in the distributor agreement. The Company is typically paid within 60 days of invoicing subsequent to the Customers obtaining control of the Company’s product.

The Company offers no discounts, rebates, rights of return, or other allowances to the Customers which would result in the establishment of reserves against product revenue. Additionally, to date, the Company has not incurred incremental costs in obtaining a Customer contract.

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, reserves for expected warranty costs, reserves for inventory valuation, scrap, and shipping and handling expenses associated with product delivery.

Shipping and Handling Expenses

Shipping and handling expenses associated with product delivery are included within cost of sales in the Company’s consolidated statements of operations.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include costs related to employee compensation, preclinical and clinical trials, manufacturing, supplies, outsource testing, consulting and depreciation and other facilities-related expenses.

Stock-Based Compensation

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.

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.

Under ASC 718, the cumulative amount of compensation cost recognized for instruments classified as equity that ordinarily would result in a future tax deduction under existing tax law shall be considered to be a deductible difference in applying ASC 740 *, Income Taxes* . The deductible temporary difference is based on the compensation cost recognized for financial reporting purposes; however, these provisions currently do not impact the Company, as all the deferred tax assets have a full valuation allowance.

Since the Company had net operating loss ("NOL") carryforwards as of December 31, 2018 and 2017, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

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 did not have any amounts accrued relating to interest and penalties as of December 31, 2018 and 2017.

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. Based on the borrowing rates currently available for loans with similar terms, the Company believes that the fair value of its long-term notes payable approximates their carrying value. The fair values of the Company's marketable investments are reported in Note 15 *—Fair Value Measurements* .

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, 2018, 2017 and 2016, consisting of common stock options and stock purchase warrants, which have been excluded from the computation of diluted loss per share, was as follows:

	2018	2017	2016
Stock-based awards	21,457,946	16,413,840	11,389,773
2023 Notes	20,480,638	—	—
Warrants	4,071,581	4,427,086	5,184,988
Total anti-dilutive shares outstanding	46,010,165	20,840,926	16,574,761

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 and stock purchase warrants using the treasury stock method.

Recent Accounting Pronouncements

Recently Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition* , and creates a new ASC Topic 606, *Revenue from Contracts with Customers* . In 2015 and 2016, the FASB issued additional ASUs related to ASC Topic 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. The Company adopted this new standard on January 1, 2018 using the full retrospective transition method. The adoption of the new standard did not materially impact the amounts reported in the Company's consolidated financial statements and there were no other significant changes impacting the timing or measurement of revenues or the Company's business process and controls.

In January 2016, the FASB issued ASU 2016-01, guidance on the classification and measurement of financial instruments. This ASU was further amended in February 2018 by ASU 2018-03. The guidance requires entities to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income. The guidance also amends certain disclosure requirements associated with the fair value of financial instruments. The Company adopted this new standard on January 1, 2018. The adoption of this guidance did not have a significant impact on the Company's financial statements.

In August 2016, the FASB issued ASU 2016-15, guidance on the classification of certain cash receipts and cash payments in the statements of cash flows, including those related to debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance, and distributions received from equity method investees. The Company adopted this new standard on January 1, 2018 on a retrospective basis. The adoption of the new standard did not impact the amounts reported in the Company's consolidated statements of cash flows.

Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, guidance for accounting for leases. 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 reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company will adopt the guidance on January 1, 2019. The Company has substantially completed the

process of reviewing its lease agreements and evaluating the impact of the lease guidance on its consolidated financial statements. The Company is still in the process of reviewing its contract manufacturing agreements for embedded leases. The Company does not anticipate recording right of use assets and lease liabilities greater than 5% of total assets and total liabilities, respectively, upon adoption of this guidance.

In June 2018, the FASB issued ASU 2018-07, 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 will adopt the guidance on January 1, 2019. The Company has determined that the guidance will not have a significant impact on its consolidated financial statements.

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

4. Marketable Securities

The Company held no marketable securities as of December 31, 2018. Marketable securities available for sale as of December 31, 2017 were as follows (in thousands):

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
Government and agency securities	$ 5,990	$ —	$ —	$ 5,990
Corporate debt securities	14,310	—	—	14,310
Total	$ 20,300	$ —	$ —	$ 20,300

At December 31, 2017, all marketable securities available-for-sale had contractual maturities of less than one year and were classified as current assets on the consolidated balance sheets.

