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

FORM 10-K

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

For the fiscal year ended December 31, 2016

Commission file number 001-37717

SENSEONICS HOLDINGS, INC.

Incorporated under the Laws of the
State of Delaware

I.R.S. Employer Identification No.
47-1210911

20451 Seneca Meadows Parkway
Germantown, MD 20876-7005
(301) 515-7260

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

Title of Each Class:	Name of Each Exchange on which Registered
Common Stock, \$0.001 par value	NYSE MKT LLC

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of June 30, 2016, 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 \$217.8 million based on the closing price of the registrant's common stock, as reported by the NYSE-MKT on such date.

As of February 22, 2017, 93,955,527 shares of common stock, \$0.001 par value, were outstanding.

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 and availability of data from our clinical trials;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approval of Eversense;
- the clinical utility of Eversense;
- our ability to develop future generations of Eversense;
- our ability to access our credit facilities in the future;
- 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.

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ABOUT THIS ANNUAL REPORT

We were originally incorporated as ASN Technologies, Inc. in Nevada on June 26, 2014. On December 4, 2015, we were reincorporated in Delaware and changed our name to Senseonics Holdings, Inc. Also, on December 4, 2015, we entered into a merger agreement with Senseonics, Incorporated and SMSI Merger Sub, Inc., or the Merger Agreement, to acquire Senseonics, Incorporated. The transactions contemplated by the Merger Agreement were consummated on December 7, 2015, referred to throughout this Annual Report as the Acquisition. Pursuant to the terms of the Merger Agreement, (i) all issued and outstanding shares of Senseonics, Incorporated's preferred stock were converted into shares of Senseonics, Incorporated common stock, \$0.01 par value per share, or the Senseonics Shares, (ii) all outstanding Senseonics Shares were exchanged for 57,739,953 shares of our common stock, \$0.001 par value per share, or the Company Shares, reflecting an exchange ratio of one Senseonics Share for 2.0975 Company Shares, or the Exchange Ratio, and (iii) all outstanding options and warrants to purchase Senseonics Shares, or the Senseonics Options and Senseonics Warrants, respectively, were each exchanged or replaced with options and warrants to acquire shares of our common stock, or the Company Options and Company Warrants, respectively. Accordingly, Senseonics, Incorporated became our wholly-owned subsidiary. In connection with the closing of the Acquisition, the directors and executive officers of Senseonics, Incorporated became directors and executive officers of the Company.

Following the closing of the Acquisition, the business of Senseonics, Incorporated became our sole focus and all of our operations following the closing of the Acquisition consist of the historical Senseonics, Incorporated business. 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 (i) Senseonics, Incorporated prior to the closing of the Acquisition, and (ii) Senseonics Holdings, Inc. and its subsidiaries subsequent to the closing of the Acquisition.

PRESENTATION OF FINANCIAL INFORMATION

On December 7, 2015, ASN Technologies, Inc. acquired all of the outstanding capital stock of Senseonics, Incorporated. While ASN Technologies, Inc. was the legal acquirer of Senseonics, Incorporated in the transaction, Senseonics, Incorporated was deemed to be the acquiring company for accounting purposes. As such, the transaction was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America, and ASN Technologies, Inc.'s historical financial statements have been replaced with Senseonics, Incorporated's historical financial statements. The historical financial statements of ASN Technologies, Inc. are not included in this Annual Report because the assets, liabilities and operations of ASN Technologies, Inc. were minimal. All common share, additional paid-in capital and per share amounts in the consolidated financial statements and related notes have been retrospectively adjusted to reflect the Exchange Ratio.

TRADEMARKS

"Senseonics," the Senseonics logo and other trademarks or service marks of Senseonics Holdings, Inc. appearing in this Annual Report are the property of Senseonics Holdings, Inc. This Annual Report contains additional trade names, trademarks and service marks of others, which are the property of their respective owners.

PART I

Item 1. Business

Overview

We are a medical technology company focused on the 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. Our first generation continuous glucose monitoring, or CGM, system, Eversense, is a reliable, long-term, implantable CGM system that we have designed to continually and accurately measure glucose levels in people with diabetes for a period of up to 90 days, as compared to five to seven days for currently available CGM systems. We believe Eversense 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. Our Eversense system is currently approved for sale in Europe and we submitted our pre-market approval, or PMA, application to the U.S. Food and Drug Administration, or FDA, in October 2016. We expect the PMA process could take between six and 18 months. We intend to initiate commercial launch in the United States immediately upon receipt of PMA approval.

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 International Diabetes Federation, or IDF, an estimated 415 million people worldwide had diabetes in 2015. The number of people with diabetes worldwide is estimated to grow to 642 million by 2040 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 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. We expect that the approval of the Eversense PMA will have an "adjunctive" label initially. Our plans will be to pursue a "non-adjunctive" label as soon as possible. Currently available CGM systems are often inconvenient, requiring frequent sensor replacement and an extra device, called a receiver, to monitor glucose readings, and have limited safety features.

We have designed Eversense to continually and accurately measure glucose levels under the skin for up to 90 days, as compared to five to seven 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 estimates by Close Concerns, Inc., an independent diabetes information company, or Close Concerns, global sales for CGM systems and insulin pumps for people with intensively managed diabetes were \$2.7 billion in 2014, of which \$523 million represented sales of CGM systems, a 31% increase from 2013. United States sales for CGM systems and insulin pumps for people with intensively managed diabetes were \$1.7 billion in 2014, of which \$381 million represented sales of CGM systems, a 33% increase compared to 2013. In comparison, global SMBG sales were \$6.7 billion in 2014, a decline of 7% compared to 2013, driven largely by downward pricing pressure.

Based on industry sources and current industry trends, we estimate that U.S. sales of CGM systems will grow at a compound annual growth rate, or CAGR, ranging from 35% to 40%, reaching approximately \$3 billion to \$3.7 billion by 2020. We also estimate that by 2020 global sales for insulin pumps will increase to \$3.5 billion, while global sales for SMBG will decline to \$5.8 billion. We expect the growth in sales of CGM systems to be driven primarily by increased penetration of CGM in the Type 1 diabetic population, as it potentially becomes a standard of care, reaching up to 45% penetration of the Type 1 diabetic population in the United States by 2020, compared to 8% in 2014. We believe that the increased penetration of CGM will be driven by higher awareness of the clinical benefits of CGM by people with diabetes, healthcare providers and third-party payors, insulin pump integration, an improving coverage and reimbursement environment and additional product innovation, including increased convenience, accuracy and sensor duration.

We initiated our U.S. pivotal trial in January 2016 and completed this trial in July 2016. In November 2016, at the Diabetes Technology Meeting we presented the trial data. 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 8.8% 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.

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. 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, LifeCell and Medtronic.

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

Diabetes Overview

Diabetes is a chronic, life-threatening disease for which there is no known cure and arises as a result of the body's inability to produce or effectively utilize the hormone insulin. Insulin regulates blood glucose levels and allows cells to utilize glucose, the primary source of energy for cells. Glucose must be maintained at certain concentrations in the blood in order to permit optimal cell function and health. For people with diabetes, the inability to produce sufficient levels of insulin, or the failure to utilize insulin effectively, causes blood glucose levels to rise above the optimal range. 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 most recent information available from the Centers for Disease Control and Prevention, or CDC, diabetes was the seventh leading cause of death in the United States in 2010, directly resulting in approximately 69,000 deaths and complications from diabetes contributed to approximately 234,000 deaths in the same year.

According to the IDF, an estimated 415 million people worldwide had diabetes in 2015. The number of people with diabetes worldwide is estimated to grow to 642 million by 2040 due to a number of reasons including changes in

dietary trends, an aging population and increased prevalence of the disease in younger people. Based on estimates by the IDF diabetes caused over 5 million deaths in 2015 and had a total global economic cost of over \$700 billion.

Diabetes is typically classified into two primary types:

- **Type 1 diabetes** is an autoimmune disorder that usually develops during childhood or adolescence and is characterized by the inability of the body to produce insulin, resulting from destruction of the hormone producing beta cells in the pancreas. People with Type 1 diabetes must administer insulin, either by injection or insulin pump, to survive. There is no known way to prevent Type 1 diabetes. Based on the most recent information available from the CDC, there were in excess of one million people with diagnosed Type 1 diabetes in the United States in 2012. Based on the most recent information available from the IDF and the CDC, we estimate that there were in excess of 1.7 million people with diagnosed Type 1 diabetes in Europe in 2015.
- **Type 2 diabetes** is a metabolic disorder which generally develops in adults and results when the body is unable to produce sufficient amounts of insulin or becomes insulin resistant. Although it is not precisely known how Type 2 diabetes develops, genetics, family history and environmental factors, such as excess weight and physical inactivity, are viewed as contributing factors. As Type 2 diabetes progresses, individuals may require diet and nutrition management, exercise, oral medications or the administration of insulin to regulate blood glucose levels. Based on the most recent information from the IDF, we estimate there were approximately 20 million people with diagnosed Type 2 diabetes in the United States in 2015. Of these people with Type 2 diabetes, we estimate that approximately 5.7 million people in the United States utilize insulin, either by injection or insulin pump, to manage their diabetes. We estimate that there were approximately 33 million people with diagnosed Type 2 diabetes in Europe in 2015.

Importance of Glucose Monitoring

If people with diabetes can maintain their blood glucose levels within normal limits, they can significantly mitigate the negative effects of diabetes. In the December 2005 edition of the *New England Journal of Medicine*, the authors of a peer-reviewed study concluded that intensive diabetes therapy, which included the use of multiple daily injections, or MDI, or an insulin pump, in combination with SMBG at least four times per day, with the goal of maintaining blood glucose levels within normal limits, has long-term beneficial effects on lowering the risk of cardiovascular disease in people with Type 1 diabetes. In the study, this intensive diabetes therapy reduced the risk of any cardiovascular disease event by 42% and the risk of non-fatal heart attack, stroke or death from cardiovascular disease by 57%, as compared to less intensive diabetes therapy. Earlier studies also demonstrated benefits of intensive diabetes therapy in lowering the long-term risks of other complications of diabetes, including vision loss, kidney damage and nerve damage.

Despite the clinically demonstrated benefits of maintaining blood glucose levels within the normal range, doing so can be challenging and inconvenient for people with diabetes. Blood glucose levels are affected by many factors, including the carbohydrate and fat content of meals, exercise, stress, illness or impending illness, hormonal releases, variability in insulin absorption rates and changes in the effects of insulin on the body. As a result, people with diabetes often experience unpredictable and significant fluctuations in their glucose levels above the normal range, which is referred to as hyperglycemia, or below the normal range, which is referred to as hypoglycemia.

- **Hyperglycemia** occurs when blood glucose levels rise above the normal range, which generally occurs when the body does not produce sufficient levels of insulin or fails to effectively utilize insulin. If not effectively managed, hyperglycemia often results in chronic long-term complications, such as heart disease, limb amputations, loss of kidney function, blindness, seizures, coma and even death.
- **Hypoglycemia** occurs when blood glucose levels fall below the normal range, which can be caused by a number of factors including excess insulin administration. In cases of severe hypoglycemia, people with diabetes risk acute complications, such as loss of consciousness, coma or death.

In an attempt to maintain blood glucose levels within the normal range, people with diabetes must first accurately measure their blood glucose levels and, if necessary, make therapeutic and dietary adjustments. When blood glucose levels are high, people with diabetes often administer insulin in an effort to decrease blood glucose levels. In contrast, when blood glucose levels are low, people with diabetes often ingest carbohydrates in an effort to raise blood glucose levels. As these adjustments are made, additional blood glucose measurements may be necessary to gauge the individual's response to the adjustments. People with diabetes frequently overcorrect and fluctuate between hyperglycemic and hypoglycemic states, often multiple times during the same day. As a result, many people with diabetes are routinely outside the normal blood glucose range, and many are often unaware that their glucose levels are either too high or too low. The inability to effectively control and monitor blood glucose levels and the associated potential for serious complications from hyperglycemia and hypoglycemia can be frustrating, overwhelming and, at times, dangerous.

Methods of Glucose Measurement

The most accurate method of measuring blood glucose levels is through laboratory testing. Outside of laboratory testing, there are three primary methods to measure blood glucose levels:

- **Real-time in-hospital testing** of blood glucose levels is performed by healthcare providers at the point of care, using *in vitro* analyzers, such as the YSI Inc., or YSI, glucose analyzer. Outside of laboratory testing, in-hospital testing is the most accurate method of measuring blood glucose levels. However, measurement of blood glucose through in-hospital testing is not a practical solution for the daily monitoring of glucose levels by people with diabetes.
- **Self-monitoring of blood glucose**, or SMBG, is the traditional method that people with diabetes use to monitor their blood glucose levels. Although less accurate than in-hospital testing, SMBG systems are the prevalent method for the daily monitoring of glucose levels. SMBG requires people with diabetes to lance their fingertips to obtain a blood drop that is applied to a test strip inserted into a blood glucose meter. SMBG testing is generally done multiple times per day.
- **Continuous glucose monitoring**, or CGM, is a way for people with diabetes to monitor glucose levels in real-time throughout the day or night. CGM systems involve the implantation of sensors into the body to measure glucose levels in the interstitial fluid, which is the fluid that surrounds tissues in the body, and typically relay the data, through a transmitter, to an external receiver every five minutes. While each individual CGM measurement is slightly less accurate than that of SMBG, the frequent, automatic measurements provided by CGM help people with diabetes reduce the risk of hypoglycemic and hyperglycemic events by providing them with real-time glucose readings, glucose trend information and alerts. Current CGM systems require twice daily calibration using blood drawn through a fingerstick. The FDA requires that CGM measurements, performed by selected systems, be confirmed with a real-time test-strip reading using blood obtained by a fingerstick prior to self-medicating with insulin. Those systems that do not have this requirements are considered to have the “dosing claim,” meaning that they are labeled as “non-adjunctive” devices.

Benefits of Continuous Glucose Monitoring

More frequent and accurate testing of blood glucose levels provides people with diabetes with a greater ability to maintain their blood glucose levels within normal limits allowing them to more effectively manage their diabetes. The American Diabetes Association, or the ADA, recommends that people with intensively managed diabetes test their blood glucose levels after eating, at bedtime, before exercise or critical tasks and after treating for low blood glucose. Significantly more frequent testing may be required to reach optimal blood glucose levels safely without falling into hypoglycemia. We use the term "intensively managed diabetes" to refer to people with Type 1 diabetes and those people with Type 2 diabetes who require insulin to be administered through an insulin pump or MDI.

The ability of people with diabetes to realize the benefits of more frequent glucose testing using SMBG is inherently limited and inconvenient. SMBG generally requires people with diabetes to draw multiple blood samples over the course of a day and night. Lancing and interchange of the fingers or alternate sites, in order to draw blood samples,

can sometimes be painful and is particularly difficult for children. Moreover, even if a person tests glucose levels with SMBG several times each day, each measurement represents a single blood glucose value at a single point in time, which limits the ability to detect trends in glucose levels. In contrast, CGM, due to its continuous and automatic monitoring, can provide significant data on trends in glucose levels. The ability to detect rising or falling glucose levels, and the rate at which such levels are rising or falling, is critical for people with diabetes, and their healthcare providers, to actively manage this condition. For instance, the risk of hypoglycemia is greatest when individuals are sleeping. CGM systems continue reading glucose levels during sleep, and even provide alerts, in contrast to SMBG, which does not allow for testing during sleep.

The beneficial effects of CGM have been validated in multiple clinical trials. According to a study published in the November 2009 edition of *Diabetes Care*, people who intensively managed their diabetes consistently with CGM over a six-month period had lower A1C levels, a measure of the three-month average of glucose in the blood, than those who did not. More recently, two studies published in the April 2011 and January 2012 editions of *Diabetes Care*, showed improved glycemic control in people with Type 1 and Type 2 diabetes who use CGM systems, compared to people who use SMBG, further supporting the benefits of CGM in helping people with diabetes stay within a healthy glycemic range.

In addition to the health benefits of continuous and automatic blood glucose measurements provided by CGM, CGM is generally considered to be more convenient than SMBG. People who intensively manage their diabetes will typically measure their blood glucose levels three to ten times per day, including during the night. For children with diabetes, this may necessitate a parent or caretaker waking the child multiple times during the night to take these measurements. People who use SMBG must carry a fully supplied kit that may include a spring-loaded needle, or lancet, disposable test strips, cleansing wipes, and the glucose meter, and then safely dispose of the used supplies, which can be inconvenient. In addition, at times, SMBG may require multiple finger pricks to obtain a sufficient blood sample for such tests, which can be further compounded by the fact that people with diabetes often experience decreased feeling in their fingers.

The Market for CGM

We estimate that, of the approximately 39 million people diagnosed with diabetes in the United States, Canada, Australia and the other select regions that we intend to target with Eversense (which include Scandinavia, Germany, the United Kingdom, Italy, Switzerland, the Netherlands, Israel, Finland and Slovenia), 35%, or approximately 13 million people, are insulin users. We believe that, of those 13 million insulin users, approximately 46%, or six million people, intensively manage their diabetes. According to estimates by Close Concerns, global sales for CGM systems and insulin pumps for people with intensively managed diabetes were \$2.7 billion in 2014, of which \$523 million represented sales of CGM systems, a 31% increase compared to 2013. United States sales for CGM systems and insulin pumps for people with intensively managed diabetes were \$1.7 billion in 2014, of which \$381 million represented sales of CGM systems, a 33% increase compared to 2013. In comparison, global SMBG sales were \$6.7 billion in 2014, a decline of 7% compared to 2013, driven largely by downward pricing pressure.

Based on industry sources and current industry trends, we estimate that U.S sales of CGM systems will grow at a CAGR ranging from 35% to 40%, reaching approximately \$3 billion to \$3.7 billion by 2020. We also estimate that by 2020 global sales for insulin pumps will increase to \$3.5 billion, while global sales for SMBG will decline to \$5.8 billion. We expect the growth in sales of CGM systems to be driven primarily by increased penetration of CGM in the Type 1 diabetic population, as it potentially becomes a standard of care, reaching up to 45% penetration of the Type 1 diabetic population in the United States by 2020, compared to 8% in 2014. We believe that the increased penetration of CGM will be driven by higher awareness of the clinical benefits of CGM by people with diabetes, healthcare providers and third-party payors, insulin pump integration, an improving coverage and reimbursement environment and additional product innovation, including increased convenience, accuracy and sensor duration.