5. Inventory, net

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

	December 31,	
	2018	2017
Finished goods	$ 1,457	$ 375
Work-in-process	7,211	2,150
Raw materials	1,563	466
Total	$ 10,231	$ 2,991

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Contract manufacturing	$ 2,962	$ 1,601
Marketing and sales	287	93
IT and software	244	214
Interest receivable	239	4
Clinical and preclinical	111	35
Other	142	145
Total prepaid expenses and other current assets	$ 3,985	$ 2,092

7. Property and Equipment, net

Property and equipment consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Laboratory equipment	$ 2,132	$ 1,019
Office furniture and equipment	122	87
Leased equipment	159	159
Leasehold improvements	647	628
	3,060	1,893
Less: Accumulated depreciation	(1,310)	(1,040)
Property and equipment, net	$ 1,750	$ 853

Depreciation expense, including amortization of property and equipment acquired under capital leases, for the years ended December 31, 2018, 2017, and 2016 was $0.3 million, $0.2 million, and $0.2 million, respectively, and is recorded within the operating expenses and cost of goods sold in the consolidated statements of operations. Gross assets recorded under capital leases were $0.2 million as of December 31, 2018 and 2017. Accumulated depreciation associated with capital leases was $0.1 million as of December 31, 2018 and 2017, respectively. The Company disposed of $0 of fully depreciated property and equipment in 2018, 2017, or 2016.

8. Other Balance Sheet Details

Accrued expenses and other current liabilities consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Contract manufacturing	$ 6,068	$ 1,209
Compensation and benefits	3,685	2,209
Interest on notes payable and 2023 Notes	1,268	180
Product warranty	816	813
Sales and marketing services	738	25
Professional services	727	917
Clinical and preclinical	147	55
Other	402	20
Total accrued expenses and other current liabilities	$ 13,851	$ 5,428

9. Commitments and Contingencies

The Company leases approximately 33,000 square feet of research and office space under a non-cancelable operating lease expiring in 2023 . The Company has an option to renew the lease for one additional five-year term. Additionally, the Company leases approximately 12,000 square feet of office space under a cancelable operating lease expiring in April 2019. Rent expense is recognized on a straight-line basis and was $0.7 million, $0.6 million, and $0.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. The contractually required cash payments under these leases at December 31, 2018 are as follows (in thousands):

2019	$ 611
2020	629
2021	648
2022	668
2023	282
Total minimum lease payments	$ 2,838

On March 31, 2016, the Company amended a corporate development agreement with a supplier to include a minimum purchase commitment per year. Total research and development expense related to the minimum payment was $1.1 million and $1.2 million during the years ended December 31, 2018 and 2017, respectively. There were no remaining future minimum payments under this commitment at December 31, 2018.

10. 401(k) Plan

The Company has a defined contribution 401(k) plan available to all full-time employees. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal income tax regulations. Participants are fully vested in their contributions. There have been no employer contributions to this plan. Administrative expenses for the plan, which are paid by the Company, were not material in 2018, 2017 or 2016.

11. Notes Payable and Stock Purchase Warrants

Term Notes Payable

On June 30, 2016, the Company entered into an Amended and Restated Loan and Security Agreement with Oxford and SVB (the "Lenders"). Pursuant to the Amended and Restated Loan and Security Agreement, the Company has borrowed an aggregate principal amount of $25.0 million in the following three tranches: $15.0 million ("Tranche 1 Term Loan"); $5.0 million ("Tranche 2 Term Loan"); and $5.0 million ("Tranche 3 Term Loan") (each, a "Term Loan," and collectively, the "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 "Notes") on June 30, 2016. The Company used approximately $11.0 million from the proceeds from the Notes to repay the outstanding balance under the Company's previously existing Loan and Security Agreement with Oxford, dated as of July 31, 2014, including the applicable final payment fee due thereunder of $1 million. The Company borrowed the Tranche 2 Term Loan in November 2016 upon the Lenders' confirmation that the Company received positive data in its U.S. pivotal trial of Eversense, and the Company filed a pre-market approval ("PMA") application for Eversense in the United States with the FDA. The Company borrowed the Tranche 3 Term Loan in March 2017 upon the Lenders' confirmation that the Company completed its first commercial sale of its second-generation transmitter in the European Union. The maturity date for all Term Loans is June 1, 2020 (the "Maturity Date").

The Term Loans bear interest at a floating annual rate of 6.31% plus the greater of (i) 90-day U.S. Dollar LIBOR reported in the Wall Street Journal or (ii) 0.64%, provided that the minimum floor interest rate is 6.95%, and require monthly payments. The monthly payments initially consisted of interest-only through December 31, 2017. In January 2018, the Company began to make monthly principal payments that will continue until the Maturity Date.