Limitations of Currently Available CGM Systems

There are a limited number of currently available CGM systems for people with diabetes to monitor their glucose levels. Although these CGM systems provide significant advantages to people with diabetes who are intensively

managing their diabetes as compared to SMBG, they have certain inherent limitations and shortcomings that we believe limit their rate of user adoption and often lead to noncompliance and discontinuation. These limitations include:

- **Short sensor life and accuracy limitations:** Currently available CGM systems generally rely on sensors that are labeled for use for between five and seven days, after which the sensor must be removed and a replacement sensor inserted. The accuracy of the CGM system may vary from sensor to sensor and over time, and generally declines when used beyond the labeled five or seven day time period. As a result, users who seek to avoid the inconvenience or the expense of changing the sensor regularly during such a short time interval may experience a decline in system performance unless a replacement sensor is inserted.
- **Inconvenience:** Currently available CGM systems generally require the user to wear or carry an extra device to receive and view the glucose readings. This could be particularly inconvenient for people using an insulin pump as it adds to the number of devices they are required to carry. Additionally, because the sensors used in currently available CGM systems may not be reinserted once removed, users are often forced to choose between incurring the costly and inconvenient premature removal of a sensor and limiting certain physical activities, which increases the risks of non-compliance.
- **Limited safety features:** Although most currently available CGM systems audibly alert the user when hypoglycemic or hyperglycemic events occur, only some systems provide predictive warnings before such events occur. In addition, no currently available CGM system provides vibratory alerts. We believe that the limited safety features of existing CGM systems leave an unmet need in connection with providing peace of mind for users, specifically when the receiver is off-line or out of range.
- **Painful and frequent insertion process:** All currently available CGM systems include a sensor that must be manually inserted transcutaneously by the user or, in the case of children, by a parent or other caregiver, generally into the abdomen, through a painful and inconvenient procedure. Because of the nature of the self-insertion process, the use of CGM systems requires significant education of the user and, in the case of children, a parent or other caregiver. These systems require people with diabetes to remove and reinsert a new sensor between 50 and 70 times per year. This frequency of required application can lead to a lack of compliance, as the user seeks to avoid the burden, pain and cost associated with replacing sensors.

Our Solution

As a result of the inherent limitations and inconvenience of existing SMBG and CGM systems, we believe that there is a significant unmet need among people with diabetes for an accurate, reliable, long-term, implantable CGM system. Consequently, we have focused our efforts on developing and designing a CGM system that we believe will provide people with diabetes a more convenient and discrete method of CGM, with significantly greater sensor duration, and equal or superior accuracy, than other currently available CGM systems. We believe that Eversense will allow people with diabetes to comply more effectively with their disease management therapies while living their lives with more freedom and greater peace of mind. Eversense is designed to be the first CGM system to continually and accurately measure glucose levels initially for up to 90 days and, in the future, for potentially up to 180 days.

Eversense consists of three components:

- a small sensor inserted subcutaneously in the upper arm by a healthcare provider;
- an external removable smart transmitter that receives, assesses and relays the data from the sensor and also 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 user's mobile device, such as a smartphone, Apple Watch or tablet.

In comparison to currently available CGM systems, we believe Eversense will provide the following important advantages:

- **Best-in-class sensor duration and long-term accuracy** —Eversense achieves continuous glucose readings for up to 90 days with an accuracy equal or superior to that of other currently available CGM systems while requiring fewer than four sensors per year. Currently available CGM sensors are labeled for use for five to seven days, requiring between 50 and 70 sensor insertions per year. We believe that the long-term accuracy and convenience of quarterly insertion and removal will significantly reduce the burden of glucose monitoring for people with diabetes using our system.
- **Enhanced convenience** —The ability of Eversense to display glucose readings on mobile devices allows people with diabetes to seamlessly blend the monitoring of their glucose levels with other uses of their mobile devices. Eversense users do not need to carry a separate handheld receiver to display glucose readings, which is required by currently available CGM systems. In addition, our easily removable smart transmitter allows users to conveniently remove and reapply the transmitter at will without having to also remove the sensor. We believe these convenient features greatly improves the quality of life and peace of mind for people with diabetes by enhancing their ability to effectively manage their condition across a wide range of activities, from sleeping to higher intensity activities, including sports.
- **Essential safety features** —Eversense is designed to continuously and accurately monitor glucose levels and provide predictive warnings using a proprietary algorithm, based on the user's personalized alarm settings, before the occurrence of hypoglycemic or hyperglycemic events. We believe the personalized alarm allows the user to intervene and potentially avoid these events entirely. Additionally, our smart transmitter provides distinct on-body vibrations in a number of alarm situations, including when low or high-glucose related readings are reached or when the transmitter is unable to communicate with the receiver. Unlike other currently available CGM systems, this vibration alert enables our system to warn users of a hypoglycemic or hyperglycemic event even when the user's mobile device is not available or nearby.
- **Quick and easy sensor insertion and removal** —Our sensor is designed to be inserted and removed by a simple, relatively painless and straightforward five-minute in-office procedure performed by a trained healthcare provider. Our initial patient feedback indicated that the procedure is quick, painless and generally well received. Feedback from healthcare professionals in Europe indicates that the procedure is easy to learn and that the professional is able to become adept at the procedure after only a minimal number of procedures.

Our Strategy

Our goal is to be the global leader in providing long-term, accurate and reliable implantable glucose monitoring systems designed help people with diabetes confidently live their lives with ease. The key elements of our strategy include:

- **Expand the European launch of Eversense and launch in United States.** Eversense was launched in Scandinavia, Italy, and Germany in 2016. Through our exclusive distributors, Rubin Medical and Roche, we intend to expand the Eversense launch across Europe. We have filed for regulatory approval for Eversense in the United States and our PMA is currently under review by the FDA. We intend to launch in the United States, through a direct sales force, following FDA approval. We also intend to seek to commercialize Eversense in other international markets, including Canada, Australia and Israel.
- **Educate and train healthcare providers and people with diabetes on the benefits Eversense.** We intend to communicate with and educate healthcare providers, including physicians, certified diabetes educators and nurses, and people with diabetes about the benefits of Eversense and how it can help improve the health and lives of people with diabetes. We have developed an insertion kit that is similar to that used in existing procedures that many healthcare providers are accustomed to performing, and we are utilizing

training programs to help them become comfortable and competent performing the sensor insertion and removal procedures. Finally, we intend to communicate on a regular basis with people with diabetes and their healthcare providers so that we can continue to understand their needs and demands, which will help us to serve them better.

- **Continuously innovate to introduce enhanced product offerings and pursue expanded indications to meet the needs of people with diabetes.** Following our first approved version of Eversense, we intend to continue to expand our Eversense line of product offerings to benefit both people with diabetes and healthcare providers, including system modifications and next generation enhancements, with the goal of increasing the convenience and functionality of the Eversense system. Our planned initiatives include: extending the approved sensor life to up to 180 days; providing on-demand, swipe measurement technology that would permit people with diabetes to perform real-time, single glucose readings by swiping their smartphone over our sensor; integrating with insulin pumps; reducing transmitter size; and improving accuracy leading to reduced, or eliminated, calibration. We have begun clinical trials for pediatric indications and intend to seek approval to market to this part of the population.
- **Establish reimbursement programs for coverage of Eversense to achieve the broadest possible acceptance of our system.** European reimbursement of CGM systems is expanding rapidly. For example, Germany recently instituted one of the broadest coverage policies in the world. Our distributors are working with governmental and private payor agencies to ensure the broadest and most comprehensive coverage possible throughout Europe and other territories. In the United States, CGM systems are generally well covered. Additionally, we have established procedure codes in the United States, which will enable reimbursement for the endocrinologist performing the insertion and removal procedures. We believe we will be well positioned to negotiate specific private payor coverage in the United States, if Eversense receives FDA approval. We believe that pursuing such a reimbursement strategy will be important in achieving the broadest possible acceptance of our system by healthcare providers and people with diabetes.
- **Maximize profitability through low cost manufacturing.** We utilize a network of third-party manufacturers that are experts in their respective areas. We are working with these subcontractors to implement scalable, flexible manufacturing that can accommodate increasing volumes and new generations of the Eversense system.

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 system has received a CE Mark in Europe and is currently being sold commercially. Our U.S. pivotal trial was completed during 2016 and we submitted our PMA to the FDA in October 2016.

We are 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 Trial

In January 2016 we began enrollment for the U.S. pivotal trial. Enrollment was completed before the end of March and the last patient completed the trial in July 2016. 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. During the trial the subjects were blinded to the real time glucose displays and alarms. The participants were also required to calibrate the system with two blood glucose measurement readings per day.

The subject 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. At the initial visit, our sensor was inserted and initial accuracy measurements were taken. Additional accuracy measurements were taken at 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 in vitro 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. A MARD of less than or equal to 20% is generally considered to be a threshold for regulatory approval of a CGM system, although currently available CGM systems generally report an average MARD of less than 13%.

During the trial, 75 subjects underwent unilateral sensor insertions and 15 subjects underwent bilateral sensor insertions in the clinic on day 1 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 8.8% 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, we recently submitted a pre-market approval, or PMA, application to the FDA to market Eversense in the United States. We expect that the PMA process could take between six and 18 months. For commercialization in the United States, we intend to distribute our product through our own direct sales and marketing organization. We have received Category III CPT codes for the insertion and removal of Eversense. Following PMA approval, we intend to pursue a Category I CPT code.

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. As with most currently available CGM systems, Eversense will initially require 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.



Smart Sensor

The smart 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, as compared to other currently available CGM sensors labeled for use for between five and seven 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 contain 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 Bluetooth. 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 Bluetooth 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 our first generation Eversense, 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.

In 2017, we anticipate that we will receive our CE Mark in Europe for both 180-day sensor life and our second generation transmitter. If we receive these approvals, we plan to launch both of these products throughout Europe. Additionally, we expect that our distributors will launch the Eversense system in a number of additional countries. In the U.S. market, we have submitted a PMA to market Eversense in the United States for our 90-day Eversense system. Assuming we receive the PMA approval, we intend to commercialize Eversense in the United States through our own direct sales and marketing organization. We also plan to submit our investigational device exemption, or IDE, application for a 180-day trial in the United States.

Future developments include applying for a dosing claim, which would permit users to dose with insulin without first confirming the blood glucose measure via a fingerstick, executing a partnership for development of an artificial pancreas system, submitting an IDE for a pediatric trial in the United States, launching the 180-day Eversense system in the United States, significantly reducing calibration requirements, continuing to improve accuracy, and initiating clinical trials for On-Demand, or "swipe", technology for Type 1 users, and extending swipe technology to Type 2 users.

Sales and Marketing

We are utilizing third-party distributors for our commercial activities in Europe. In 2016, we began selling Eversense in Sweden, Denmark, Italy and Germany 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.

Based on the size and maturity of the U.S. market, our plan is to invest in developing a direct sales force and infrastructure to support the launch of the product in the United States and target what we estimate to be approximately 2,100 endocrinologists in the United States who are clinically active and diabetes-focused.

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. In a survey of 45 physicians and over 400 people with diabetes conducted by a prominent global strategy consulting firm that we commissioned in 2015, 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. Approximately three out of four physicians preferred Eversense for their patients with intensively managed diabetes. In addition, approximately four out of five intensively managed non-CGM patients who preferred a CGM option over SMBG preferred Eversense over other currently available CGM systems. We intend to educate healthcare providers and people with diabetes on the advantages

of Eversense compared to SMBG and other currently available CGM systems. We also intend to establish a customer care center to provide ongoing support to people with diabetes and healthcare providers.

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, injunctions 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 that occurs after December 31, 2017, 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 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. Roche is obligated to purchase from us specified minimum volumes of Eversense components at pre-determined prices, which pricing is subject to renegotiation in certain circumstances.

The distribution agreement, as amended, has an initial term through December 31, 2018, which may be extended through December 31, 2019 if we and Roche agree upon the minimum purchase requirements for 2019. The distribution agreement 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

Reimbursement from private third-party healthcare payors and, to a lesser extent, Medicare will be an important element of our success. The Centers for Medicare and Medicaid, or CMS, established, effective 2008, Alpha-Numeric Healthcare Common Procedure Coding System codes that will be applicable to each of the components of Eversense. Recently Medicare adopted a national coverage determination with respect to one of the currently offered CGM systems. This national coverage determination was based on the decision by FDA to indicate the approved CGM system as a “non-adjunctive” device meaning that the user would not need to perform a confirmatory fingerstick prior to initiating treatment indicated by the information provided by the CGM system. Additionally, CMS does reimburse patients for the cost of certain related medical services such as data interpretation. Until such time as adequate coverage is extended by CMS and/or its contractors, as applicable, reimbursement of our products will generally be limited to customers covered by those third-party payors that have adopted policies recognizing coverage and reimbursement for CGM devices. Currently 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 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. We intend to seek coverage for Eversense as a medical benefit, which could avoid some of these restrictions, although we may not be successful in doing so. In addition, customers who are insured by payors that do not offer coverage for our devices will have to bear the financial cost of the products.

We have received Category III CPT codes for the insertion and removal of Eversense. Following PMA approval, we intend to pursue a Category I CPT code.

We have employed a reimbursement consultant to assist us in securing reimbursement agreements with third-party payors. In addition, we intend to commence negotiations with third-party payors in 2017. However, unless third-party and government payors provide adequate coverage and reimbursement for Eversense and the related insertion and removal procedures, people with diabetes might choose not to use our products on a widespread basis.

Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, their coverage policies may be restrictive, or they may not cover or provide adequate payment for our products. In order to obtain reimbursement arrangements, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. Our revenue may be limited by the continuing efforts of government and third-party payors to contain or reduce the costs of healthcare through various increasingly sophisticated means, such as requiring prospective reimbursement and second opinions, purchasing in groups, or redesigning benefits. Our future dependence on the commercial success of Eversense makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, unless government and other third-party payors provide adequate coverage and reimbursement for our products and the related insertion and removal procedures, 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, private health insurance plans, and labor unions. 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.

Manufacturing and Quality Assurance

We currently outsource the manufacture 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 requirements. We believe the manufacturers we currently utilize have sufficient capacity to meet our launch 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 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.

Research and Development

Our research and development team includes employees who specialize in chemistry, software engineering, electrical engineering, mechanical engineering and graphical user interface design, many of whom have considerable experience in diabetes-related medical devices. Our research and development team focuses on the products currently under development, including our clinical trials, as well as feasibility studies in which we are evaluating different design configurations to enhance product functionality for future generations of Eversense. Our research and development expenses were \$26.3 million, \$18.3 million and \$12.9 million for the years ended December 31, 2016 and 2015, and 2014, respectively.

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 and Medtronic. 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 recently approved by the FDA for marketing as a non-adjunctive device.

As the industry evolves, we anticipate encountering increasing competition from companies that integrate CGM with insulin pumps. We are aware of three companies, Johnson & Johnson, Medtronic and Tandem Diabetes Care, Inc., which have received FDA approval for CGM-integrated insulin pumps. Johnson & Johnson's system integrates Dexcom's CGM sensor technology and smartphone compatibility.

In addition to CGM providers, we will also compete with providers of traditional SMBG systems. Four companies currently account for substantially all of the worldwide sales of SMBG systems: Roche Diabetes Care, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; Abbott; and Asencia, a Panasonic Healthcare Holdings company.

We may also compete with companies, including Roche Diagnostics and 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 in Europe, which eliminates the need for routine fingersticks by reading glucose levels through a transcutaneous sensor that can be worn for up to 14 days. 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 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, 2016, we held a total of approximately 230 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 42 issued United States patents, 187 patents issued in countries outside the United States and 123 pending patent applications worldwide. Our patents expire between 2015 and 2030, 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 2035.

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 12 pending U.S. trademark applications, including applications for the "Eversense" trademark, and eight pending foreign trademark applications, as well as four 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, the U.S. Centers for Medicare & Medicaid Services, or 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, pre-clinical 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 the European Commission's Directive 93/42/EEC concerning medical devices and its amendments 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. The PMA approval process is more comprehensive than the 510(k) clearance process and typically takes several years to complete. Eversense is a Class III device, which is how other currently available CGM systems are also classified by the FDA. 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. Both the 510(k) clearance and PMA processes can be expensive, lengthy and require payment of significant user fees.

We filed our PMA application for the Eversense system in October 2016. A PMA application must be supported by valid scientific evidence that typically includes extensive technical, pre-clinical, 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. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to evaluate compliance with QSR, which requires manufacturers to implement and follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application generally takes between one and three years, but may take significantly longer. 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 pre-clinical 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.

If an FDA evaluation of a PMA application is favorable, the FDA will either issue an approval letter, or approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of a device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

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

Clinical trials are typically required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to us or our study that the FDA deems to make the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

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 primary regulatory body in Europe is that of the European Union, the European Commission, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for 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 and, accordingly, can be commercially distributed throughout Europe. 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." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. 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;
- labeling regulations that prohibit the promotion of products for uncleared, unapproved or "off-label" uses, and impose other restrictions on labeling, advertising and promotion;
- 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 may require us to conduct post-market surveillance studies or establish and maintain a system for tracking our products through the chain of distribution to the patient level. The FDA and the Food and Drug Branch of the California Department of Health Services enforce regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

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.

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 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. 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.

Foreign data privacy regulations, such as the EU Data Protection Directive (Directive 95/46/EC), and the country-specific regulations that implement Directive 95/46/EC, also govern the processing of personally identifiable data, and may be stricter than U.S. laws.

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 and civil 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. 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 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 Anti-Kickback Statute has been implicated and potentially violated.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to five years, fines of up to \$25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which do not have the same exceptions and apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs. Further, the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, or PPACA. Specifically, as noted above, under the 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 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 plan to provide the initial training to patients necessary for appropriate use of our products either through our own diabetes educators or by contracting with outside diabetes educators that have completed an appropriate training course. Outside diabetes educators are reimbursed for their services at fair market value.

Noncompliance with the federal anti-kickback legislation could result in our exclusion from Medicare, Medicaid or other governmental programs, restrictions on our ability to operate in certain jurisdictions, and significant civil and criminal penalties.

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 fines ranging from \$5,500 to \$11,000 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 or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

There are other federal anti-fraud laws 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 in the 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. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. 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 this statute is a felony and may result in fines or imprisonment.

Civil Monetary Penalties Law

In addition to the Anti-Kickback Statute and the civil and criminal False Claims Acts, 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 civil money penalties of up to \$10,000 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 Payment 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 the Secretary of Human Health Services 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 foreign jurisdictions.

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.

Employees

As of December 31, 2016, we had 58 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.

Information about Segments

We currently operate in a single business segment, glucose monitoring systems. See “Note 3—Summary of Significant Accounting Policies—Segment Information” to our consolidated financial statements contained in Part II, Item 8 of this Annual Report.

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-MKT 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. The public may read and copy the materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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 \$43.9 million, \$29.9 million and \$18.9 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of \$204.7 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 Europe.

To implement our business strategy we need to, among other things, gain regulatory approval in the United States and other regions where we intend to sell our products, expand our commercial launch in Europe, establish our sales and marketing infrastructure to initiate sales of our products in the United States 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 Europe and our products are not yet approved for sale in the United States. If we are unable to successfully receive regulatory approval for and commercialize Eversense in the United States, or if we experience significant delays in doing so, our business will be harmed.

We have no products that are approved for commercial sale in the United States and have limited commercialization experience in Europe. We have invested substantially all of our efforts and financial resources to the development of Eversense. Our ability to generate revenue from our products will depend heavily on their successful regulatory approval and commercialization of products in the United States, expanded commercialization of products in 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;
- launching U.S. commercial sales of Eversense, if approved for marketing;
- market acceptance of Eversense by people with diabetes, the medical community and third-party payors;
- our ability to obtain adequate coverage and reimbursement for Eversense and the related insertion and removal procedures;
- 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.