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

The Amended and Restated Loan and Security Agreement contains customary events of default, including bankruptcy, the failure to make payments when due, the occurrence of a material impairment on the Lenders' security interest over the collateral, a material adverse change, the occurrence of a default under certain other agreements entered into by the Company, the rendering of certain types of judgments against the Company, the revocation of certain government approvals of the Company, 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 Lenders.

Pursuant to the Amended and Restated Loan and Security Agreement, the Company also issued 10-year stock purchase warrants to purchase an aggregate of 116,581, 63,025 and 80,645 shares of common stock with exercise prices of $3.86, $2.38 and $1.86 per share, respectively, to the Lenders.

The Notes are collateralized by all of the Company's consolidated assets. The Notes also contain 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. The Company incurred issuance costs related to the Notes of approximately $0.6 million that are being amortized as additional interest expense over the term of the Notes using the effective interest method. The fair value of the stock purchase warrants, which was estimated to be $0.5 million, was recorded as a discount to the Notes, which is also being amortized as additional interest expense over the term of the Notes using the effective interest method.

At maturity (or earlier prepayment), the Company is also required to make a final payment equal to 9.00% of the aggregate principal balances of the funded Term Loans. This fee is being accrued as additional interest expense over the term of the Notes using the effective interest method.

The Company estimates the fair value of the term notes based on borrowing rates currently available for loans with similar terms (Level 2). At December 31, 2018, the fair value of the term notes was $16.7 million based on prevailing market rates for secured debt.

2023 Notes

In January 2018, the Company issued $50.0 million in aggregate principal amount of 2023 Notes, and in February 2018, the Company issued an additional $3.0 million in aggregate principal amount of 2023 Notes. 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, beginning on August 1, 2018. The 2023 Notes will mature on February 1, 2023, unless earlier repurchased or converted. Payment of the principal of, and accrued and unpaid interest, if any, on the maturity date, and the fundamental change repurchase price of (excluding cash payable in lieu of delivering fractional shares of common stock), the 2023 Notes is subordinated to the prior payment in full in cash or other payment satisfactory to the holders of senior debt, of all existing and future senior debt, which includes the Company's indebtedness under the Amended and Restated Loan and Security Agreement with the Lenders and any refinancing thereof.

The 2023 Notes are convertible into shares of the Company's common stock at the option of the holders at any time prior to the close of business on the business day immediately preceding the maturity date. The conversion rate is initially 294.1176 shares of common stock per $1,000 principal amount of 2023 Notes (equivalent to an initial conversion price of approximately $3.40 per share of common stock), subject to customary adjustments. 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. In addition, following 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 2023 Notes in connection with such a corporate event.

In the second quarter of 2018, the Company issued 85,007 shares of common stock upon the conversion of $250,000 in aggregate principal amount of the 2023 Notes. As of December 31, 2018, the aggregate outstanding principal amount of the 2023 Notes was $52.7 million.

The Company estimates the fair value of the 2023 Notes using commonly accepted valuation methodologies and market-risk measurements that are indirectly observable, such as credit risk (Level 2). At December 31, 2018, the fair value of the 2023 Notes, excluding the derivative liability, was $41.0 million

The following are the scheduled maturities of the Term Loans and 2023 Notes as of December 31, 2018 (in thousands):

2019	$ 10,000
2020	5,000
2021	—
2022	—
2023	52,700
Total	$ 67,700

12. Stockholders' Equity

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

At December 31, 2018, the Company had authorized 450,000,000 shares of common stock and 176,918,381 shares of common stock were issued and outstanding.

Preferred Stock

As of December 31, 2018 and 2017, 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, 2018 or 2017.

Stock Purchase Warrants

In connection with the issuance of the Notes, the Company also 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 exercise prices of $3.86, $2.38 and $1.86 per share, respectively. The fair value of the warrants, which the Company estimated to be $0.5 million, was recorded as a discount to the Notes. These warrants expire on June 30, 2026, November 22, 2026 and March 29, 2027, respectively, and are classified in equity. In connection with the Company's original Loan and Security Agreement with Oxford in 2014, the Company issued to Oxford 10-year stock purchase warrants to purchase an aggregate of 167,570 shares of common stock at an exercise price of $1.79 per share. The fair value of the warrants, which the Company estimated to be $0.2 million, was recorded as a discount to the promissory notes issued to Oxford in connection with the

original Loan and Security Agreement. These warrants expire on November 2, 2020, July 14, 2021 and August 19, 2021, and are classified in equity. The unamortized deferred financing fees and debt discount related to the notes rollover amount will be amortized along with the deferred financing costs and the discount created by the new issuance of the warrants over the term of the loan using the effective interest method. For the years ended December 31, 2018, 2017 and 2016, the Company recorded amortization of discount of debt of $0.2 million, $0.2 million, and $0.1 million, respectively, within interest expense in the accompanying statement of operations.