Whether regulatory approval will be granted in the U.S. is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Eversense's success in clinical trials will not guarantee regulatory approval. The FDA, or other comparable foreign regulatory authorities, may require that we conduct additional clinical trials, provide additional data, take additional manufacturing steps, or require other conditions before they will grant us approval. If the FDA, or other comparable foreign regulatory authorities, require additional clinical trials or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA, or other comparable foreign regulatory authorities, may not consider sufficient any additional required clinical trials, data or information that we perform and complete or generate.

In cases where we are successful in obtaining regulatory approval to market one or more of our products, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain 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 or clearance 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. It is possible that Eversense will never obtain regulatory approval in the United States, even if we expend substantial time and resources seeking such approval. 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 launching Eversense into commercial markets and achieving and maintaining market acceptance. In order for us to sell Eversense to people with diabetes, we must convince 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 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 convincing 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 Eversense or 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 adequate coverage and 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. For example, a future product enhancement involves on-demand, swipe measurement technology that would permit people with diabetes to perform real-time, single glucose readings by swiping their smartphone over our sensor. We do not believe that such technology would require cGMP-compliant manufacturing for smartphones used for these real-time readings. 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 Eversense or 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 Eversense or 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 adequate coverage or 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 Europe and, if approved, the United States 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 adequate coverage and 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 pay 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. As of December 31, 2016, 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 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-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 for Eversense. Failure to secure or retain adequate coverage or 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.

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 three companies, Johnson & Johnson, 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. Four companies currently account for substantially all of the worldwide sales of SMBG systems: Roche Diabetes Care, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; Abbott; and Bayer Diabetes Care, which has agreed to merge with Panasonic Healthcare Holdings. We may also compete with companies, including Roche Diagnostics and Abbott, developing non-invasive CGM products. For example, Abbott has commercialized, in Europe, 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. 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 and Africa (EMEA), excluding Scandinavia, Finland and Israel. Under these agreements, Rubin and Roche will generally be 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 only recently received regulatory approval, 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 and Africa, 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, even if we receive regulatory approval.

We have not yet commercialized Eversense in the United States. To achieve commercial success in the United States for Eversense, we will need to establish and expand our sales and marketing infrastructure to drive adoption of our products, and we plan to include a team of diabetes educators that will train healthcare providers and people with diabetes on the use of Eversense. 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 diabetes educators fail to achieve their objectives or if we are not able to recruit and retain a network of diabetes educators, 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 persuade those healthcare providers to 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 and the ability of our diabetes educators to train healthcare providers and people with diabetes on the use of 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 develop programs to help with retention aimed at customers, their caregivers and healthcare providers, which include 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.

To date, we have launched Eversense in Europe through distributors but have not yet commercialized Eversense in the United States. 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 if Eversense receives regulatory approval. Therefore, 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, lodged sensors 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 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. 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 launch 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, 2016 was completed, we did not have sufficient cash to fund our operations through December 31, 2017 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, 2016, we had approximately \$20.3 million in cash and cash equivalents and marketable securities, 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 believe our existing cash and cash equivalents, together with potential borrowings under our credit facility with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, if we are able to meet the milestone conditions for such borrowings, will be sufficient to fund our operations through the third quarter of 2017. 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 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, which currently consists of our term loan with Oxford and SVB. In addition, although we potentially have the ability to borrow additional funds under the Amended and Restated Loan and Security Agreement, we may be unable to borrow those additional funds or we may be unable to generate sufficient cash to service any additional indebtedness that we do incur.

In June 2016, we issued secured Notes to Oxford and SVB, or the Lenders, in a private placement for aggregate gross proceeds of \$15.0 million, pursuant to a Term Loan under our Amended and Restated Loan and Security Agreement that matures on June 1, 2020. 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. In November 2016, we borrowed an additional \$5 million upon the achievement of certain milestones. Our obligations under the Amended and Restated Loan and Security Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. Our Amended and Restated Loan and Security Agreement with the Lenders 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, 2016. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

In addition, pursuant to the Amended and Restated Loan and Security Agreement, we may also have the ability to borrow up to an aggregate of an additional \$10 million upon the achievement of specified milestones, and the funding of specific tranches under the agreement, through the end of 2017. We will not be able to borrow the additional \$10 million under the Amended and Restated Loan and Security Agreement if we do not achieve the specified milestones.

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the conditions of the Amended and Restated Loan and Security Agreement could result in an event of default, which could result in an acceleration of amounts due under the Amended and Restated Loan and Security Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the Lenders could seek to enforce security interests in the collateral securing such indebtedness, which would have a material adverse effect on our business.

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 Europe and the United States 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.

Risks Related to Development of our Products

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, the development and commercialization of our products.

While we have completed our pivotal trials in Europe and the United States for our first generation Eversense system, we anticipate that we will need to conduct future clinical trials in order to expand into the pediatric space and to introduce new versions of our system. 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.

We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our products, including:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts with third parties or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- clinical trials of Eversense may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development programs;
- the number of people with diabetes required for clinical trials of Eversense may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or people with diabetes may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our products may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors conducting the clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our products may be greater than we anticipate; and
- the supply or quality of our products or other materials necessary to conduct clinical trials of our products may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of Eversense beyond those that we currently contemplate, 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 at all;
- be delayed in obtaining marketing approval for Eversense in Europe, the United States or elsewhere;
- 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. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. 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.

Changes in the configuration of Eversense may result in additional costs or delay.

As products are developed through clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and configuration, are altered along the way in an effort to optimize processes and results. For example, we have already modified the configuration of Eversense several times in an effort to maximize the duration of our sensor, and we may need to make future configuration modifications prior to or after commencing sales. Any changes we make carry the risk that they will not achieve the intended objectives. Any of these changes could cause our products to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered device. Such changes may also require additional testing, regulatory notification or regulatory approval. This could delay completion of clinical trials, increase costs, delay approval of our future products and jeopardize our ability to commence sales and generate revenue.

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, R. Don Elsey, our Chief Financial Officer, Mukul Jain, our Chief Operating Officer, Mirasol Panlilio, our Vice President, Global Sales and Marketing, and Lynne Kelley, our Chief Medical Officer, 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 potentially implement 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, 2016, we had 58 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, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, 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, 2016, we held a total of approximately 230 issued patents and pending patent applications that relate to our CGM system. Our intellectual property portfolio includes 42 issued United States patents, 187 patents issued in countries outside the United States, and 123 pending patent applications worldwide. Our patents expire between 2015 and 2030, 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 2035. We are also seeking patent protection for our proprietary technology in Europe, Japan, China, Canada, Israel, Australia and other countries and regions throughout the world. We also have 12 pending U.S. trademark applications and eight pending foreign trademark applications, as well as four 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.

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 we would, or might be claimed to, infringe by commercializing our products. Although we are not aware of any such patent rights, 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 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;
- pre-clinical 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.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act or approval of a pre-market approval, or PMA, application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and accuracy and safety, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the accuracy and safety of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k)

may require a new 510(k). The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or 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. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process.

The FDA can delay, limit or deny clearance or 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 clearance or approval; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared or approved products on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development 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 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 civil whistleblower or qui tam actions that 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 laws 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 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, or the PPACA, on device manufacturers regarding any "transfer of value" made or distributed to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and to report detailed payment data and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year;
- 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 EU Data Protection Directive (Directive 95/46/EC), and the country-specific regulations that implement Directive 95/46/EC, 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 civil and criminal penalties, damages, fines, disgorgement of profits, exclusion from governmental health care programs, 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.

Further, the advertising and promotion of our products is subject to the laws of EEA Member States implementing Directive 93/42/EEC concerning medical devices, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. EEA Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national codes of conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare providers harming our business, operating results and financial condition.

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

Currently marketed CGM systems, are intended as adjunctive to SMBG, which means that the devices (including Eversense) are 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. The CGM manufacturer has 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 the CGM manufacturer. 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 the manufacturer could incur significant defense costs. Also, if there should be widespread off-label use of CGMs by patients, and resulting adverse medical events, the FDA or other regulatory bodies might require CGM manufacturers, including us, if we commercialize Eversense, to implement additional measures to reduce off-label use, which could be costly or reduce adoption of CGMs.

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.

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;
- 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); and
- creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

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. 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.

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-MKT, 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, or otherwise will dilute our existing stockholders.

Our certificate of incorporation authorizes us to issue up to 250,000,000 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.

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.

We may be unable to utilize our federal net operating loss carryforwards to reduce our income taxes.

As of December 31, 2016, we had federal and state net operating loss, or NOL, carryforwards of \$143.1 million, which, if not utilized, will begin to expire at various dates starting in 2018. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. 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 newly public company in the United States, we have begun to incur, 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-MKT, 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-MKT. 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 and accounting 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-MKT, 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. As a newly public company, we have only limited research coverage by securities or industry analysts. 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 believe that our current facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

From time to time, we are subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

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

Market Information for Common Stock

Our common stock began trading on the NYSE-MKT on March 18, 2016 under the symbol “SENS.” Beginning on December 23, 2015 through March 17, 2016 our common stock qualified for quotation on the electronic marketplace operated by OTC Markets Group, Inc. under the symbol “SENH.” The following table sets forth for the periods indicate the high and low bid prices of our common stock on the electronic marketplace operated by OTC Markets Group, Inc. and the NYSE-MKT. The below quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

	<u>High</u>	<u>Low</u>
2017		
First Quarter (through February 22, 2017)	\$ 2.92	\$ 2.28
Year Ended December 31, 2016		
First Quarter	\$ 3.45	\$ 2.53
Second Quarter	4.05	2.80
Third Quarter	4.24	3.00
Fourth Quarter	3.90	2.17
Year Ended December 31, 2015		
Fourth Quarter (from December 23, 2015)	\$ 3.50	\$ 3.25

On February 22, 2017, the last reported bid price for our common stock was \$2.32 per share.

Dividend Policy

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

Stockholders

As of February 22, 2017, we had 93,955,527 shares of common stock outstanding held by 165 holders of record.

Performance Graph

The following graph compares the performance of our common stock since March 18, 2016, the date of which our common stock commenced trading on the NYSE-MKT, 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.

Use of Proceeds from Public Offering of Common Stock

On March 17, 2016, our Registration Statement on Form S-1, as amended (File No. 333-208984) was declared effective in connection with our public offering, pursuant to which we sold 17,239,143 shares of our common stock, including the partial exercise of the underwriters' option to purchase additional shares, at a price to the public of \$2.85 per share. The offering closed on March 23, 2016 and we closed on the partial exercise of the underwriters' option to purchase additional shares on April 5, 2016. As a result, we received aggregate net proceeds of \$44.8 million (after deducting underwriters' discounts and commissions of \$2.7 million and additional offering related costs of \$1.4 million). The joint bookrunning managing underwriters of the offering were Leerink Partners LLC and Canaccord Genuity Inc.

No expenses incurred by us in connection with our public offering were paid directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from our public offering from that described in the final prospectus filed by us with the Securities and Exchange Commission on March 18, 2016 pursuant to Rule 424(b) of the Securities Act.

Recent Sales of Unregistered Securities

In December 2016, we issued 1,768 shares of common stock upon the net exercise of warrants at an exercise price of \$1.79 per share. The issuance of these securities was exempt from registration under Section 3(a)(9) of the Securities Act.

Item 6. Selected Consolidated Financial Data

The following selected financial data for the years ended December 31, 2016, 2015 and 2014 and the balance sheet data as of December 31, 2016 and 2015 is derived from our audited consolidated financial statements included elsewhere in this Annual Report. The following balance sheet data as of December 31, 2014 is derived from our audited consolidated financial statements not included in this Annual Report. 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,		
	2016	2015	2014
	(in thousands, except share and per share data)		
Statement of Operations Data:			
Revenue	\$ 332	\$ 38	\$ —
Cost of sales	660	—	—
Gross profit	(328)	38	—
Expenses:			
Sales and marketing expenses	2,736	792	95
Research and development expenses	26,347	18,251	12,881
General and administrative expenses	13,022	9,807	5,726
Operating loss	(42,433)	(28,812)	(18,702)
Other income (expense), net:			
Interest income	80	9	—
Interest expense	(1,602)	(1,100)	(191)
Other income	25	26	8
Net loss	(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	<u>\$ (43,930)</u>	<u>\$ (30,284)</u>	<u>\$ (18,885)</u>
Basic and diluted net loss per common share	<u>\$ (0.49)</u>	<u>\$ (4.32)</u>	<u>\$ (9.89)</u>
Basic and diluted weighted-average shares outstanding	<u>89,243,853</u>	<u>7,002,317</u>	<u>1,908,587</u>

	December 31,		
	2016	2015	2014
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	\$ 13,047	\$ 3,939	\$ 18,923
Working capital	9,806	(2,371)	17,593
Marketable securities	7,291	—	—
Total assets	22,271	5,423	19,995
Notes payable, net of discount, including current portion	19,066	9,819	9,815
Total liabilities	27,148	15,120	12,082
Additional paid-in capital	199,751	151,019	138,673
Accumulated deficit	(204,722)	(160,792)	(130,915)
Total stockholders' deficit	(4,877)	(9,697)	(7,913)

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and 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 were originally incorporated as ASN Technologies, Inc. in Nevada on June 26, 2014. On December 4, 2015, we were reincorporated in Delaware and changed our name to Senseonics Holdings, Inc. Also, on December 4, 2015, we entered into a merger agreement with Senseonics, Incorporated and SMSI Merger Sub, Inc., or the Merger Agreement, to acquire Senseonics, Incorporated. Senseonics, Incorporated was originally incorporated on October 30, 1996 and commenced operations on January 15, 1997. The transactions contemplated by the Merger Agreement were consummated on December 7, 2015, referred to herein as the Acquisition. Pursuant to the terms of the Merger Agreement, (i) all issued and outstanding shares of Senseonics, Incorporated's preferred stock were converted into shares of Senseonics, Incorporated common stock, \$0.01 par value per share, or the Senseonics Shares, (ii) all outstanding Senseonics Shares were exchanged for 57,739,953 shares of our common stock, \$0.001 par value per share, or the Company Shares, reflecting an exchange ratio of one Senseonics Share for 2.0975 Company Shares, or the Exchange Ratio, and (iii) all outstanding options and warrants to purchase Senseonics Shares, or the Senseonics Options and Senseonics Warrants, respectively, were each exchanged or replaced with options and warrants to acquire shares of our common stock, or the Company Options and Company Warrants, respectively. Accordingly, Senseonics, Incorporated became our wholly-owned subsidiary.

Following the closing of the Acquisition, the business of Senseonics, Incorporated became our sole focus and all of our operations following the closing of the Acquisition consist of the historical Senseonics, Incorporated business. Unless otherwise indicated or the context otherwise requires, all references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "the Company," "we," "our," "ours," "us" or similar terms refer to (i) Senseonics, Incorporated prior to the closing of the Acquisition, and (ii) Senseonics Holdings, Inc. and its subsidiaries subsequent to the closing of the Acquisition and all share and per share information in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section gives retroactive effect to the exchange of Senseonics Shares, Senseonics Options and Senseonics Warrants for Company Shares, Company Options and Company Warrants, respectively, in the Acquisition, as well as the corresponding exercise price adjustments for the such options and warrants.

We are 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. Our first generation continuous glucose monitoring, or CGM, system, Eversense, is a reliable, long-term, implantable CGM system that we have designed to continually and accurately measure glucose levels in people with diabetes for a period of up to 90 days, as compared to five to seven days for currently available CGM systems. We believe Eversense 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.

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.

In March 2016, we completed a public offering of our common stock, or the 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 cash proceeds from the 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 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 cash 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, to potentially borrow up to an aggregate principal amount of \$30.0 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. On November 22, 2016, we borrowed an additional \$5 million upon achieving certain milestones. The agreement also permits us to borrow up to an additional \$10 million upon the achievement of specified milestones, and the funding of specific tranches under the agreement, through the end of 2017. The agreement provides for monthly payments of interest only for a period of 12 months, followed by an amortization period of 36 months. However, if we satisfy certain milestones and borrow an additional \$5 million under the agreement, the interest only period will be extended by an additional six months and the amortization period will be 30 months.

We have never been profitable and our net losses were \$43.9 million, \$29.9 million and \$18.9 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, our accumulated deficit totaled \$204.7 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 July 2015, we applied for, and in May 2016, we received our CE mark, which allows us to market and sell Eversense in Europe. In connection with our CE Mark, we have agreed to conduct post market surveillance activities. In June 2016, we commenced commercialization of Eversense in Sweden and in December 2016 we commenced commercialization of Eversense in Norway through our distribution agreement with Rubin, which also has the right to distribute Eversense in Denmark. Rubin markets and sells medical products for diabetes treatment in the Scandinavian region, including as the exclusive Scandinavian distributor for the insulin pump manufacturer Animas Corporation.

In May 2016, we entered into a distribution agreement with Roche, pursuant to which we granted Roche the exclusive right to market, sell and distribute Eversense in Germany, Italy and the Netherlands. In November 2016, we entered into an amendment to the distribution agreement 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. Roche is a pioneer in the development of blood glucose monitoring systems and a global leader for diabetes management systems and services. We began distributing Eversense through Roche in Germany in September 2016 and in Italy and the Netherlands in the fourth quarter of 2016.

United States Development of Eversense

We recently 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 8.8% utilizing two calibration points for Eversense across the 40-400 mg/dL range when compared to YSI blood reference values during the 90-day continuous wear period. Based on the data from this trial, in October 2016 we submitted a pre-market approval, or PMA, application to the FDA to market Eversense in the United States. We expect that the PMA process could take between six and 18 months. For commercialization in the United States, we intend to distribute our product through our

own direct sales and marketing organization. We have received Category III CPT codes for the insertion and removal of Eversense. Following PMA approval, we intend to pursue a Category I CPT code.

We expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, we expect that our expenses will increase substantially as we continue the research and development of our other products and maintain, expand and protect our intellectual property portfolio and seek regulatory approvals in other jurisdictions. Furthermore, we have begun to incur, and 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 may 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, 2016, we generated product revenue from sales of the Eversense system in Europe pursuant to distribution agreements with Roche and Rubin, and we expect to begin marketing Eversense in additional European countries throughout 2017. We expect our revenue from European product sales will increase as we ramp up our commercialization efforts through the remainder of 2017 and into 2018. In the future, subject to regulatory approval, we also intend to seek to commercialize Eversense in the United States, as well as other international markets. 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 the Eversense product to Roche and Rubin for distribution in various regions in Europe. 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 spread 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 and other related costs, including stock-based compensation, for personnel who perform sales and marketing functions. Other significant costs include promotional materials and tradeshow expenses.

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

Research and Development

The largest component of our total operating expenses has historically been research and development expenses. 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 commercialize our products.

The following table summarizes our research and development expenses by functional area for the years ended December 31, 2016, 2015 and 2014.

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Clinical development	\$ 4,242	\$ 4,145	\$ 1,940
Contract R&D and consulting	8,071	3,158	1,631
Contract fabrication and manufacturing	5,536	4,796	3,518
Personnel related	6,491	4,525	4,178
Other R&D expenses	2,007	1,627	1,614
Total R&D expenses	<u>\$ 26,347</u>	<u>\$ 18,251</u>	<u>\$ 12,881</u>

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 not otherwise included in research and development expenses, 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-MKT 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 and interest expense primarily consists of interest expense on the secured notes, or the Notes, we issued to Oxford in connection with our original Loan and Security Agreement in July and December 2014 and the Notes we issued to Oxford and SVB in connection with our Amended and Restated Loan and Security Agreement in June and November 2016. We refer to Oxford and SVB together as the Lenders. This interest expense primarily consists of (i) contractual interest on the Notes, (ii) amortization of debt discount related to warrants, or the warrants, that we issued to the Lenders in connection with the Notes, and (iii) the accrual into interest expense of a final payment obligation that we are required to pay to the Lenders at maturity of the Notes.

Other income (expense) for the year ended December 31, 2016 primarily includes the change in the fair value of the warrant liability during the particular period, which results from the marking to market at the end of every reporting period of the fair value of the warrant liability related to warrants issued to Oxford. In December 2015, in connection with the Acquisition, the warrants were amended. As a result, the warrants were reclassified from a liability to equity and are no longer be marked to market and, therefore, do not impact other income (expense) in future periods.

Results of Operations**Comparison of the Years Ended December 31, 2016 and 2015**

The following table sets forth our results of operations for the years ended December 31, 2016 and 2015.

	Year Ended December 31,		Period-to- Period Change
	2016	2015	
	(in thousands)		
Revenue	\$ 332	\$ 38	\$ 294
Cost of sales	660	—	660
Gross profit	(328)	38	(366)
Expenses:			
Sales and marketing expenses	2,736	792	1,944
Research and development expenses	26,347	18,251	8,096
General and administrative expenses	13,022	9,807	3,215
Operating loss	(42,433)	(28,812)	(13,621)
Other income (expense), net:			
Interest expense, net	(1,522)	(1,091)	(431)
Other income	25	26	(1)
Total other expense, net	(1,497)	(1,065)	(432)
Net loss	<u>\$ (43,930)</u>	<u>\$ (29,877)</u>	<u>\$ (14,053)</u>

Revenue

Revenue for the year ended December 31, 2016 was \$0.3 million. This revenue consisted of product sales of Eversense through our distributor partners Rubin and Roche in Europe. Revenue for the year ended December 31, 2015 was \$38,000. This revenue consisted of grant revenue for delivery of sensors for a National Health Institute grant from the University of California Santa Barbara, which we do not expect this to be a meaningful source of revenue in the future.

Cost of sales

Our cost of sales was \$0.7 million for the year ended December 31, 2016, resulting from the manufacturing and distribution of shipments of Eversense to Roche and Rubin for distribution in Europe. We did not have any cost of sales during the year ended December 31, 2015.

Gross profit was \$(0.3) million for the year ended December 31, 2016. Gross profit as a percentage of revenue, or gross margin, was (101)% for the year ended December 31, 2016.

Sales and marketing expenses

Sales and marketing expenses were \$2.7 million for the year ended December 31, 2016, compared to \$0.8 million for the year ended December 31, 2015, an increase of \$1.9 million. The increase was primarily due to an increase in personnel-related expenses of \$1.7 million and an increase of \$0.2 million of other expenses to support the launch of Eversense in Europe.

Research and development expenses

Research and development expenses were \$26.3 million for the year ended December 31, 2016, compared to \$18.3 million for the year ended December 31, 2015, an increase of \$8.0 million. The increase was primarily due to an increase in contract research and development and consulting expenses for future versions of Eversense of \$5.0 million,

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a \$2.0 million increase in personnel-related expenses, a \$0.6 million increase in contract fabrication and process development expenses and a \$0.4 million increase in other research and development expenses.

General and administrative expenses

General and administrative expenses were \$13.0 million for the year ended December 31, 2016, compared to \$9.8 million for the year ended December 31, 2015, an increase of \$3.2 million. The increase was primarily due to an increase in personnel-related expenses of \$2.3 million, in part to support our operations as a public company, and an increase of \$0.9 million in facilities expenses related to our expansion.

Total other expense, net

Total other expense, net, for the year ended December 31, 2016 and 2015 was \$1.5 million and \$1.1 million, respectively, consisting primarily of interest expense on the Oxford and SVB notes.

Comparison of the Years Ended December 31, 2015 and 2014

The following table sets forth our results of operations for the years ended December 31, 2015 and 2014.

	Year Ended December 31,		Period-to- Period Change
	2015	2014	
	(in thousands)		
Revenue	\$ 38	\$ —	\$ 38
Expenses:			
Sales and marketing expense	792	95	697
Research and development expenses	18,251	12,881	5,370
General and administrative expenses	9,807	5,726	4,081
Operating loss	(28,812)	(18,702)	(10,110)
Other income (expense):			
Interest expense, net	(1,091)	(191)	(900)
Other income	26	8	18
Total other expense, net	(1,065)	(183)	(882)
Net loss	\$ (29,877)	\$ (18,885)	\$ (10,992)

Revenue

Revenue for the year ended December 31, 2015 was \$38,000. This revenue consisted of grant revenue for delivery of sensors for a National Health Institute grant from the University of California Santa Barbara. However, we do not expect this to be a meaningful source of revenue in the future. We did not generate any revenue for the year ended December 31, 2014.

Research and development expenses

Research and development expenses were \$18.3 million for the year ended December 31, 2015, compared to \$12.9 million for the year ended December 31, 2014, an increase of \$5.4 million. The increase was primarily due to an increase in clinical development expenses of \$2.2 million as a result of our completed European pivotal trial, a \$1.3 million increase in contract fabrication and manufacturing, a \$1.5 million increase in contract research and development and consulting expenses for future versions of Eversense and a \$0.4 million increase in personnel expenses.

Administrative expenses

Administrative expenses were \$9.8 million for the year ended December 31, 2015, compared to \$5.7 million for the year ended December 31, 2014, an increase of \$4.1 million. The increase was primarily due to an increase in legal

and accounting expenses of \$2.4 million, an increase in personnel-related expenses of \$1.2 million and an increase of \$0.4 million of other expenses.

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 \$43.9 million, \$29.9 million and \$18.9 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of \$204.7 million.

To date, we have funded our operations principally through the issuance of preferred stock, common stock and debt. As of December 31, 2016, we had cash and cash equivalents and marketable securities of \$20.3 million. Under the terms of the Amended and Restated Loan and Security Agreement with Oxford and SVB, we may borrow up to an aggregate principal amount of \$30.0 million. Under this debt facility, we initially borrowed an aggregate of \$15 million from the 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 from the Oxford and SVB upon achieving certain milestones. The agreement provides for monthly payments of interest only for a period of 12 months, followed by an amortization period of 36 months. However, if we satisfy certain milestones and borrow an additional \$5 million under the agreement, the interest only period will be extended by an additional six months and the amortization period will be 30 months.

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 2017 and beyond. Upon the completion of the audit of our consolidated financial statements for the year ended December 31, 2016, we did not have sufficient cash to fund our operations beyond the third quarter of 2017 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.

On March 23, 2016, we closed the Offering of our common stock. Additionally, we closed on the partial exercise by the underwriters of the Offering on their option to purchase additional shares on April 5, 2016. As a result of these events, we received aggregate net proceeds of \$44.8 million (after deducting underwriters' discounts and commissions of \$2.7 million and additional offering related costs of \$1.4 million).

We expect our existing capital resources as of December 31, 2016 will enable us to fund our operations through the third quarter of 2017. We have based this estimate on assumptions, including that we will meet the conditions to borrow the Tranche 3 Term Loan, as defined below, by completing the first commercial sale of our second-generation transmitter in the European Union on or before April 30, 2017, and that we will meet the conditions to borrow the Tranche 4 Term Loan, as defined below, by receiving PMA approval from the FDA for Eversense, and achieving a trailing six-month revenue for the applicable period of measurement of at least \$4.0 million, on or before September 30, 2017.

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 may potentially borrow up to an aggregate principal amount of \$30.0 million in the following four tranches: \$15.0 million, or the Tranche 1 Term Loan; \$5.0 million, or the Tranche 2 Term Loan; \$5.0 million, or the Tranche 3 Term Loan; and \$5.0 million, or the Tranche 4 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. We may borrow the Tranche 3 Term Loan on or before April 30, 2017 if complete the first commercial sale of our second-generation transmitter in the European Union. We may borrow the Tranche 4 Term Loan on or before December 31, 2017 if we borrow the Tranche 2 and Tranche 3 Term Loans, receive PMA approval from the FDA for Eversense, and achieve trailing six-month revenue for the applicable period of measurement of at least \$4.0 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 initially consist of interest-only. After twelve months, the monthly payments will convert to payments of principal and monthly accrued interest, with the principal amount being amortized over the ensuing 36 months. However, if we borrow the Tranche 3 Term Loan, the interest-only period will be extended by an additional six months, and the amortization period will be shortened to 30 months.

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 and 63,025 shares of common stock with an exercise price of \$3.86 and \$2.38 per share, respectively.

The Notes are collateralized by all of our consolidated assets other than our intellectual property. 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 \$568,648 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 \$421,840, 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 the event that we achieve the requirements to borrow the Tranche 3 Term Loan or the Tranche 4 Term Loan, and elect not to borrow either tranche, we are obligated to pay the Lenders a non-utilization fee of 2.00% of the undrawn amounts.

On December 7, 2015, we entered into a Note Purchase Agreement with Energy Capital pursuant to which we were entitled to borrow an aggregate principal amount of up to \$10.0 million, or the Energy Capital note, subject to the conditions specified in the Note Purchase Agreement. During the year ended December 31, 2016, we borrowed an aggregate of \$2.5 million from Energy Capital. We repaid these borrowings in full with a portion of the proceeds of the Offering prior to December 31, 2016, and the Note Purchase Agreement was terminated.

Funding Requirements and Outlook

Our primary uses of capital are, and we expect will continue to be, research and development, compensation and related expenses, costs associated with product launch and establishment of a direct sales force in the United States, 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 believe our existing cash and cash equivalents, together with potential borrowings under our credit facility with Oxford and SVB, if we are able to meet the milestone conditions for such borrowings, will be sufficient to fund our operating expenses through the third quarter of 2017. 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.

We anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses 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, 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.

Cash Flows

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

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash used in operating activities	\$ (38,016)	\$ (25,465)	\$ (19,270)
Net cash used in investing activities	(7,770)	(202)	(29)
Net cash provided by financing activities	54,894	10,683	29,976
Net increase (decrease) in cash and cash equivalents	<u>\$ 9,108</u>	<u>\$ (14,984)</u>	<u>\$ 10,677</u>

Net cash used in operating activities

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 used in operating activities was \$25.5 million for the year ended December 31, 2015, and consisted primarily of a net loss of \$29.9 million, partially offset by a net change in assets and liabilities of \$2.8 million (consisting primarily of an increase in accounts payable and accrued expenses of \$3.2 million, partially offset by an increase in prepaid expenses, deposits and other assets of \$0.4 million), stock-based compensation expense of \$1.4 million and depreciation expense of \$0.1 million.

Net cash used in operating activities was \$19.3 million for the year ended December 31, 2014, and consisted primarily of a net loss of \$18.9 million and a net change in assets and liabilities of \$1.2 million (consisting of a decrease in accounts payable and accrued expenses of \$0.7 million and an increase in prepaid expenses, deposits and other assets of \$0.5 million), partially offset by stock-based compensation expense of \$0.5 million and depreciation expense of \$0.2 million.

Net cash used in investing activities

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 used in investing activities was \$0.2 million for the year ended December 31, 2015, and consisted entirely of capital expenditures for laboratory equipment.

Net cash used in investing activities was \$29,000 for the year ended December 31, 2014, and consisted entirely of capital expenditures for laboratory equipment.

Net cash provided by financing activities

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, the net proceeds of \$9.0 million from the issuance of the Oxford and SVB note, and \$0.2 million from the exercise of stock options.

Net cash provided by financing activities was \$10.7 million for the year ended December 31, 2015, and consisted primarily of the net proceeds of \$10.7 million from our issuance of Series E convertible preferred stock.

Net cash provided by financing activities was \$30.0 million for the year ended December 31, 2014, and consisted primarily of the net proceeds of \$20.1 million from our issuance of Series D convertible preferred stock, and the net proceeds of \$9.9 million from the issuance of promissory notes to Oxford.

Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2016.

Contractual Obligations	Payment due by period				
	Total	2017	2018-2019 (in thousands)	2020-2021	After 2021
Operating lease obligations	\$ 4,053	\$ 608	\$ 1,218	\$ 1,277	\$ 950
Payments under corporate development agreement ⁽¹⁾	2,259	970	381	908	—
Principal payments under Notes ⁽²⁾	20,000	3,889	13,333	2,778	—
Interest payments under Notes ⁽²⁾	2,854	1,387	1,416	51	—
Total contractual obligations	\$ 29,166	\$ 6,854	\$ 16,348	\$ 5,014	\$ 950

- (1) Represents minimum payment obligations under a corporate development agreement to purchase current application-specific integrated circuits, which are subcomponents of the sensors used in Eversense.
- (2) Represents the principal and interest payment schedule for the \$20.0 million principal amount of the Oxford and SVB notes that were outstanding as of December 31, 2016, assuming that we do not launch our second generation transmitter and borrow an additional \$5 million under the credit facility by April 30, 2017, in which case, principal payments will begin on July 1, 2017. In the event we do launch our second generation transmitter and borrow an additional \$5 million under the credit facility by April 30, 2017, the principal payments will begin on January 1, 2018. In such event, the schedule for principal payments on the Oxford and SVB notes will be as follows (in thousands): \$0 in 2017; \$20,690 in 2018-2019; and \$4,310 in 2020-2021, and the schedule for interest payments on the Oxford notes will be as follows: \$1,734 in 2017; \$2,198 in 2018-2019 and \$78 in 2020-2021. 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

Revenue is generated from sales of sensor kits, transmitter kits, and related supplies under agreements for research and third-party distributors that resell the product to customers. We are paid for our sales directly by third-party distributors, regardless of whether or not the distributors resell the products to their customers.

We recognize product sales revenue when all of the following criteria are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred;
- the price is fixed or determinable; and
- collectability is reasonably assured.

We offer no rights of return and have no significant post-delivery obligations and, therefore, the above criteria are generally met as products are shipped to, or received by, third-party distributors.

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 2,464,011 shares and 1,540,612 shares were granted during the years ended December 31, 2016 and 2015, 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 historical experience for the years ended December 31, 2016 and 2015 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, 2016, 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.

Recent Accounting Pronouncements

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. We do not intend to adopt the guidance early. We currently expect that the adoption of this guidance likely will change the way we recognize revenue generated under customer contracts. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The

standard is effective for the reporting periods ending December 15, 2016 and for annual periods and interim periods thereafter. We adopted the guidance and have included expanded discussions on going concern.

In April 2015, the FASB issued accounting guidance requiring that debt issuance costs related to a recognized liability be presented on the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected. The standard is effective for reporting periods beginning after December 15, 2015. We adopted this guidance and the debt on our consolidated balance sheets is disclosed net of issuance costs.

In April 2015, the FASB issued accounting guidance related to Internal-Use Software specifically for the Customer's Accounting for Fees Paid in a Cloud Computing Arrangement. The amendments in this Update provide guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The standard is effective for reporting periods beginning after December 15, 2015. An entity can elect to adopt the amendments either 1) prospectively for all arrangements entered into or materially modified after the effective date or 2) retrospectively. We decided to adopt the standards prospectively and will be accounting for the new cloud arrangements in accordance with the new standards. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In November 2015, the FASB issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented. We adopted this guidance for the year ended December 31, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued 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. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We currently expect that the adoption of this guidance likely will change the way we account for our operating leases and likely will result in recording the future benefits of those leases and the related minimum lease payments on our balance sheet. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and cash payments in the statement 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 guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis and must be applied to all periods presented, but may be applied prospectively if retrospective application would be impracticable. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated statements of cash flows.

In June 2016, the FASB issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018,

including interim periods within those fiscal years. We currently expect that the adoption of this guidance likely will change the way we assess the collectibility of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. We adopted this guidance as of January 1, 2017. From January 1, 2017 onward, in accordance with the new guidance, no excess tax benefits or tax deficiencies will be recognized in additional paid-in capital. Our existing additional paid-in capital pool balance at December 31, 2016 is \$204.7 million. We will account for forfeitures as they occur, rather than using an estimated forfeiture rate. We estimate that this change in accounting will not result in an adjustment to retained earnings as of January 1, 2017. We will also present the impact of classifying excess tax benefits as an operating activity in the Statement of Cash Flows on a prospective basis and prior periods will not be adjusted. The adoption of the remaining amendments is not expected to have a material impact on our consolidated financial statements.

In November 2016, the FASB issued guidance to reduce diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The revised guidance requires that amounts generally described as restricted cash and restricted cash equivalents be included in with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the statement of cash flows. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis. We adopted this guidance as of January 1, 2017, on a retrospective basis, and all periods will be presented under this guidance. The adoption of this new guidance will have no impact on our consolidated financial statements.

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our results of operations, financial position, 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 are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, (i) not being required to provide 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) not being required to comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (a) the last day of the fiscal year in which we have total annual gross revenues of \$1.0 billion or more; (b) the last day of our fiscal year ending December 31, 2019; (c) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous six years; or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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, 2016, 2015 and 2014, we had cash and cash equivalents of \$13.0 million, \$3.9 million and \$18.9 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 notes is fixed. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Foreign Currency Risk

We expect that our international sales through distributors and the costs we incur in connection with our international operations will be denominated in U.S. dollars. Therefore, we do not expect that our results of operations will be materially affected by foreign exchange rate risks. However, our distributors' sales of our products in international markets to their customers will be denominated in local currencies. Therefore, it is possible that, when the U.S. dollar appreciates, products sales could be adversely impacted, as our products will become more expensive to the customers of our distributors. 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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Senseonics Holdings, Inc.

We have audited the accompanying consolidated balance sheets of Senseonics Holdings, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Senseonics Holdings, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles .

The accompanying 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 recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

McLean, VA
February 23, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the statements of operations, of changes in stockholders' equity and of cash flows for the year ended December 31, 2014 present fairly, in all material respects, the results of operations and cash flows of Senseonics Holdings, Inc. (the Company) for the year ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

The accompanying 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 and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ PricewaterhouseCoopers LLP

Baltimore, Maryland

July 10, 2015, except for note 1 as to which the date is January 13, 2016

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

	<u>December 31,</u>	
	<u>2016</u>	<u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,047	\$ 3,939
Marketable securities	7,291	—
Accounts receivable	251	—
Inventory	477	—
Prepaid expenses and other current assets	365	1,025
Total current assets	<u>21,431</u>	<u>4,964</u>
Deposits and other assets	105	148
Property and equipment, net	735	311
Total assets	<u>\$ 22,271</u>	<u>\$ 5,423</u>
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 3,070	\$ 1,252
Accrued expenses and other current liabilities	4,666	3,694
Note payable, current portion	3,889	2,389
Total current liabilities	<u>11,625</u>	<u>7,335</u>
Note payable, net of discount	15,177	7,430
Accrued interest	273	327
Other liabilities	73	28
Total liabilities	<u>27,148</u>	<u>15,120</u>
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value per share; 250,000,000 shares authorized, 93,569,642 and 75,760,061 shares issued and outstanding as of December 31, 2016 and 2015	94	76
Additional paid-in capital	199,751	151,019
Accumulated deficit	<u>(204,722)</u>	<u>(160,792)</u>
Total stockholders' deficit	<u>(4,877)</u>	<u>(9,697)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 22,271</u>	<u>\$ 5,423</u>

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,		
	2016	2015	2014
Revenue	\$ 332	\$ 38	\$ —
Cost of sales	660	—	—
Gross profit	(328)	38	—
Expenses:			
Sales and marketing expenses	2,736	792	95
Research and development expenses	26,347	18,251	12,881
General and administrative expenses	13,022	9,807	5,726
Operating loss	(42,433)	(28,812)	(18,702)
Other income (expense), net:			
Interest income	80	9	—
Interest expense	(1,602)	(1,100)	(191)
Other income (expense)	25	26	8
Net loss	(43,930)	(29,877)	(18,885)
Other comprehensive income (loss)	—	—	—
Total comprehensive loss	\$ (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	\$ (43,930)	\$ (30,284)	\$ (18,885)
Basic and diluted net loss per common share	\$ (0.49)	\$ (4.32)	\$ (9.89)
Basic and diluted weighted-average shares outstanding	89,243,853	7,002,317	1,908,587

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

Senseonics Holdings, Inc.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(in thousands)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional Paid-In	Treasury Stock		Accumulated	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	Deficit									
Balance, December 31, 2013	600	\$ 6	1,202	\$ 12	2,074	\$ 21	14,403	\$ 144	—	\$ —	1,943	\$ 2	\$118,088	44	\$ (84)	\$(112,030)	\$ 6,159
Sale of Series D preferred stock	—	—	—	—	—	—	5,374	54	—	—	—	—	20,036	—	—	—	20,090
Exercise of stock options for cash	—	—	—	—	—	—	—	—	—	—	19	—	10	—	—	—	10
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	539	—	—	—	539
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(18,885)	(18,885)
Balance, December 31, 2014	600	\$ 6	1,202	\$ 12	2,074	\$ 21	19,777	\$ 198	—	\$ —	1,962	\$ 2	\$138,673	44	\$ (84)	\$(130,915)	\$ 7,913
Sale Series E preferred stock	—	—	—	—	—	—	—	—	2,712	27	—	—	10,606	—	—	—	10,633
Exercise of stock options for cash and vesting of RSAs	—	—	—	—	—	—	—	—	—	—	520	1	62	—	—	—	63
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	1,433	—	—	—	1,433
Reclassification of warrant liability	—	—	—	—	—	—	—	—	—	—	—	—	151	—	—	—	151
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(29,877)	(29,877)
Effect of reverse merger and conversion of preferred stock to common stock	(600)	(6)	(1,202)	(12)	(2,074)	(21)	(19,777)	(198)	(2,712)	(27)	73,278	73	94	(44)	84	—	(13)
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 for cash and vesting of RSAs	—	—	—	—	—	—	—	—	—	—	570	1	1,324	—	—	—	1,325
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	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)

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,		
	2016	2015	2014
Cash flows from operating activities			
Net loss	\$ (43,930)	\$ (29,877)	\$ (18,885)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	155	118	189
Non-cash interest expense (debt discount and deferred costs)	252	77	67
Change in fair value of warrants	430	(46)	(8)
Stock-based compensation expense	2,421	1,433	539
Changes in assets and liabilities:			
Accounts receivable	(250)	—	—
Prepaid expenses and other current assets	659	(314)	(514)
Inventory	(477)	—	—
Deposits and other assets	43	(89)	—
Accounts payable	1,817	3,232	(674)
Accrued expenses and other current liabilities	893	—	—
Accrued interest	(54)	—	—
Deferred rent	25	1	16
Net cash used in operating activities	<u>(38,016)</u>	<u>(25,465)</u>	<u>(19,270)</u>
Cash flows from investing activities			
Capital expenditures	(479)	(202)	(29)
Purchase of marketable securities	(7,291)	—	—
Net cash used in investing activities	<u>(7,770)</u>	<u>(202)</u>	<u>(29)</u>
Cash flows from financing activities			
Sale of Series D convertible preferred stock, net of costs	—	—	20,090
Sale of Series E convertible preferred stock, net of costs	—	10,633	—
Repurchase shares as result of reverse merger	—	(12)	—
Proceeds from issuance of common stock, net of issuance costs	45,737	—	—
Proceeds from exercise of stock options	161	62	10
Proceeds from notes payable, net of costs	22,500	—	9,879
Repayments of notes payable	(12,500)	—	—
Deferred financing costs and discount of notes payable	(1,004)	—	—
Principal payments under capital lease obligations	—	—	(3)
Net cash provided by financing activities	<u>54,894</u>	<u>10,683</u>	<u>29,976</u>
Net increase (decrease) in cash and cash equivalents	9,108	(14,984)	10,677
Cash and cash equivalents, at beginning of period	3,939	18,923	8,246
Cash and cash equivalents, at end of period	<u>\$ 13,047</u>	<u>\$ 3,939</u>	<u>\$ 18,923</u>
Supplemental disclosure of cash flow information			
Cash paid during the year for interest	<u>\$ 893</u>	<u>\$ 660</u>	<u>\$ 93</u>

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

Senseonics Holdings, Inc.

Notes to Consolidated Financial Statements

1. Organization

Senseonics, Incorporated, (“Senseonics”), which, subsequent to the Acquisition described below, is a wholly-owned subsidiary of Senseonics Holdings, Inc. (“Senseonics Holdings or the “Company”). The Company is 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 was originally incorporated on October 30, 1996 and commenced operations on January 15, 1997.

ASN Technologies, Inc. (“ASN”) was incorporated in Nevada on June 26, 2014. On December 4, 2015, ASN reincorporated in Delaware and changed its name to Senseonics Holdings, Inc.

On December 7, 2015, the Company acquired 100% of the outstanding capital stock of Senseonics (the "Acquisition"). While the Company was the legal acquirer of Senseonics in the transaction, since (i) former Senseonics' stockholders owned 80% of the combined company on a fully diluted basis immediately following the transaction, and (ii) all members of the combined company's executive management and Board of Directors were from Senseonics, Senseonics was deemed to be the acquiring company for accounting purposes. As such, the transaction was accounted for as a reverse recapitalization in accordance with U.S. GAAP and, in the accompanying consolidated financial statements, ASN's historical consolidated financial statements have been replaced with Senseonics' historical consolidated financial statements.

Pursuant to the terms of 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.

In connection with the reverse recapitalization, the Company transferred its former operations to a former officer, director and stockholder in exchange for the (i) satisfaction of a promissory note issued to the Company's former officer, director and stockholder in the principal amount of \$9,000 and (ii) assumption of liabilities related to the former operations. No gain or loss was recorded as a result of the transfer.

Senseonics Holdings and its wholly-owned subsidiary Senseonics are hereinafter referred to as the “Company” unless stated otherwise.

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 efforts, will require significant uses of working capital throughout 2017 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 “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. Management has concluded that, based on the Company's current operating plans, the receipt of potential future borrowings under the Amended and Restated Loan and Security Agreement with Oxford and SVB, if the Company is able to meet the milestone conditions for such borrowings, its existing cash, cash equivalents, and marketable securities available for sale will be sufficient to meet the Company's anticipated operating needs through the third quarter of 2017. Accordingly, since management has concluded that the Company does not have sufficient funds to support operations through February 2018, the Company believes that doubt about the Company's ability to continue as a going concern exists. The Company's auditors have also included explanatory language in their opinion that substantial 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 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, 2016. 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 Accounting

The accompanying condensed 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 (CODM), or decision-making group, in deciding how to allocate resources and in accessing performance. The Company views its operations and manages its business in one segment, glucose monitoring systems.

Comprehensive Income (Loss)

Comprehensive income (loss) comprises net income (loss) and other changes in equity that are excluded from net income (loss). For the years ended December 31, 2016, 2015 and 2014, the Company's net loss equaled its comprehensive loss and, accordingly, no additional disclosure is presented.

Inventory

Inventory consist principally of finished goods and is valued at the lower of cost to purchase or the net realizable value of such inventory. Cost is determined using the standard cost method that approximates first in, first out. Market is determined by the lower of replacement cost or net realizable value. 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.

Marketable Securities

Marketable securities consist of debt securities in government-sponsored entities, corporate debt securities, U.S. Treasury securities and commercial paper. The Company's investments are classified as available for sale. Such securities are carried at estimated 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.

Cash and Cash Equivalents and Concentration of Credit Risk

Cash equivalents are highly-liquid instruments with original maturities of three months or less and consist of U.S. Government and U.S. Government agency securities and money market funds with major commercial banks and financial institutions. Cash equivalents are recorded at cost plus accrued interest.

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.

Revenue Recognition

Revenue is generated from sales of sensor kits, transmitter kits, and related supplies under agreements for research and third-party distributors that resell the product to customers. The Company is paid for its sales directly by third-party distributors, regardless of whether or not the distributors resell the products to their customers.

The Company recognizes product sales revenue when all of the following criteria are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred;
- the price is fixed or determinable; and
- collectability is reasonably assured.

The Company offers no rights of return and has no significant post-delivery obligations and therefore, the above criteria are generally met as products are shipped to, or received by, third-party distributors.

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.

Warranty Reserve

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

Property and Equipment

Property and equipment are stated at historical cost and depreciated on a straight-line basis over the estimated useful lives, generally five years. Equipment under capital leases is depreciated on a straight-line basis over the lesser of its estimated useful life or the lease term. Leasehold improvements are depreciated over the shorter of the remaining lease term or useful lives of the assets. 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 2016, 2015 and 2014.

Treasury Stock

The Company records purchases of common stock for treasury at cost, and carries the cost of treasury stock as a reduction in stockholders' equity. The Company maintained 43,907 shares of common stock in treasury as of December 31, 2014; the treasury stock was retired effective with the Acquisition. There is no treasury stock outstanding as of December 31, 2016.

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 Accounting Standards Codification (“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, 2016 and 2015, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The carrying amount of our Term Notes Payable approximate fair value as they were issued in the current year. The fair values of our marketable investments are reported in Note 13 —*Fair Value Measurements*, respectively.

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, 2016 and 2015.

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.

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 was 16,574,761, 14,261,768 and 34,435,548 at December 31, 2016, 2015 and 2014, respectively, consisting of common stock options and stock purchase warrants, which have been excluded from the computation of diluted loss per share, as follows:

	December 31,		
	2016	2015	2014
Convertible preferred shares	—	—	23,653,592
Common stock options	11,389,773	9,251,164	8,393,081
Stock purchase warrants	5,184,988	5,010,604	2,388,875
Total anti-dilutive outstanding	16,574,761	14,261,768	34,435,548

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

In May 2014, the Financial Accounting Standards Board (“FASB”) issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. The Company does not intend to adopt the guidance early. The Company currently expects that the adoption of this guidance likely will change the way it recognizes revenue generated under customer contracts. The Company has not yet begun to evaluate the specific impacts of this guidance nor has the Company determined the manner in which it will adopt this guidance.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity’s ability to continue as a going concern. The guidance 1) provides a definition for the term “substantial doubt,” 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management’s plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management’s plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for the annual reporting period ending after December 15, 2016 and for annual periods and interim periods thereafter. The Company adopted the guidance and has included the expanded discussion on going concern above.

In April 2015, the FASB issued accounting guidance requiring that debt issuance costs related to a recognized liability be presented on the balance sheet as a direct reduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected. The standard is effective for reporting periods beginning after December 15, 2015. The Company adopted the guidance and the debt on the consolidated balance sheets is disclosed net of issuance costs.

In April 2015, the FASB issued accounting guidance related to Internal-Use Software specifically for the Customer's Accounting for Fees Paid in a Cloud Computing Arrangement. The amendments in this Update provide guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The standard is effective for reporting periods beginning after December 15, 2015. An entity can elect to adopt the amendments either 1) prospectively for all arrangements entered into or materially modified after the effective date or 2) retrospectively. The Company decided to adopt the standards prospectively and will be accounting for the new cloud arrangements in accordance with the new standards. The adoption of this guidance will not have a material impact on the financial statements.

In November 2015, the FASB issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented. The Company adopted this guidance for the year ended December 31, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued 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. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. The Company currently expects that the adoption of this guidance likely will change the way the Company accounts for its operating leases and likely will result in recording the future benefits of those leases and the related minimum lease payments on its balance sheet. The Company has not yet begun to evaluate the specific impacts of this guidance nor has it determined the manner in which it will adopt this guidance.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. The Company early adopted this guidance as of January 1, 2017. From January 1, 2017 onward, in accordance with the new guidance, no excess tax benefits or tax deficiencies will be recognized in additional paid-in capital. The Company's existing additional paid-in capital pool balance at December 31, 2016 is \$204.7 million. The Company will account for forfeitures as they occur, rather than using an estimated forfeiture rate. The Company estimates that this change in accounting will not result in a cumulative-effect adjustment to retained earnings as of January 1, 2017. The Company will also present the impact of classifying excess tax benefits as an operating activity in the statement of cash flows on a prospective basis and prior periods will not be adjusted. The adoption of the remaining amendments is not expected to have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company currently expects that the adoption of this guidance likely will change the way the Company assesses the collectibility of its receivables and recoverability of other financial instruments. The Company has not yet begun to evaluate the specific impacts of this guidance nor has it determined the manner in which it will adopt this guidance.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and cash payments in the statement 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 guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis and must be applied to all periods presented, but may be applied prospectively if retrospective application would be impracticable. The Company is currently evaluating the impact, if any, that the adoption of this guidance will have on its consolidated statements of cash flows.

In November 2016, the FASB issued guidance to reduce diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The revised guidance requires that amounts generally described as restricted cash and restricted cash equivalents be included in with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the statement of cash flows. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis. The Company adopted this guidance as of January 1, 2017, on a retrospective basis, and all periods will be presented under this guidance. The adoption of this new guidance will have no impact on the Company's consolidated financial statements.

The Company has evaluated all other issued and unadopted Accounting Standards Updates and believes the adoption of these standards will not have a material impact on the results of operations, financial position, or cash flows.

4. Marketable Securities

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

	December 31, 2016			Estimated Market Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government agencies	\$ 1,201	\$ —	\$ —	\$ 1,201
Commercial paper	6,090	—	—	6,090
Total	\$ 7,291	\$ —	\$ —	\$ 7,291

There were no marketable securities in 2015.

5. Property and Equipment

Property and equipment consisted of the following as of December 31, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Laboratory equipment	\$ 780	\$ 518
Office furniture and equipment	58	57
Leased equipment	159	—
Leasehold improvements	551	394
	1,548	969
Less: Accumulated depreciation	(813)	(658)
Property and equipment, net	\$ 735	\$ 311

Depreciation expense for the years ended December 31, 2016 and 2015, and 2014 was \$154,722, \$118,174 and \$189,325, respectively and is recorded within the administrative expenses in the consolidated statements of operations. The Company disposed of \$0, \$143,155, and \$1,070,595 of fully depreciated property and equipment in 2016, 2015, and 2014, respectively.

6. Other Balance Sheet Details

Accrued expenses and other current liabilities consisted of the following as of December 31, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Clinical and preclinical	\$ 500	\$ 871
Contract manufacturing	1,328	754
Compensation and benefits	1,774	593
Legal	314	243
Audit and tax related	320	376
Other	244	183
Financing costs	—	655
Total accrued expenses	4,480	3,675
Equipment lease, current portion	79	—
Deferred rent, current portion	—	7
Compensation and benefits	29	12
Other	78	—
Total accrued expenses and other current liabilities	\$ 4,666	\$ 3,694

7. 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. Rent expense is recognized on a straight-line basis and was \$544,504 for the year ended December 31, 2016 and \$386,438 for each of the years ended December 31, 2015 and 2014. The contractually required cash payments under this lease at December 31, 2016 are as follows (in thousands):

2017	\$ 608
2018	607
2019	611
2020	629
2021	648
2022	668
2023	282
Total minimum lease payments	\$ 4,053

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 \$470,000 during the year ended December 31, 2016. There were approximately \$2.3 million of future minimum payments under this commitment at December 31, 2016.

8. 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 2016, 2015 or 2014.

9. 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 may potentially borrow up to an aggregate principal amount of \$30.0 million in the following four tranches: \$15.0 million (“Tranche 1 Term Loan”); \$5.0 million (“Tranche 2 Term Loan”); \$5.0 million (“Tranche 3 Term Loan”); and \$5.0 million (“Tranche 4 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 may borrow the Tranche 3 Term Loan on or before April 30, 2017 if it completes the first commercial sale of its second-generation transmitter in the European Union. The Company may borrow the Tranche 4 Term Loan on or before December 31, 2017 if it borrows the Tranche 3 Term Loan, receives PMA approval from the FDA for Eversense, and achieves trailing six-month revenue for the applicable period of measurement of at least \$4.0 million. 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 consist of interest-only. After twelve months, the monthly payments will convert to payments of principal and monthly accrued interest, with the principal amount being amortized over the ensuing 36 months. However, if the Company borrows the Tranche 3 Term Loan, the interest-only period will be extended by an additional six months, and the amortization period will be shortened to 30 months.

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 and 63,025 shares of common stock with an exercise price of \$3.86 and \$2.38 per share, respectively, to the Lenders (see Note 10).

The Notes are collateralized by all of the Company’s consolidated assets other than its intellectual property. 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 \$568,648 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

\$421,840, 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. In the event that the Company achieves the requirements to borrow the Tranche 3 Term Loan or the Tranche 4 Term Loan, and elects not to borrow either tranche, the Company is obligated to pay the Lenders a non-utilization fee of 2.00% of the undrawn amounts.

The following are the scheduled maturities of the Oxford and SVB notes as of December 31, 2016, assuming the Company does not launch the second generation transmitter and borrow the Tranche 3 Term Loan by April 30, 2017, in which case, principal payments will begin on July 1, 2017 (in thousands):

2017	\$ 3,889
2018	6,667
2019	6,667
2020	2,777
Total	<u>\$ 20,000</u>

Energy Capital, LLC Borrowing Facility

On December 7, 2015, the Company entered into a note purchase agreement (the "Purchase Agreement") with Energy Capital, LLC ("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 amounts were repaid in full prior to December 31, 2016 and the facility was terminated.

10. Stockholders' Equity (Deficit)

Pursuant to the terms of 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, 2016, the Company had authorized 250,000,000 shares of common stock and 93,569,642 shares of common stock were issued and outstanding.

Preferred Stock

As of December 31, 2016 and 2015, 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, 2016 or 2015.

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 and 63,025 shares of common stock at an exercise price of \$3.86 and \$2.38 per share respectively. The fair value of the warrants, which the Company estimated to be \$421,840, was recorded as a discount to the Notes. These warrants expire on June 30, 2026 and November 22, 2026, 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 \$205,150, 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, 2016 and 2015, the Company recorded amortization of discount of debt of \$110,136 and \$72,229, 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, 2016, 4,894,146 shares remained available for grant under the amended and restated 2015 Plan. Effective January 1, 2017, 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 8,169,083 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.					
	2016		2015		2014	
Expected term of options	6.5	years	6.5	years	6.25 -6.5	years
Expected volatility rate	58.99 -61.39	%	54.02 -54.25	%	55.52 -56.42	%
Risk-free rate	1.40 - 2.30	%	0.70 -1.90	%	2.00 -2.10	%
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 historical experience for the years ended December 31, 2016 and 2015 and have not been material.