Stock-Based Compensation

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 connection with the Offering, 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"). The amended and restated 2015 plan became effective as of the date of the pricing of the Offering. 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 initially reserved for issuance pursuant to equity awards was 17,251,115 shares, representing 8,000,000 shares plus up to an additional 9,251,115 shares in the event that options that were outstanding under the Company's equity incentive plans as of February 16, 2016 expire or otherwise terminate without having been exercised (in such case, the shares not acquired will revert to and become available for issuance under the amended and restated 2015 Plan). The number of shares of the Company's common stock reserved for issuance under its amended and restated 2015 Plan 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, 2018, 752,493 shares remained available for grant under the amended and restated 2015 Plan. Effective January 1, 2019, 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 6,944,635 shares.

On May 8, 1997, the Company adopted the 1997 Stock Option Plan (the "1997 Plan" and, together with the 2015 Plan, the "Plans"), 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 Plan provisions. The 1997 Plan was amended in September 2001, to clarify certain provisions regarding the method of exercise, amendment and termination of the 1997 Plan, and the effect of changes in capitalization of the Company. The Board of Directors, which administers the 1997 Plan, determines the number of options granted, the vesting period and the exercise price. The Board of Directors may terminate the 1997 Plan at any time. Options granted under the 1997 Plan expire ten years after the date of grant. The total number of shares of common stock that may be issued pursuant to options under the 1997 Plan may not exceed, in the aggregate, 9,175,860 shares of common stock, less any shares of common stock issued by the Company as restricted common stock.

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.

Prior to the completion of the Acquisition, the fair value of the common stock was determined and approved by the Board of Directors after considering several factors, including the results obtained from an independent third-party valuation, the Company's historical financial performance and financial position, the Company's future prospects and opportunity for liquidity events, the price per share of its convertible preferred stock offerings and general industry and economic trends. In establishing the estimated fair value of the common stock, the Company considered the guidance set forth in American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation.* Subsequent to the completion of the Acquisition, the fair value of the common stock

was obtained from quoted market prices on the Over-the-Counter Bulletin Board (OTCBB) as provided by OTC Market Groups, Inc.

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

	For the year ended December 31,					
	2018		2017		2016	
Expected term of options	6.5	years	6.5	years	6.5	years
Expected volatility rate	63.52 -66.95	%	60.66 -75.43	%	58.99 -61.39	%
Risk-free rate	2.45 -3.08	%	1.90 -2.30	%	1.40 -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. Given the lack of historic exercise data, 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.

Due to a lack of a public market for the Company's common stock for an extended period of time, the Company utilized 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. Pre-vesting forfeitures are based on the Company's actual forfeitures for the years ended December 31, 2018 and 2017 and have not been material.

Employee stock-based compensation expense for employee granted stock options was $6.4 million, $4.1 million, and $3.6 million for the years ended December 31, 2018 and 2017 and 2016, respectively, classified as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Sales and marketing	$ 1,685	$ 509	$ 202
Research and development	1,364	930	518
General and administrative	3,326	2,659	2,865
Total stock-based compensation	$ 6,375	$ 4,098	$ 3,585

Stock-based compensation expense for restricted stock awards was $0.3 million, $0.3 million, and $1.6 million for the years ended December 31, 2018, 2017 and 2016 respectively, all of which was classified as administrative expense in the accompanying consolidated statements of operations.

As of December 31, 2018, there was $15.8 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 2.88 years. There was no unrecognized compensation cost related to non-vested restricted stock awards as of December 31, 2018.

Stock option activity under the Plans during the years ended December 31, 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	
Options granted	5,674	$ 2.24	
Options exercised	(509)	$ 0.64	
Options canceled/forfeited	(159)	$ 2.47	
Options outstanding as of December 31, 2017	16,395	$ 1.61	
Options granted	7,533	$ 3.03	
Options exercised	(1,439)	$ 1.20	
Options canceled/forfeited	(1,031)	$ 2.43	
Options outstanding as of December 31, 2018	21,458		6.68
Options vested and expected to vest as of December 31, 2018	21,458	$ 2.10	
Options exercisable as of December 31, 2018	11,637	$ 1.47	5.27

The weighted average grant-date fair value of stock option awards granted in 2018, 2017 and 2016 was $1.91, $1.36, and $1.76 per share, respectively.

For the years ended December 31, 2018 and 2017 and 2016, 1,438,671, 508,625, and 268,670 options were exercised, respectively, with an aggregate intrinsic value at the time of exercise of $3.7 million, $1.0 million, and $0.7 million, respectively.

The total fair value of options that vested during 2018 and 2017 were approximately $5.4 million and $3.6 million, respectively.

The aggregate intrinsic value of the options currently exercisable at December 31, 2018 was $14.0 million. The aggregate intrinsic value of stock options outstanding at December 31, 2018 was $15.4 million, which approximated the aggregate intrinsic value of options vested and expected to vest as of December 31, 2018.

The weighted average grant date fair value of the unvested stock option awards outstanding at December 31, 2018 and 2017 was $1.76 and $1.25 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, 2018 were $1.20, $0.92 and $1.46 per share, respectively.

Restricted Stock Awards

The Company issued 398,525 shares of restricted stock to the chairman of the Company's board of directors (the "Chairman") in December 2015, half of which were vested upon grant and half of which vested upon the completion of the Offering, pursuant to an agreement between the Company and the Chairman, as described in greater detail in Note 14. In June 2016, the Company issued a fully vested restricted stock award for 300,000 shares of common stock to the Chairman to settle the outstanding obligations under the agreement. The Company recognized stock-based compensation expense of $1.2 million in the year ended December 31, 2016, related to the grant and vesting of this restricted stock.

The Company issued 91,786 shares of fully vested restricted stock in lieu of cash payment to members of the board of directors and consultants for services performed during 2018. Additionally, the Company granted 23,450 shares of restricted stock in 2017, which vest on a straight-line basis over the requisite service period through 2018, to an employee in lieu of cash payment for services performed while employed by the Company.

A summary of the Company's restricted stock award activity for the year ended December 31, 2018 is presented below:

	Number of Shares	Weighted-Average Grant Price
Restricted Stock Awards nonvested at December 31, 2017	18,760	
Granted	91,786	$ 3.40
Vested	110,546	$ 3.26
Cancelled and forfeited	—	$ —
Restricted Stock Awards nonvested at December 31, 2018	—	

For the year ended December 31, 2018, the weighted average share price on date of exercise for restricted stock awards was $3.40.

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, 2018 and 2017 is as follows (in thousands):

	December 31,	
Deferred income tax assets (liabilities)	**2018**	**2017**
Deferred Tax Assets:		
Net operating loss carryforwards	$ 67,823	$ 54,748
Capitalized start-up costs	10,487	13,229
R&E credit carryforwards	7,875	6,680
Stock-based compensation	2,024	1,508
Change in fair value of derivative liability	3,978	—
Other	355	265
Total deferred tax asset	92,542	76,430
Deferred tax liabilities:		
Amortization of debt discount	(3,419)	—
Net deferred tax assets before valuation allowance	89,123	76,430
Valuation allowance	(89,123)	(76,430)
Net deferred tax assets	$ —	$ —

The net change in valuation allowance for the years ended December 31, 2018 and 2017 was a net increase of $12.7 million and a net decrease of $7.3 million, respectively.

The increase in valuation allowance is primarily due to net losses and credits incurred in 2018. 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, 2018, the Company had NOL carryforwards of $291.4 million and had research and experimental credit carryforwards of $7.9 million. These carryforwards will expire in varying amounts between 2019 and 2038. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of NOL carryforwards and research and development

credit carryforwards which can be available in future years. No income tax benefit was recognized in the Company's Statement of Operations for stock-based compensation arrangements due to the Company's net loss position.