Employee stock-based compensation expense for employee granted stock options was \$3.6 million, \$1.4 million and \$0.5 million for the years ended December 31, 2016, 2015 and 2014 respectively of which \$201,667 was classified as sales and marketing expenses in 2016, \$517,721 \$462,006 and \$105,465 was classified as research and development expenses and \$1,312,574, \$583,653 and \$433,733 was classified as administrative expenses in the accompanying consolidated statements of operations in 2016, 2015 and 2014, respectively. Stock-based compensation expense for restricted stock awards was \$1,551,600, \$387,600 and \$0 for the years ended December 31, 2016, 2015 and 2014, respectively, all of which was classified as administrative expense in the accompanying consolidated statements of operations.

As of December 31, 2016, there was \$5.1 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 2.74 years. The aggregate intrinsic value of stock options outstanding at December 31, 2016 was \$16.9 million, which approximated the aggregate intrinsic value of options vested and expected to vest as of December 31, 2016 as a result of immaterial pre-vesting forfeitures. The total fair value of options that vested during 2016 and 2015 were approximately \$1.5 million and \$0.8 million, respectively.

Stock option activity under the Plans during the years ended December 31, 2016 and 2015 is as follows:

	<u>Number of Shares in (in thousands)</u>	<u>Weighted- Average Exercise Price</u>
Options outstanding as of December 31, 2014	8,393	\$ 0.53
Options granted	1,540	\$ 1.90
Options exercised	(121)	\$ 0.51
Options canceled/forfeited	(561)	\$ 0.50
Options outstanding as of December 31, 2015	9,251	\$ 0.74
Options granted	2,464	\$ 3.09
Options exercised	(269)	\$ 0.60
Options canceled/forfeited	(57)	\$ 1.43
Options outstanding as of December 31, 2016	11,389	\$ 1.26
Options vested and expected to vest as of December 31, 2016	11,389	\$ 1.26

Outstanding stock options at December 31, 2016 have a weighted-average remaining contractual life of 7.2 years, which approximates the weighted-average remaining contractual life of the options vested and expected to vest at December 31, 2016, and will vest ratably over a minimum period of two years. At December 31, 2016, there were 6,134,676 exercisable stock options with a weighted-average exercise price of \$0.75 and a weighted-average remaining contractual life of 6.0 years. The aggregate intrinsic value of the options currently exercisable at December 31, 2016 was \$11.9 million. For the years ended December 31, 2016 and 2015, 268,670 and 121,250 options were exercised, respectively, with an aggregate intrinsic value at the time of exercise of \$669,997 and \$123,224, respectively.

During the second quarter of 2015, the Company modified certain outstanding stock options, including acceleration of vesting on certain options, and the removal of certain performance conditions on other options. No other terms of the awards were modified. The modification of the vesting period resulted in \$34,912 of additional expense on the date of modification. The modification of the performance conditions resulted in incremental compensation cost of \$0.9 million, of which \$245,636 was expensed upon modification. The remaining incremental compensation cost will be recognized over the remaining vesting of two years for the 2013 grants and between 2.68 and 3.18 years for the 2014 grants.

The weighted average grant date fair value of the unvested stock option awards outstanding at December 31, 2016 and 2015 was \$1.11 and \$0.62 per share, respectively. The weighted average grant-date fair value of stock option awards granted in 2016 and 2015 was \$1.76 and \$1.02 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, 2016 were \$0.77, \$0.40 and \$1.04 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 12. 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.

A summary of the Company's Restricted Stock Awards as of December 31, 2016 is presented below:

	Number of Shares (in thousands)
Restricted Stock Awards nonvested at December 31, 2015	199
Granted	300
Vested	(499)
Cancelled and forfeited	—
Restricted Stock Awards nonvested at December 31, 2016	—
Vested and expected to vest at December 31, 2016	—

In August 2015, the Company completed a private offering of 2,711,926 shares of Series E Stock at a purchase price of \$3.93 per share for total proceeds of \$10.7 million. The Company recognized a beneficial conversion feature of \$406,783 associated with the Series E Stock since the initial effective conversion price was determined to be less than the fair value of the underlying common stock into which the Series E Stock is convertible. The beneficial conversion feature was recognized as a "deemed dividend" at issuance since the Series E Stock is convertible at any time at the option of the holders.

Prior to their conversion to common stock in connection with the Acquisition, all series of preferred stock were equity classified. The holders of preferred stock were entitled to receive dividends as may be declared by the board of directors. The Company did not declare or otherwise recognize any preferred stock dividends during the years ended December 31, 2016 and 2015.

Pursuant to the terms of the Acquisition (i) all outstanding shares of common stock of Senseonics, Incorporated \$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, Incorporated 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 or preferred stock of Senseonics, Incorporated were exchanged for or replaced with options and warrants to acquire shares of the Company's common stock using the same exchange ratio. As a result, the Company did not have any shares of preferred stock issued or outstanding as of December 31, 2016 or 2015.

11. 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, 2016 and 2015 is as follows (in thousands):

	December 31,	
	2016	2015
Deferred income tax assets (Liabilities)		
Net operating loss carryforwards	\$ 56,425	\$ 40,617
Capitalized start-up costs	20,483	19,546
R&E credit carryforwards	5,533	4,698
Stock based compensation	1,290	777
Other	27	(6)
Deferred income tax assets	83,758	65,632
Valuation allowance	(83,758)	(65,632)
Net deferred income tax assets (liabilities)	<u>\$ —</u>	<u>\$ —</u>

The increase in valuation allowance is primarily due to net losses and credits incurred in 2016, 2015 and 2014. 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, 2016, the Company had NOL carryforwards of \$143.1 million and had research and experimental credit carryforwards of \$6.9 million. These carryforwards will expire in varying amounts between 2018 and 2036. 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, 2016, 2015 and 2014 is as follows:

	Year Ended December 31,		
	2016	2015	2014
Tax at U.S. Federal Statutory rate	34.00 %	34.00 %	34.00 %
State taxes, net	5.45	5.45	5.39
Research and development credit	1.82	2.01	3.05
Other non-deductible items	0.07	(1.05)	(1.20)
Increase in valuation allowance	(41.34)	(40.41)	(41.24)
Effective income tax rate	0.00 %	0.00 %	0.00 %

A breakdown of the Company's uncertain tax position during 2016, 2015, and 2014 is as follows (in thousands):

	2016	2015	2014
Gross unrecognized tax benefit at beginning of year	\$ 1,174	\$ 1,025	\$ 922
Increase from tax positions taken in prior years	9	—	(12)
Increase from tax positions in current year	200	149	115
Settlements with taxing authorities	—	—	—
Lapse of statute of limitations / expiration	—	—	—
Gross unrecognized tax benefit at end of year	\$ 1,383	\$ 1,174	\$ 1,025

As of December 31, 2016, 2015, and 2014 the Company had uncertain tax positions totaling \$1.4 million, \$1.2 million, and \$1.0 million, respectively. The Company did not incur any penalties or interest payable to taxing authorities in 2016, 2015 or 2014.

The Company's U.S. Federal and state income tax returns from 1998 to 2015 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.

12. Related Party Transactions

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 \$785,000. 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 9, 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.

13. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to settle a liability in an orderly transaction between market participants at the measurement date. Fair value has a three level hierarchy from highest priority (Level 1) to lowest priority (Level 3). The fair value hierarchy reflects whether the inputs are observable from independent sources or rely on unobservable inputs based on the Company's market assumptions. The three levels of the fair value hierarchy are described below:

- Level 1 - Quoted prices for identical assets or liabilities (unadjusted) in active markets.
- Level 2 - Observable inputs other than quoted prices that are either directly or indirectly observable for the assets or liability.
- Level 3 - Unobservable inputs that are supported by little or no market activity.

The levels are not necessarily an indication of the risk of liquidity associated with the financial assets or liabilities disclosed.

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, 2016 and 2015 (in thousands):

	December 31, 2016			
	Total	Level 1	Level 2	Level 3
Money market funds	\$ 10,601	\$ 10,601	\$ —	\$ —
U.S. government agencies	1,201	—	1,201	—
Commercial paper	6,589	—	6,589	—

	December 31, 2015			
	Total	Level 1	Level 2	Level 3
Money market funds	\$ 3,938	\$ 3,938	\$ —	\$ —

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 2016, 2015, and 2014.

14. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal 2016 and 2015 is presented in the following table, in thousands, except per share data:

	For the Quarter Ended			
	March 31	June 30	September 30	December 31
2016:				
Revenue	\$ —	\$ 19	\$ 37	\$ 276
Gross profit	\$ —	\$ (15)	\$ (77)	\$ (236)
Operating expenses	\$ 10,928	\$ 11,535	\$ 10,435	\$ 9,207
Operating loss	\$ (10,928)	\$ (11,550)	\$ (10,512)	\$ (9,443)
Net loss	\$ (11,216)	\$ (11,861)	\$ (10,887)	\$ (9,965)
Basic and diluted net loss per share (1)	\$ (0.15)	\$ (0.13)	\$ (0.12)	\$ (0.11)
2015:				
Revenue	\$ 15	\$ 23	\$ —	\$ —
Gross profit	\$ 15	\$ 23	\$ —	\$ —
Operating expenses	\$ 5,414	\$ 6,931	\$ 8,315	\$ 8,190
Operating loss	\$ (5,399)	\$ (6,908)	\$ (8,315)	\$ (8,190)
Net loss	\$ (5,693)	\$ (7,185)	\$ (8,585)	\$ (8,414)
Basic and diluted net loss per share (1)	\$ (2.94)	\$ (3.68)	\$ (4.39)	\$ (0.39)

(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.

15. 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 \$40,000 and \$0 as of December 31, 2016 and 2015, 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.

16. Subsequent Events

Events occurring after December 31, 2016 and through the date that these consolidated financial statements were issued were evaluated to ensure that any subsequent events that met the criteria for recognition have been included.

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, 2016, 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, 2016, 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, 2016 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, 2016.

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

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth information concerning our directors and executive officers, including their ages as of February 22, 2017. There are no family relationships among any of our directors or executive officers.

We seek to assemble a board that, as a whole, possesses the appropriate balance of professional and industry knowledge, financial expertise and high-level management experience necessary to oversee and direct our business. To that end, our board intends to maintain membership of directors who complement and strengthen the skills of other members and who also exhibit integrity, collegiality, sound business judgment and other qualities that we view as critical to effective functioning of the board. The brief biographies below include information, as of the date of this report, regarding the specific and particular experience, qualifications, attributes or skills of each director that led the board to believe that the director should serve on the board.

Name	Age	Position
<i>Executive Officers:</i>		
Timothy T. Goodnow, Ph.D.	55	President, Chief Executive Officer and Director
R. Don Elsey	63	Chief Financial Officer, Secretary and Treasurer
Mukul Jain, Ph.D.	44	Chief Operating Officer
Mirasol Panlilio	52	Vice President, Global Sales and Marketing
Lynne Kelley, M.D., FACS	54	Chief Medical Officer
<i>Non-Management Directors:</i>		
Stephen P. DeFalco	55	Chairman of the Board of Directors
M. James Barrett, Ph.D.	74	Director
Steven Edelman, M.D.	61	Director
Edward J. Fiorentino	58	Director
Peter Justin Klein, M.D., J.D.	39	Director
Douglas S. Prince	63	Director
Douglas A. Roeder	46	Director

Executive Officers

Timothy T. Goodnow, Ph.D.

Dr. Goodnow was elected as one of our directors and was appointed as our President and Chief Executive Officer in December 2015. From December 2010 to December 2015, Dr. Goodnow served on the board of directors of Senseonics, Incorporated and he served as the President and Chief Executive Officer of Senseonics, Incorporated from March 2011 to December 2015. Dr. Goodnow served as Vice President, Technical Operations of Abbott Diabetes Care, a healthcare company, from 2000 to February 2011. Prior to that, he held positions at TheraSense, Verax Biomedical, Inc. and Dade Behring and Baxter Healthcare. Dr. Goodnow received his Ph.D. and B.S. in chemistry from The University of Miami. Our board of directors believes that Dr. Goodnow's experience as our Chief Executive Officer, his background in medical device development and his knowledge of the diabetes industry qualify him to serve as a director of our company.

R. Don Elsey

Mr. Elsey was appointed as our Chief Financial Officer in December 2015. Mr. Elsey served as the Chief Financial Officer of Senseonics, Incorporated from February 2015 to December 2015. He previously served as the Senior Vice President, Finance and Chief Financial Officer of Regado Biosciences, Inc., a public biopharmaceutical company, from May 2014 to February 2015. He also served as the Chief Financial Officer of LifeCell, Inc., a private regenerative medicine company, from December 2012 to February 2014 and as Senior Vice President and Chief Financial Officer of Emergent BioSolutions, Inc., a public biopharmaceutical company, from 2005 to December 2012. Prior to that, Mr. Elsey served as the Director of Finance and Administration at IGEN International, Inc., a public biotechnology

company, and its successor BioVeris Corporation, from 2000 to 2005. Prior to joining IGEN, he served as Director of Finance at Applera, a genomics and sequencing company, and in several finance positions at International Business Machines, Inc. Mr. Elsey serves on the board of directors of RegeneRx Biopharmaceuticals, Inc., a public biopharmaceuticals company, as well as on the board of the Cancer Support Community. Mr. Elsey received his M.B.A. in finance and his B.A. in economics from Michigan State University.

Mukul Jain, Ph.D.

Dr. Jain was appointed as our Chief Operating Officer in January 2017. Dr. Jain previously served as our Vice President Operations, Quality and Regulatory from December 2015 to January 2017. Dr. Jain served as Senior Director, Quality and Regulatory of Senseonics, Incorporated from January 2012 to January 2014 and as Vice President Operations, Quality and Regulatory of Senseonics, Incorporated from January 2014 to December 2015. Prior to that, Dr. Jain held various positions at Medtronic, Inc., a medical technology and services company, from 1999 to January 2012, most recently as a senior program manager. Dr. Jain received his M.B.A. from the University of Minnesota, Carlson School of Management, his Ph.D. in chemical engineering from the University of South Carolina and his B.Tech. from the Indian Institute of Technology, Kanpur.

Mirasol Panlilio

Ms. Panlilio was appointed as our Vice President, Global Sales and Marketing in December 2015. Ms. Panlilio served as the Vice President, Global Sales and Marketing of Senseonics, Incorporated from June 2014 to December 2015. Prior to joining Senseonics, Incorporated, Ms. Panlilio served as Vice President, Global Marketing and Sales at Viveve, Inc. from October 2012 to May 2014, an Independent Marketing Consultant at MGP Retail Consulting, LLC from May 2011 to June 2014, Vice President of Sales and Marketing for Arkal Medical, Inc. from 2010 to May 2011 and Vice President of Marketing and Sales at Veralight, Inc. from 2007 to 2010. From 2003 to 2007, Ms. Panlilio worked at Abbott Diabetes Care. Ms. Panlilio received her B.S. in business administration from San Jose State University.

Lynne Kelley, M.D., FACS

Dr. Kelley was appointed as our Chief Medical Officer in January 2016. From January 2011 to January 2016, Dr. Kelley was the World Wide Vice President of Medical Affairs Medical Surgical Systems of Becton, Dickinson & Company. Prior to that, Dr. Kelley was the Vice President Medical Director for Kimberly Clark from November 2007 to December 2010. From 2005 to 2007, Dr. Kelley served as the medical director for the peripheral interventions and vascular surgery business of Boston Scientific. Before her assignment with Boston Scientific, Dr. Kelley was an assistant professor of vascular surgery and radiology at Yale University from 2003 to 2005. Dr. Kelley is a board certified general and vascular surgeon. Dr. Kelley received her M.D. from Dartmouth Medical School and her B.A. in Biology from Boston University.

Non-Management Directors

Stephen P. DeFalco

Mr. DeFalco was elected as a director and our chairman in December 2015. Mr. DeFalco served as chairman of the Senseonics, Incorporated board of directors from June 2010 to December 2015 and served as Senseonics, Incorporated's interim Chief Executive Officer from 2010 to March 2011. Since October 2011, Mr. DeFalco has served as the Chief Executive Officer of Crane & Co, Inc., a global technology company, and also serves on its board of directors. Previously, from May 2005 to July 2010, he served as the Chief Executive Officer and on the board of directors of MDS, Inc., a public life sciences company. Mr. DeFalco received his M.B.A. from the Massachusetts Institute of Technology—Sloan School of Management, his M.S.E.E. from Syracuse University and his B.S.M.E. from the Massachusetts Institute of Technology. Our board of directors believes that Mr. DeFalco's leadership, executive, managerial and business experience with life sciences companies qualifies him to serve as a director of our company.

M. James Barrett, Ph.D.

Dr. Barrett was elected to our board of directors in December 2015. Dr. Barrett founded Senseonics, Incorporated and served as a member of the board of directors of Senseonics, Incorporated from November 1996 to December 2015. He served as the Chief Executive Officer of Senseonics, Incorporated from 1997 to 2001. He currently serves as a General Partner of New Enterprise Associates, or NEA, a venture capital firm, where he specializes in biotechnology and works with members of NEA's healthcare investment group on medical devices, healthcare information systems and healthcare services companies. Prior to joining NEA and Senseonics, Incorporated, he led three NEA-funded companies, serving from 1987 to 1995 as Chairman and Chief Executive Officer at Genetic Therapy, Inc. and from 1982 to 1987 as President and Chief Executive Officer at Life Technologies, Inc. and its predecessor, Bethesda Research Laboratories, Inc. Previously, Dr. Barrett worked at SmithKline Beecham Corporation, where he held a variety of positions, including President of its In Vitro Diagnostic Division and President of SmithKline Clinical Laboratories. He currently serves on the boards of directors of the publicly-held life sciences companies GlycoMimetics, Inc., Clovis Oncology, Inc., Proteostasis Therapeutics, Inc. and Roka Bioscience, Inc. In the past five years, he has served on the boards of directors of the publicly traded companies Amicus Therapeutics, Inc., Inhibitex, Inc. (acquired by Bristol-Myers Squibb Co.), Loxo Oncology, Inc., Supernus Pharmaceuticals, Inc., Targacept, Inc. and Zosano Pharma Corporation. Dr. Barrett received his Ph.D. in biochemistry from the University of Tennessee, his M.B.A. from the University of Santa Clara and his B.S. from Boston College. Our board of directors believes that Dr. Barrett's experience overseeing NEA's investments in biotechnology, serving as a member of the board of directors of other public companies, prior senior management experience, including as President and Chief Executive Officer of biopharmaceutical companies, and his strong capital markets experience qualify him to serve as a director of our company.

Steven Edelman, M.D.

Dr. Edelman was elected to our board of directors in September 2016. Dr. Edelman has served as a Professor of Medicine in the Division of Endocrinology, Diabetes & Metabolism at the University of California, San Diego and the Veterans Affairs Healthcare System of San Diego since 2001. He also currently serves as a director of Taking Control of Your Diabetes, a non-profit organization promoting patient education, motivation and self-advocacy that he founded in 1995, and the Diabetes Care Clinic VA Medical Center. Dr. Edelman received his B.A. and his M.S. in Biology from the University of California, Los Angeles and his M.D. from the University of California, Davis. Our board of directors believes that Dr. Edelman's substantial diabetes industry experience qualifies him to serve as a director of our company.