A reconciliation of the Company's estimated U.S. federal statutory rate to the Company's effective income tax rate for the years ended December 31, 2018, 2017 and 2016 is as follows:

	Year Ended December 31,		
	2018	2017	2016
Tax at U.S. Federal Statutory rate	21.00 %	34.00 %	34.00 %
State taxes, net	2.27	5.15	5.45
Research and development credit	1.27	1.79	1.82
Tax reform	—	(52.54)	—
State tax rates changes	(10.64)	—	—
Other non-deductible items	(0.39)	(0.86)	0.07
Increase (decrease) in valuation allowance	(13.51)	12.46	(41.34)
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, 2016 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 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 has completed our 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 2018, 2017 and 2016 is as follows (in thousands):

	2018	2017	2016
Gross unrecognized tax benefit at beginning of year	$ 1,670	$ 1,383	$ 1,174
Increase from tax positions taken in prior years	—	22	9
Increase from tax positions in current year	323	265	200
Lapse of statute of limitations / expiration	(24)	—	—
Gross unrecognized tax benefit at end of year	$ 1,969	$ 1,670	$ 1,383

The Company did not incur any penalties or interest payable to taxing authorities in 2018, 2017 and 2016.

The Company's U.S. Federal and state income tax returns from 1999 to 2017 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, 2018 and 2017, revenues from Roche were $16.2 million and $5.8 million, respectively, and amounts due from them were $6.3 million and $3.3 million, respectively.

In December 2015, the Chairman received a restricted stock award of 398,525 shares of common stock pursuant to an agreement entered into with the Company (the "December Agreement") that superseded a pre-existing agreement. One half of the shares covered by this restricted stock award were fully vested on grant. The remainder vested in full upon the completion of the Company's Offering, which was the specific performance condition of the award. Additionally, as a result of the completion of the Offering, pursuant to the December Agreement, the Chairman was entitled to receive estimated compensation in the amount of $0.8 million. In June 2016, the Chairman received a restricted stock award of 300,000 shares of common stock pursuant to an agreement entered into with the Company that superseded the December Agreement and satisfied the outstanding compensation obligation under the December Agreement. All of the shares covered by this restricted stock award were fully vested on date of grant.

As described in Note 11, on December 7, 2015, the Company entered into a note purchase agreement with a stockholder, Energy Capital, pursuant to which the Company could borrow an aggregate principal amount of up to $10.0 million from Energy Capital. During the year ended December 31, 2016, the Company borrowed an aggregate of $2.5 million from Energy Capital under the facility, which was repaid in full in 2016 and the facility was terminated.

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 was derived from quoted prices in active markets for identical assets. The valuation technique used to measure the fair value of the Company's debt instruments, all of which have counterparties with high credit ratings, were valued based on quoted market prices.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company has segregated its financial assets and liabilities that are measured at fair value on a recurring basis into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below. The inputs used in measuring the fair value of the Company's money market funds included in cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of the funds.

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, 2018 and 2017 (in thousands):

	December 31, 2018			
	Total	Level 1	Level 2	Level 3
Liabilities				
Embedded conversion option	$ 17,091	$ —	$ —	$ 17,091

	December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 4,706	$ 4,706	$ —	$ —
Government and agency securities	7,987	—	7,987	—
Corporate debt securities	17,708	—	17,708	—

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 2023 Notes
December 31, 2017	$ —
Issuance of the 2023 Notes	17,300
Change in fair value included in other income (expense)	(209)
December 31, 2018	$ 17,091

The recurring Level 3 fair value measurements of the embedded features of the 2023 Notes, using the binomial valuation technique, include the following significant unobservable inputs:

Unobservable Inputs	Assumptions
Discount rate	13.2 %
Stock price volatility	67 %
Risk free rate	2.5 %
Dividend yield	— %

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, 2018 and 2017. 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 .

Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

The Company has no financial assets and liabilities that are measured at fair value on a non-recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company has no non-financial assets and liabilities that are measured at fair value on a recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

The Company measures its long-lived assets, including property and equipment, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be impaired. No such fair value impairment was recognized in 2018, 2017, and 2016.

16. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal years 2018 and 2017 is presented in the following table (in thousands, except per share data):

	For the Quarter Ended			
	March 31	June 30	September 30	December 31
2018:				
Revenue, 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)
2017:				
Revenue, primarily from a related party	$ 553	$ 814	$ 2,097	$ 2,909
Gross profit	$ (492)	$ (900)	$ (860)	$ (1,133)
Operating expenses	$ 11,905	$ 10,741	$ 15,745	$ 14,537
Operating loss	$ 12,397	$ 11,641	$ 16,605	$ 15,670
Net loss	$ 13,073	$ 12,374	$ 17,379	$ 16,275
Basic and diluted net loss per share (1)	$ (0.14)	$ (0.12)	$ (0.13)	$ (0.12)

(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, accordingly, has recorded aggregate liabilities for all claims of approximately $0, $0, and $40,000 as of December 31, 2018, 2017 and 2016, respectively. These amounts are reported on the consolidated balance sheets within accrued and other liabilities and other noncurrent liabilities. The Company believes, based upon information it currently possesses and considering established accruals for liabilities and its insurance coverage, that the ultimate outcome of these proceedings and actions is unlikely to have a material effect on the Company's consolidated financial statements.

18. Subsequent Events

On January 31, 2019, the Company entered into an amendment to its distribution agreement (the “Amendment”) with Roche Diagnostics International AG and Roche Diabetes Care GmbH (collectively, “Roche”), which amends that certain distribution agreement, by and between the Company and Roche, dated May 23, 2016, as amended (the “Distribution Agreement”). Pursuant to the Amendment, the term of the Distribution Agreement has been extended through January 31, 2021. The parties have agreed to certain purchases of Eversense and pricing terms for the extended term of the Distribution Agreement. In addition, Roche ’ s role as the exclusive distributor of Eversense has been expanded to provide Roche with 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. Except as modified by the Amendment, the material terms and conditions of the Distribution Agreement remain in full force and effect.

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, 2018, 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, 2018, 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, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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, 2018.

This Annual Report does not include an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Item 9B. Other Information

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, or the 2019 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 2019 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 2019 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," "Executive Officers Who Are Not Directors" 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 2019 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 2019 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 2019 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 2019 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm."

Item 15. Exhibits and Financi al 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).
10.1	Lease Agreement, dated as of February 4, 2008, by and between Senseonics, Incorporated and Seneca Meadows Corporate Center III Limited Partnership, as amended by the First Amendment to Lease, dated as of September 25, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.1.1	Second Amendment to Lease, by and between Senseonics, Incorporated and Seneca Meadows Corporate Center III L.L.L.P., dated as of January 21, 2016 (incorporated by reference to Exhibit 10.1.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-208984) filed on February 17, 2016).
10.2+	Amended and Restated 1997 Stock Option Plan of Senseonics, Incorporated, as amended to date (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.3+	Form of Incentive Stock Option Agreement under Senseonics, Incorporated Amended and Restated 1997 Stock Option Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).

Exhibit Number	Description of Document
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+	Amended and Restated Executive Employment Agreement by and between Senseonics, Incorporated and R. Don Elsey, dated as of July 27, 2015 (incorporated by reference to Exhibit 10.13 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 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).
10.14	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).
10.15	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).
10.16	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).
10.17#	Exclusive Distribution Agreement, by and between Senseonics, Incorporated and Rubin Medical, dated as of September 14, 2015 (incorporated by reference to Exhibit 10.24 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.18+	Form of 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-8 (File No. 333-210586) filed on April 4, 2016).
10.19+*	Non-Employee Director Compensation Policy, as amended.
10.20	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).
10.21	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).

Exhibit Number	Description of Document
10.22#	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).
10.23	Amended and Restated Loan and Security Agreement, by and among the Registrant, Senseonics, Incorporated, Oxford Finance LLC and Silicon Valley Bank, dated as of June 30, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed on August 9, 2016).
10.24	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).
10.25	Form of Secured Promissory Note issued by the Registrant to Oxford Finance LLC and Silicon Valley Bank, dated as of June 30, 2016 (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed on August 9, 2016).
10.26#	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).
10.27	First Amendment to Amended and Restated Loan and Security Agreement, by and among the Registrant, Senseonics, Incorporated, Oxford Finance LLC and Silicon Valley Bank, dated as of March 29, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed on May 4, 2017).
10.28	Second Amendment to Amended and Restated Loan and Security Agreement, by and among the Registrant, Senseonics, Incorporated, Oxford Finance LLC and Silicon Valley Bank, dated as of March 29, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37717) filed on October 31, 2017).
10.29	Sales Agreement, dated March 30, 2018, by and between the Registrant and Cowen and Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on March 30, 2018).
10.30+	Third Amendment to Amended and Restated Loan and Security Agreement, by and among the Registrant, Senseonics Incorporated, Oxford Finance LLC and Silicon Valley Bank, dated as of January 25, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the Quarter ended March 31, 2018 (File No. 001-37717) filed on May 10, 2018).
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.
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.