Edward J. Fiorentino

Mr. Fiorentino was elected to our board of directors in December 2015. Mr. Fiorentino served on the Senseonics, Incorporated board of directors from March 2012 to December 2015. Since March 2016, Mr. Fiorentino has served as Chairman and Chief Executive Officer of TerSera Therapeutics, a specialty pharmaceutical company. Previously, from August 2013 to January 2016, Mr. Fiorentino has served as Chairman and Chief Executive Officer of Crealta Pharmaceuticals, a specialty pharmaceutical company. From March 2009 to June 2013, he was the Chief Executive Officer of Actient Pharmaceuticals. Prior to Actient, Mr. Fiorentino served in various positions at Abbott Laboratories, including Corporate Vice President of Pharmaceutical Commercial Operations, for more than 20 years. He also previously served as Senior Vice President and President of Abbott Diabetes Care and was Executive Vice President of TAP Pharmaceuticals. Mr. Fiorentino received his B.S. in Business Administration from the State University of New York and his M.B.A. from Syracuse University. Our board of directors believes that Mr. Fiorentino's substantial healthcare and pharmaceutical experience qualifies him to serve as a director of our company.

Peter Justin Klein, M.D., J.D.

Dr. Klein was elected to our board of directors in December 2015. Dr. Klein served on the Senseonics, Incorporated board of directors from September 2013 to December 2015. Dr. Klein has served as a Partner at NEA since 2006. Prior to joining NEA, Dr. Klein worked for the Duke University Health System. Dr. Klein currently serves as a director of several private life sciences companies. Dr. Klein received his A.B., B.S. and M.D. from Duke University and his J.D. from Harvard Law School. Our board of directors believes that Dr. Klein's significant legal and medical

expertise in healthcare and his services as a venture capital investor and director of multiple biotechnology and medical device companies qualify him to serve as a director of our company.

Douglas S. Prince

Mr. Prince was elected to our board of directors in December 2015. Mr. Prince served on the Senseonics, Incorporated board of directors from February 2015 to December 2015. Mr. Prince has acted as the Chief Financial Officer of Crane & Co. Inc., a global technology company, since February 2013. Prior to Crane & Co., from October 2010 to January 2013, Mr. Prince served as the Chief Financial Officer of Northern Power Systems Corp., an energy technology company. From 2007 to 2010, Mr. Prince served as Chief Financial Officer of MDS Inc., a public life sciences company. Mr. Prince received his B.B.A. in Business Administration from the University of Kentucky. Our board of directors believes that Mr. Prince's executive experience and financial expertise qualify him to serve as a director of our company.

Douglas A. Roeder

Mr. Roeder was elected to our board of directors in December 2015. Mr. Roeder served on the Senseonics, Incorporated board of directors from October 2011 to December 2015. Mr. Roeder joined Delphi Ventures as an Associate in 1998, and has been a Partner of Delphi Ventures since 2000, focusing on medical devices, diagnostics and biotechnology. Prior to joining Delphi Ventures, Mr. Roeder was an Associate with Alex, Brown & Sons Healthcare Investment Banking Group. Mr. Roeder currently serves on the boards of directors of Tandem Diabetes, Inc. and several private companies. Mr. Roeder previously served on the board of directors of TriVascular Technologies, Inc. from 2008 to 2016. Mr. Roeder received his A.B. from Dartmouth College. Our board of directors believes that Mr. Roeder's substantial experience with companies in the healthcare sector and his venture capital, financial and business experience qualify him to serve as a director of our company.

Section 16(a) Beneficial Ownership Reporting Compliance

Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of copies of such forms that we have received, or written representations from our reporting persons, we believe that during the fiscal year ended December 31, 2016, all of our reporting persons complied with all applicable SEC filing requirements under Section 16(a) of the Exchange Act.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.senseonics.com. The nominating and corporate governance committee of our board of directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. In addition, we intend to post on our website all disclosures that are required by law or the NYSE-MKT listing standards concerning any amendments to, or waivers from, any provision of the Code of Conduct.

Audit Committee and Audit Committee Financial Expert

We have a separately designated standing audit committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Our audit committee reviews our internal accounting procedures and consults with and reviews the services provided by our independent registered public accountants. Our audit committee consists of three directors, Mr. Prince, Mr. Fiorentino and Dr. Klein, and our board of directors has determined that each of them is independent within the meaning of NYSE-MKT listing requirements and the independence requirements contemplated by Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Mr. Prince is the chairman of the audit committee and our board of directors has determined that Mr. Prince is an "audit committee financial expert" as defined by SEC rules and regulations implementing Section 407 of the Sarbanes-Oxley Act. Our board of directors has determined that the composition of our audit committee meets the criteria for independence under, and the functioning of our audit committee complies with, the applicable requirements of the Sarbanes-Oxley Act, NYSE-MKT listing

requirements and SEC rules and regulations. We intend to continue to evaluate the requirements applicable to us and we intend to comply with the future requirements to the extent that they become applicable to our audit committee.

Stockholder Recommendation of Director Nominees

Our nominating and corporate governance committee will consider director candidates recommended by stockholders. The nominating and corporate governance committee does not intend to alter the manner in which it evaluates candidates, based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the nominating and corporate governance committee to become nominees for election to our board of directors may do so by delivering a written recommendation to the nominating and corporate governance committee at the following address: 20451 Seneca Meadows Parkway, Germantown, Maryland 20876-7005 at least 90 days, but not more than 120 days, prior to the anniversary date of the mailing of our proxy statement for the last annual meeting. Submissions must include the full name of the proposed nominee, a description of the proposed nominee's business experience for at least the previous five years, complete biographical information, a description of the proposed nominee's qualifications as a director and a representation that the nominating stockholder is a beneficial or record holder of our stock and has been a holder for at least one year. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected.

Item 11. Executive Compensation

All shares of Senseonics, Incorporated common stock converted into shares of Senseonics Holdings common stock, and all Senseonics Options converted into Company Options, in connection with the Closing of the Acquisition pursuant to the Exchange Ratio. With respect to the options, corresponding adjustments were also made to their exercise prices. The share and per share information included in this "Executive Compensation" section gives effect to the conversion of such shares and options in the Acquisition and related exercise price adjustments. The Summary Compensation Table and the Narrative to Summary Compensation Table below reflect compensation earned by our named executive officers for their service to Senseonics, Incorporated from January 1, 2015 to December 7, 2015, the date of the Closing of the Acquisition, and for their service to Senseonics Holdings, Inc. beginning on December 7, 2015.

Our Chief Executive Officer and our two other most highly compensated executive officers for the year ended December 31, 2016 were:

- Timothy T. Goodnow, Ph.D., President and Chief Executive Officer;
- R. Don Elsey, Chief Financial Officer; and
- Lynne E. Kelley, M.D., FACS Chief Medical Officer.

We refer to these executive officers in this Annual Report as our named executive officers.

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the years ended December 31, 2016 and 2015.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Option Awards (\$)⁽¹⁾</u>	<u>Non-Equity Incentive Plan Compensation (\$)⁽²⁾</u>	<u>Total (\$)</u>
Timothy T. Goodnow	2016	475,998	586,871	318,150	1,381,019
President and Chief Executive Officer	2015	365,791	231,704	152,718	750,213
R. Don Elsey ⁽³⁾	2016	355,625	472,275	153,300	981,200
Chief Financial Officer	2015	286,667	141,229	85,577	513,473
Lynne E. Kelley ⁽⁴⁾	2016	365,000	565,507	134,138	1,064,645
Chief Medical Officer					

- (1) The amounts include the full grant date fair value for awards granted during the indicated year. The grant date fair value was computed in accordance with ASC Topic 718, *Compensation—Stock Compensation*. Unlike the calculations contained in our audited consolidated financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note 10 to our audited consolidated financial statements included in this Annual Report.
- (2) The amounts reflect bonus paid on the achievement of specified corporate goals, as discussed further below under "—Narrative to Summary Compensation Table—Annual Bonus."
- (3) Mr. Elsey became an executive officer of Senseonics, Incorporated in February 2015 and amounts represent compensation earned since that date.
- (4) Ms. Kelley became an executive officer of Senseonics, Incorporated in January 2016 and amounts represent compensation earned since that date.

Narrative to Summary Compensation Table

We review compensation annually for all employees, including our named executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

Our compensation committee has historically determined our executives' compensation. Our compensation committee typically reviews and discusses management's proposed compensation with the chief executive officer for all executives other than the chief executive officer. Based on those discussions and its discretion, our compensation committee then approves the compensation of each executive officer after discussions without members of management present.

Our compensation committee has engaged Towers Watson, a compensation consultant, and reviewed Towers Watson's compensation data for executives at similarly sized medical device companies when determining executive compensation.

Annual Base Salary

Senseonics, Incorporated entered into employment agreements with each of its named executive officers that establish their base salaries and target bonus opportunities. In connection with the Acquisition, we assumed those employment agreements. The base salaries will be reviewed periodically by our compensation committee. The following table presents the annual base salaries for each of our named executive officers for 2015, 2016 and 2017. The 2015 base salaries became effective on January 1, 2015, the 2016 base salaries became effective on March 16, 2016, and the 2017 base salaries became effective on January 1, 2017 for all of the named executive officers.

Name	2015 Base Salary (\$)	2016 Base Salary (\$)	2017 Base Salary (\$)
Timothy T. Goodnow	365,791	505,000	520,000
R. Don Elsey	320,000	365,000	376,000
Lynne E. Kelley	N/A	365,000	370,000

Annual Bonus

We seek to motivate and reward our executives for achievements relative to our corporate goals and expectations for each fiscal year. Each named executive officer has a target bonus opportunity, defined as a percentage of his or her annual salary. The following table presents the annual target bonus opportunity, as a percentage of annual base salary, for each of our named executive officers for 2015, 2016 and 2017.

Name	Target Bonus (as a % of Base Salary) (%) 2015	Target Bonus (as a % of Base Salary) (%) 2016	Target Bonus (as a % of Base Salary) (%) 2017
Timothy T. Goodnow	50	60	75
R. Don Elsey	35	40	50
Lynne E. Kelley	N/A	35	35

For 2015, bonuses were based on Senseonics, Incorporated's achievement of specified corporate goals, including completing enrollment in the European pivotal clinical trial, receiving IDE approval for the U.S. pivotal clinical trial, obtaining CE Mark approval for Eversense, commercializing Eversense in at least one European market and completing a successful surveillance audit. Based on the level of achievement, the Senseonics, Incorporated compensation committee awarded Dr. Goodnow and Mr. Elsey 84% of their target bonuses based on their 2015 base salary, respectively.

For 2016, bonuses were based on our achievement of specified corporate goals, including submitting regulatory approval documents related to our U.S. clinical trial, increasing manufacturing capacity, completing the enrollment of our European pivotal clinical trial, demonstrating an increase in sensor manufacturing capacity, completing development of the second generation transmitter, launching Eversense in multiple European markets, completing a successful surveillance audit, and managing the total spend of the organization within the approved budget. Based on the level of achievement, our compensation committee awarded each of Dr. Goodnow, Mr. Elsey and Dr. Kelley 105% of their target bonuses based on their 2016 base salary.

These actual bonus amounts are reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

Long-Term Incentives

Our 1997 stock option plan, or the 1997 plan, authorized us, and the amended and restated 2015 equity incentive plan, or the 2015 plan, authorizes us to make grants to eligible recipients of non-qualified stock options and incentive stock options.

We award stock options on the date the compensation committee approves the grant. We set the option exercise price and grant date fair value based on its per-share valuation on the date of grant.

In July 2015, the Senseonics, Incorporated board of directors awarded to Dr. Goodnow and Mr. Elsey options to purchase 220,237 and 134,240 shares of our common stock, respectively. Each of these options was originally issued with an exercise price of \$1.95 per share.

In April 2016, our board of directors awarded Dr. Kelley an option to purchase 334,996 shares of our common stock, with an exercise price of \$2.97 per share. 83,750 shares underlying this option vested on January 4, 2017, and the remainder of the shares vest in 36 equal monthly installments through January 4, 2020. In April 2016, our board of directors also awarded to Dr. Goodnow and Mr. Elsey options to purchase 347,652 and 279,767 shares of our common stock, respectively. Each of these options was issued with an exercise price of \$2.97 per share. The shares underlying the options granted to Dr. Goodnow and Mr. Elsey vest in 48 equal monthly installments. All shares subject to vesting under these option grants will vest in full and become immediately exercisable upon the closing of a change in control of our company.

Outstanding Equity Awards at End of 2016

The following table provides information about outstanding Company Options held by each of our named executive officers at December 31, 2016. All of these options were granted under the 1997 plan or the 2015 plan. None of our named executive officers held any other stock awards at the end of 2016.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Timothy T. Goodnow	2,038,610	—	0.54	12/2/2020
	589,093	—	0.54	2/28/2021
	267,734	196,640 ⁽²⁾	0.54	6/4/2024
	78,001	142,235 ⁽³⁾	1.95	7/22/2025
	57,942	289,710 ⁽⁵⁾	2.97	4/12/2026
R. Don Elsey	298,019	352,205 ⁽⁴⁾	0.54	12/4/2024
	47,453	86,787 ⁽³⁾	1.95	7/22/2025
	46,628	233,139 ⁽⁵⁾	2.97	4/12/2026
Lynne E. Kelley	—	334,996 ⁽⁶⁾	2.97	4/12/2026

- (1) All shares subject to vesting under these options will vest in full and become immediately exercisable upon the closing of a change in control of our company.
- (2) The unvested shares underlying this option vest in 18 equal monthly installments, subject to the officer's continued service through each applicable vesting date.
- (3) The unvested shares underlying this option vest in 31 equal monthly installments, subject to the officer's continued service through each applicable vesting date.
- (4) The unvested shares underlying this option vest in 26 equal monthly installments, subject to the officer's continued service through each applicable vesting date.
- (5) The unvested shares underlying this option vest in 40 equal monthly installments, subject to the officer's continued service through each applicable vesting date.
- (6) The unvested shares underlying this option vest as to 25% of the shares in January 2017 and the remaining shares vest in 36 equal monthly installments, subject to the officers continued service through each applicable vesting date.

Employment Agreements

Below are descriptions of employment agreements that our named executive officers entered into with us or Senseonics, Incorporated. We assumed the employment agreements with Dr. Goodnow and Mr. Elsey in connection with the Acquisition.

Agreement with Dr. Goodnow

In July 2015, Senseonics, Incorporated entered into an amended and restated employment agreement with Dr. Goodnow that governs the terms of his employment with us. Pursuant to the agreement, Dr. Goodnow is entitled to an annual base salary of \$365,791 and is eligible to receive an annual performance bonus of up to 50% of his base salary, as determined by our board of directors. If Dr. Goodnow's employment is terminated by us for reasons other than for cause or if he resigns for good reason (each as defined in his employment agreement), he would be entitled to receive severance payments equal to continued payment of his base salary for 18 months, 100% of his target bonus, employee benefit coverage for up to 18 months, and reimbursement of expenses owed to him through the date of his termination. If Dr. Goodnow's employment is terminated by us other than for cause or if he resigns for good reason, coincident with a change in control (as defined in his employment agreement), he would be entitled to the benefits described above, although he would be entitled to 150%, rather than 100%, of his target bonus, and 50% of his then unvested equity awards would become fully vested. Additionally, if Dr. Goodnow's employment is terminated by us or any successor entity without cause within 12 months following a change in control, then 100% of his then unvested equity awards shall become fully vested.

Agreement with Mr. Elsey

In July 2015, Senseonics, Incorporated entered into an amended and restated employment agreement with Mr. Elsey that governs the terms of his employment with us. Pursuant to the agreement, Mr. Elsey is entitled to an annual base salary of \$320,000 and is eligible to receive an annual performance bonus of up to 35% of his base salary, as determined by our board of directors. If Mr. Elsey's employment is terminated by us for reasons other than for cause or if he resigns for good reason (each as defined in his employment agreement), he would be entitled to receive severance payments equal to continued payment of his base salary for one year, a prorated portion of his target bonus for the year in which his service is terminated, employee benefit coverage for up to one year, and reimbursement of expenses owed to him through the date of his termination. If Mr. Elsey's employment is terminated by us other than for cause or if he resigns for good reason, coincident with a change in control (as defined in his employment agreement), he would be entitled to the benefits described above, although in lieu of the bonus described above, he would be entitled to 125% of his target bonus, and 50% of his then unvested equity awards would become fully vested. Additionally, if Mr. Elsey's employment is terminated by us or any successor entity without cause within 12 months following a change in control, then 100% of his then unvested equity awards shall become fully vested.

Agreement with Dr. Kelley

In April 2016, we entered into an employment agreement with Dr. Kelley that governs the terms of her employment with us. Pursuant to the agreement, Dr. Kelley is entitled to an annual base salary of \$365,000 and is eligible to receive an annual performance bonus of up to 35% of her base salary, as determined by our board of directors. If Dr. Kelley's employment is terminated by us for reasons other than for cause or if she resigns for good reason (each as defined in her employment agreement), she would be entitled to receive severance payments equal to continued payment of her base salary for nine months, a prorated portion of her target bonus for the year in which her service is terminated, employee benefit coverage for up to nine months, and reimbursement of expenses owed to her through the date of her termination. If Dr. Kelley's employment is terminated by us other than for cause or if she resigns for good reason, coincident with a change in control (as defined in her employment agreement), she would be entitled to the benefits described above, although in lieu of the bonus described above, she would be entitled to the larger of 75% of her target bonus or her pro rata portion of her target bonus. Additionally, if Dr. Kelley's employment is terminated by us or any successor entity without cause within 12 months following a change in control, then 100% of her then unvested equity awards shall become fully vested.

401(k) Plan

We maintain a defined contribution employee retirement plan for our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Internal Revenue Code so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute a portion of his or her pre-tax compensation, up to the statutory limit. Under our 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee, subject to participants' ability to give investment directions by following specified procedures. We do not currently make discretionary contributions or matching contributions to our 401(k) plan.

Equity Incentive Plans

2015 Equity Incentive Plan

The Senseonics, Incorporated board of directors adopted our 2015 Equity Incentive Plan, or the 2015 plan, on December 1, 2015, and the Senseonics, Incorporated stockholders subsequently approved the 2015 Plan on December 4, 2015. In connection with the Acquisition, we assumed the 2015 plan, including all awards that were then outstanding under the 2015 plan. In connection with our public offering, in February 2016, our board of directors adopted and our stockholders approved an Amended and Restated 2015 Equity Incentive Plan, or the amended and restated 2015 plan. The amended and restated 2015 plan became effective on March 17, 2016.

Authorized Shares

The number of shares of common stock that may be issued pursuant to equity awards under the 2015 plan was initially 839,000 shares. Pursuant to the amended and restated 2015 plan, which become effective upon the pricing of our public offering, the number of shares of common stock that may be issued pursuant to equity awards was initially up to 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 1997 plan 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 our common stock reserved for issuance under our 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 our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by our board of directors. The maximum number of shares that may be issued pursuant to exercise of incentive stock options under the amended and restated 2015 plan will be 17,251,115 shares. As of December 31, 2016, a total of 4,894,146 shares were available for future issuance and options to purchase 11,354,418 shares of common stock at a weighted average exercise price of \$1.27 per share were outstanding. As of January 1, 2017, the number of shares of common stock that may be issued under the amended and restated 2015 plan was automatically increased by 3,274,937 shares, representing 3.5% of the total number of shares of common stock outstanding on December 31, 2016, increasing the number of shares of common stock remaining available for issuance under the amended and restated 2015 plan to 8,169,083 shares.