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 15, 2019

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Timothy T. Goodnow, Ph.D., and Jon Isaacson, 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 15, 2019
/s/ Jon Isaacson Jon Isaacson	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 15, 2019
/s/ Stephen P. DeFalco Stephen P. DeFalco	Chairman of the Board of Directors	March 15, 2019
/s/ M. James Barrett, Ph.D. M. James Barrett, Ph.D.	Director	March 15, 2019
/s/ Steven Edelman, M.D. Steven Edelman, M.D.	Director	March 15, 2019
/s/ Edward J. Fiorentino Edward J. Fiorentino	Director	March 15, 2019
/s/ Peter Justin Klein, M.D., J.D. Peter Justin Klein, M.D., J.D.	Director	March 15, 2019
/s/ Douglas Prince Douglas Prince	Director	March 15, 2019
/s/ Douglas A. Roeder Douglas A. Roeder	Director	March 15, 2019

Senseonics Holdings, Inc.
Non-Employee Director Compensation Policy
(As amended effective October 1, 2018)

Each member of the Board of Directors (the " ***Board*** ") who is not also serving as an employee of Senseonics Holdings, Inc. (the " ***Company*** ") or any of its subsidiaries (each such member, an " ***Eligible Director*** ") will receive the compensation described in this Non-Employee Director Compensation Policy. A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer :
    a. All Eligible Directors: $37,500
    b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $30,000

2. Annual Committee Member Service Retainer :
    a. Member of the Audit Committee: $7,500
    b. Member of the Compensation Committee: $6,000
    c. Member of the Nominating and Corporate Governance Committee: $4,000

3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer) :
    a. Chairman of the Audit Committee: $11,250
    b. Chairman of the Compensation Committee: $6,600
    c. Chairman of the Nominating and Corporate Governance Committee: $3,625

Election to Receive Common Stock in Lieu of Cash

An Eligible Director may make an election to receive all or a portion of his or her annual cash compensation described above in the form of shares of the Company's common stock (the " ***Common Stock*** "). Elections must be made in multiples of 5% of an Eligible Director's aggregate cash retainer.

1. Timing of Elections:
    a. *Current Eligible Directors* : Elections must be made prior to the beginning of each fiscal year with respect to cash compensation to be earned during such fiscal year.
    b. *New Eligible Directors* : Elections for the first quarter of service must be made within 30 days of becoming an Eligible Director, provided that such election shall be applicable only to the portion of the cash retainers earned after the date of the election.

c. *New committee member or committee chair* : Elections for the first quarter of service must be made prior to the date that the Eligible Director becomes a committee member or committee chair (or, if a new Eligible Director, within 30 days of becoming a committee member or committee chair, provided that such election shall be applicable only to the portion of the cash retainer earned after the date of the election).

2. Description of Common Stock : The shares of Common Stock will be granted under the Company's 2015 Equity Incentive Plan, as amended (the "Plan"). The Common Stock will be granted as soon as reasonably practicable following the last day of each fiscal quarter in which the service occurred. The actual number of shares of Common Stock granted will be determined based on the closing price of the Company's Common Stock on the NYSE MKT on the date of grant.

Equity Compensation

The equity compensation set forth below will be granted under the Company's Amended and Restated 2015 Equity Incentive Plan (the " ***Plan*** "), subject to the approval of the Plan by the Company's stockholders. All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant : For each Eligible Director, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase shares of Common Stock with an aggregate Black Scholes option value of $212,500. The shares subject to each such stock option will vest monthly over a three year period, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date.

2. Annual Grant : On the date of each annual stockholders meeting of the Company, each Eligible Director who continues to serve as a member of the Board following such stockholders meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase shares of Common Stock with an aggregate Black Scholes option value of $106,500. The shares subject to each such stock option will vest on the earlier of the one year anniversary of the grant date or the next annual stockholders meeting , subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date.

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-3 No. 333-224057) of Senseonics Holdings, Inc.,

(2) Registration Statement (Form S-8 No. 333-210586) pertaining to the equity incentive plans and employee stock purchase plan of Senseonics Holdings, Inc., and

(3) Registration Statement (Form S-8 No. 333-224827) pertaining to the equity incentive plans and employee stock purchase plan of Senseonics Holdings, Inc.;

of our report dated March 12, 2019, with respect to the consolidated financial statements of Senseonics Holdings, Inc. included in this Annual Report (Form 10-K) of Senseonics Holdings, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young, LLP
Tysons, VA
March 15, 2019

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 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 15, 2019

/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, Jon Issacson, 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 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 15, 2019

/s/ Jon Issacson
Jon Issacson
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 Jon Isaacson, 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, 2018 (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 15th day of March, 2019.

/s/ Timothy T. Goodnow, Ph.D.

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

/s/ Jon Issacson

Jon Issacson
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.