Shares issued under our 2015 plan may be authorized but unissued or reacquired shares of our common stock. Shares subject to stock awards granted under our 2015 plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2015 plan. Additionally, shares issued pursuant to stock awards under our 2015 plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under our 2015 plan.

Administration

Our board of directors, or a duly authorized committee thereof, has the authority to administer our 2015 plan. Our board of directors has delegated its authority to administer our 2015 plan to our compensation committee under the terms of the compensation committee's charter. Our board of directors may also delegate to one or more of our officers

the authority to (i) designate employees other than officers to receive specified stock awards and (ii) determine the number of shares of our common stock to be subject to such stock awards. Subject to the terms of our 2015 plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2015 plan.

The administrator has the power to modify outstanding awards under our 2015 plan. Subject to the terms of our 2015 plan, the administrator has the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration or take any other action that is treated as a repricing under GAAP with the consent of any adversely affected participant.

Section 162(m) Limits

No participant may be granted stock awards covering more than 1,000,000 shares of our common stock under our 2015 plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common stock on the date of grant. Additionally, no participant may be granted in a calendar year a performance stock award covering more than 1,000,000 shares of our common stock or a performance cash award having a maximum value in excess of \$3.0 million under our 2015 plan. These limitations enable us to grant awards that will be exempt from the \$1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code.

Performance Awards

Our 2015 plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the \$1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To enable us to grant performance-based awards that will qualify, our compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

Corporate Transactions

Our 2015 plan provides that in the event of a specified corporate transaction, including without limitation a consolidation, merger or similar transaction involving our company, the sale, lease or other disposition of all or substantially all of the assets of our company or the consolidated assets of our company and our subsidiaries, or a sale or disposition of at least 50% of the outstanding capital stock of our company, the administrator will determine how to treat each outstanding equity award. The administrator may:

- arrange for the assumption, continuation or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by us; or
- cancel the stock award prior to the transaction in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the stock award.

The administrator is not obligated to treat all equity awards or portions of equity awards, even those that are of the same type, in the same manner. The administrator may take different actions with respect to the vested and unvested portions of an equity award.

Change of Control

The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, which the equity award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. In the absence of such a provision, no such acceleration of the award will occur.

Plan Amendment or Termination

Our board has the authority to amend, suspend or terminate our 2015 plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No incentive stock options may be granted after the tenth anniversary of the date our board of directors adopted our 2015 plan.

1997 Stock Option Plan

The board of directors and stockholders of Senseonics, Incorporated approved the 1997 plan, which became effective in March 1997, and it was further amended and restated by the Senseonics, Incorporated board of directors and stockholders most recently in June 2011. In connection with the Acquisition, we assumed the 1997 plan. As of December 31, 2016, there were outstanding stock options covering a total of 9,251,164 shares granted under the 1997 plan.

Upon the effectiveness of the 2015 Plan, we no longer grant awards under the 1997 plan.

Types of Awards. The 1997 plan provided for the grant of incentive stock options and nonqualified stock options. Nonqualified stock options may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Incentive stock options may be granted only to employees.

Share Reserve. The aggregate number of shares of common stock reserved for issuance pursuant to stock options under the 1997 plan was 10,644,109 shares, less any shares issued as restricted stock, which was also the maximum number of shares that may be issued upon the exercise of ISOs under the 1997 plan.

If a stock option granted under the 1997 plan expires, terminates or is otherwise canceled without being exercised in full, or if we reacquire shares of unvested common stock issued pursuant to the founder's stock purchase agreements, the shares of our common stock not acquired pursuant to the stock option or forfeited will again become available for subsequent issuance as options under the 2015 plan.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 1997 plan. Subject to the terms of the 1997 plan, the our board of directors or the authorized committee, referred to herein as the plan administrator, has full power and authority to take all actions and make all determinations required or provided under the 1997 plan and any stock option agreement for stock options granted under the 1997 plan. The plan administrator determines recipients, dates of grant, the numbers and types of stock options to be granted and the terms and conditions of the stock options, including the period of their exercisability and vesting schedule. Subject to the limitations set forth below, the plan administrator will also determine the exercise price of stock options granted and the types of consideration to be paid upon exercise of stock options.

Stock Options. Incentive stock options and nonqualified stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 1997 plan, provided that the exercise price of a stock option cannot be less than the greater of par value or 100% of the fair market value of our common stock on the date of grant. Options granted under the 1997 plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 1997 plan. In accordance with an optionholder's stock option agreement, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. If an optionholder's service relationship with us or any of our

affiliates ceases due to disability or death, the optionholder may generally exercise any vested options for a period of 12 months following disability or death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and included in the option agreement and may include (i) cash or check, (ii) the tender of shares of the common stock of Senseonics, Incorporated previously owned by the optionholder, (iii) a combination of the foregoing, and (iv) after our shares of common stock become publicly traded on an established securities market, a broker-assisted cashless exercise.

Unless the plan administrator provides otherwise in the stock option agreement governing the terms of the option, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order.

Tax Limitations on Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as nonqualified stock options. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (ii) the option is not exercisable after the expiration of five years from the date of grant.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 1997 plan and (ii) the class and number of shares and exercise price, strike price, or purchase price of all outstanding stock options.

Certain Reorganizations and Mergers. If we are the surviving corporation in any reorganization, merger or consolidation with any other corporation, the number and class of shares and the exercise price subject to stock options previously granted under the 1997 plan will be proportionately adjusted to reflect the transaction.

Other Corporate Transactions. In the event of (i) our dissolution or liquidation, (ii) a merger, consolidation or reorganization following which we are not the surviving corporation, (iii) a sale of substantially all of our assets to another person or entity or (iv) any transaction that results in a change in control, the 1997 plan and all stock options granted under the 1997 plan will terminate, unless in connection with the transaction the board approves the continuation of the 1997 plan, the assumption of outstanding stock options by the successor corporation or the substitution of outstanding options for new options covering stock of the successor corporation or its parent, with appropriate adjustments to the number and kind of shares and the exercise prices of the stock options. In the event the 1997 plan and outstanding stock options are terminated in connection with a transaction, the optionholders will have an opportunity to exercise their vested outstanding stock options before the occurrence of the transaction during such period as determined by the board in its sole discretion.

Under the 1997 plan, a change in control is generally defined as any transaction that results in any person or entity, other than a person or entity who was a holder of Senseonics, Incorporated securities on June 30, 1998, owning 50% or more of the combined voting power of all classes of our stock, unless (i) the person or entity becomes the owner of 50% or more of the combined voting power of our stock due to our issuing new securities to the person or entity (other than an issuance pursuant to an underwritten public offering in which the acquisition is not approved by the board) or (ii) at least two-thirds of members of the board determine that the transaction does not constitute a change in control for purposes of the 1997 plan.

Amendment and Termination. The Senseonics, Incorporated board of directors has the authority to amend, suspend, or terminate the 1997 plan, provided that such action does not alter or impair the existing rights or obligations of any participant without such participant's written consent.

2016 Employee Stock Purchase Plan

In February 2016, our board of directors adopted and our stockholders approved a 2016 Employee Stock Purchase Plan, or our 2016 ESPP. The 2016 ESPP became effective on March 17, 2016. We have no current plans to grant purchase rights under our 2016 ESPP.

The maximum number of shares of our common stock that may be issued under our 2016 ESPP was initially 800,000 shares. Additionally, the number of shares of our common stock reserved for issuance under our 2016 ESPP will automatically increase on January 1 of each year, beginning on January 1, 2017 and ending on and including January 1, 2026, by 1.0% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year; provided, however, our board of directors may act prior to the first day of any calendar year to provide that there will be no January 1 increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of common stock. As of January 1, 2017, the number of shares of common stock that may be issued under the 2016 ESPP was automatically increased by 935,696 shares, representing 1.0% of the total number of shares of common stock outstanding on December 31, 2016, increasing the number of shares of common stock available for issuance under the amended and restated 2015 plan to 1,735,696 shares. Shares subject to purchase rights granted under our 2016 ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under our 2016 ESPP.

Our board of directors, or a duly authorized committee thereof, will administer our 2016 ESPP. We expect our board of directors will delegate its authority to administer our 2016 ESPP to our compensation committee under the terms of the compensation committee's charter.

Employees, including executive officers, of ours or any of our designated affiliates may have to satisfy one or more of the following service requirements before participating in our 2016 ESPP, as determined by the administrator: (i) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year; or (ii) continuous employment with us or one of our affiliates for a minimum period of time, not to exceed two years, prior to the first date of an offering. An employee may not be granted rights to purchase stock under our 2016 ESPP if such employee (i) immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our common stock, or (ii) holds rights to purchase stock under our 2016 ESPP that would accrue at a rate that exceeds \$25,000 worth of our stock for each calendar year that the rights remain outstanding.

A component of our 2016 ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Code and the provisions of this component will be construed in a manner that is consistent with the requirements of Section 423 of the Code. In addition, the 2016 ESPP authorizes the grant of options to purchase shares of our common stock that do not meet the requirements of Section 423 of the Code because of deviations necessary to permit participation in the 2016 ESPP by employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws. Any such options must be granted pursuant to rules, procedures or subplans adopted by our board designed to achieve these objectives for eligible employees and our company. The administrator may specify offerings with a duration of not more than 27 months, and may specify one or more shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for the employees who are participating in the offering. The administrator, in its discretion, will determine the terms of offerings under our 2016 ESPP.

Our 2016 ESPP permits participants to purchase shares of our common stock through payroll deductions of up to 15% of their earnings. Unless otherwise determined by the administrator, the purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first day of an offering or on the date of purchase. Participants may end their participation at any time during an offering and will be paid their accrued contributions that have not yet been used to purchase shares. Participation ends automatically upon termination of employment with us.

A participant may not transfer purchase rights under our 2016 ESPP other than by will, the laws of descent and distribution or as otherwise provided under our 2016 ESPP.

In the event of a specified corporate transaction, such as a merger or change in control of our company, a successor corporation may assume, continue or substitute each outstanding purchase right. If the successor corporation does not assume, continue or substitute for the outstanding purchase rights, the offering in progress will be shortened and a new exercise date will be set. The participants' purchase rights will be exercised on the new exercise date and such purchase rights will terminate immediately thereafter.

Our board of directors has the authority to amend, suspend or terminate our 2016 ESPP, at any time and for any reason. Our 2016 ESPP will remain in effect until terminated by our board of directors in accordance with the terms of the 2016 ESPP.

Non-Employee Director Compensation

In February 2016, our board of directors approved a non-employee director compensation policy which became effective upon the completion of our public offering. Under this director compensation policy, we pay each of our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairman of each committee receives a higher retainer for such service. These retainers are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment is prorated for any portion of such quarter that the director is not serving on our board of directors. No retainers were paid in respect of any period prior to the completion of our public offering. The retainers paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

	Member Annual Service Retainer	Chairman Additional Annual Service Retainer
Board of Directors	\$ 35,000	\$ 20,000
Audit Committee	7,500	11,250
Compensation Committee	6,000	6,600
Nominating and Corporate Governance Committee	4,000	3,625

In addition, under our non-employee director compensation policy, each non-employee director elected to our board of directors will receive an 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 director's continued service as a director. Further, on the date of each annual meeting of stockholders each non-employee director that continues to serve as a non-employee member on our board of directors will receive an 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 one year anniversary of the grant date, subject to the director's continued service as a director. The exercise price of these options will equal the fair market value of our common stock on the date of grant.

This policy is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

On June 20, 2016, we entered into a letter agreement with Mr. DeFalco, pursuant to which we granted Mr. DeFalco a fully vested restricted stock award under the 2015 plan for 300,000 shares of our common stock in full satisfaction of our remaining obligations under that certain Transaction Bonus Agreement, dated December 4, 2015, by and between Senseonics, Incorporated and Mr. DeFalco. For additional information, see "Certain Relationships and Related Party Transactions, and Director Independence – Letter Agreement with Stephen P. DeFalco."

Director Compensation Table

The following table sets forth information regarding compensation earned during the year ended December 31, 2016 by our non-employee directors for service on the board of directors from January 1, 2016 to December 31, 2016. Board and committee retainers were prorated for the period from March 17, 2016 to December 31, 2016. Timothy T. Goodnow, our President and Chief Executive Officer, also served on our board of directors, but did not receive any additional compensation for his service as a director and therefore is not included in the table below. Dr. Goodnow's compensation as an executive officer is set forth below under "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash (\$)	Stock Awards ⁽¹⁾ (\$)	Option Awards ⁽²⁾ (\$)	Total (\$)
Stephen P. DeFalco ⁽³⁾	46,969	1,164,000	107,171	1,318,140
M. James Barrett ⁽³⁾	29,250	—	107,171	136,421
Edward J. Fiorentino ⁽⁴⁾	36,375	—	107,171	143,546
Justin Klein ⁽³⁾	36,375	—	107,171	143,546
Douglas S. Prince ⁽⁴⁾	43,313	—	107,171	150,484
Douglas A. Roeder ⁽³⁾	38,700	—	107,171	145,871
Steven Edelman ⁽⁵⁾	28,250	—	212,498	240,748

- (1) This column reflects the full grant date fair value of restricted stock granted during the year as measured pursuant to ASC Topic 718 as stock-based compensation in our consolidated financial statements. The restricted stock was granted to Mr. DeFalco in satisfaction of our obligation to make a cash payment upon the completion of our public offering pursuant to the Transaction Bonus Agreement, dated December 4, 2015, by and between Senseonics, Incorporated and Mr. DeFalco, as described in "Certain Relationships and Related Party Transactions, and Director Independence – Letter Agreement with Stephen P. DeFalco." Unlike the calculations contained in our consolidated financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting but assumes that the director will perform the requisite service for the award to vest in full. The assumptions we used in valuing stock awards are described in Note 10 to our audited consolidated financial statements included in this Annual Report.
- (2) This column reflects the full grant date fair value for stock options granted during the year as measured pursuant to ASC Topic 718 as stock-based compensation in our consolidated financial statements. Unlike the calculations contained in our consolidated financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting but assumes that the director will perform the requisite service for the award to vest in full. The assumptions we used in valuing stock awards are described in Note 10 to our audited consolidated financial statements included in this Annual Report.
- (3) As of December 31, 2016, this director held options to purchase 54,629 shares of our common stock.
- (4) As of December 31, 2016, this director held options to purchase 138,529 shares of our common stock.
- (5) As of December 31, 2016, Dr. Edelman held options to purchase 94,599 shares of our common stock.

Compensation Committee

We have a separately designated standing compensation committee. The compensation committee is composed of three directors: Mr. Roeder, Dr. Klein and Mr. Fiorentino. Mr. Roeder serves as the chairman of the committee. All members of the compensation committee are independent, as defined in NYSE-MKT listing rules, are non-employee directors as defined in Rule 16b-3 under the Exchange Act and are outside directors, as defined in Section 162(m) of the Internal Revenue Code of 1986, as amended. Our board of directors has determined that the composition of our compensation committee meets the criteria for independence under, and the functioning of our compensation committee complies with, the applicable requirements of the Sarbanes-Oxley Act, NYSE-MKT listing requirements and SEC rules and regulations. We intend to continue to evaluate the requirements applicable to us and we intend to comply with the future requirements to the extent that they become applicable to our compensation committee.

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

The following table sets forth certain information regarding the ownership of our common stock as of December 31, 2016 by (i) each director; (ii) each of our named executive officers; (iii) all currently serving executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock. Except as otherwise noted below, the address for persons listed in the table is c/o Senseonics Holdings, Inc., 20451 Seneca Meadows Parkway, Germantown, MD 20876.

This table is based upon information supplied by our named executive officers, directors and principal stockholders and a review of Schedule 13G and Schedule 13D filings with the Securities and Exchange Commission. Unless otherwise indicated in the footnotes to the table and subject to common property laws where applicable, we believe that each stockholder named in the table has sole voting and investment power with regard to the shares indicated as being beneficially owned. Applicable percentages are based on 93,569,642 shares of common stock outstanding as of December 31, 2016, adjusted as required by the rules promulgated by the SEC.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>
<i>Principal Stockholders:</i>		
Entities affiliated with New Enterprise Associates, Inc. ⁽¹⁾	28,223,900	29.6 %
HealthCare Ventures VI, L.P. ⁽²⁾	6,099,436	6.5
Entities affiliated with Delphi Ventures ⁽³⁾	10,118,876	10.8
Roche Finance Ltd. ⁽⁴⁾	8,042,414	8.5
Energy Capital, LLC ⁽⁵⁾	8,013,810	8.6
SBLE, LLC ⁽⁶⁾	5,907,197	6.3
<i>Named Executive Officers and Directors:</i>		
Timothy T. Goodnow, Ph.D. ⁽⁷⁾	3,326,169	3.4
R. Don Elsey ⁽⁸⁾	443,063	*
Lynne E. Kelley ⁽⁸⁾	92,811	*
M. James Barrett, Ph.D. ⁽⁹⁾	16,545,189	17.5
Peter Justin Klein, M.D., J.D. ⁽¹⁰⁾	6,683	*
Stephen P. DeFalco ⁽¹¹⁾	698,525	*
Edward J. Fiorentino ⁽⁸⁾	83,900	*
Douglas S. Prince ⁽⁸⁾	83,900	*
Douglas A. Roeder ⁽³⁾	10,118,876	10.8
Steven Edelman, M.D. ⁽⁸⁾	13,319	*
All current directors and executive officers as a group (12 persons) ⁽¹²⁾	32,364,555	32.5

* Represents beneficial ownership of less than 1%.

(1) Consists of (a) 14,818,985 shares of common stock and 1,079,436 shares of common stock underlying immediately exercisable warrants held by New Enterprise Associates 10, Limited Partnership, or NEA 10, (b) 8,949,292 shares of common stock and 701,630 shares of common stock underlying immediately exercisable warrants held by New Enterprise Associates 9, Limited Partnership, or NEA 9, and (c) 2,534,912 shares of common stock and 139,645 shares of common stock underlying immediately exercisable warrants held by New Enterprise Associates VII, Limited Partnership, or NEA VII. The shares held by NEA 10 are indirectly held by NEA Partners 10, Limited Partnership, or Partners 10, the sole general partner of NEA 10. The individual general partners of Partners 10 are M. James Barrett, a member of our board of directors, Peter J. Barris and Scott D. Sandell, or the NEA 10 GPs. Partners 10 and the NEA 10 GPs may be deemed to share voting and dispositive power over, and be the indirect beneficial owners of, the shares held by NEA 10. The shares held by NEA 9 are indirectly held by NEA Partners 9, Limited Partnership, or Partners 9, the sole general partner of NEA 9. The individual general partner of Partners 9 is Peter J. Barris. Partners 9 and Peter J. Barris may be deemed to share voting and dispositive power over, and be the

- indirect beneficial owners of, the shares held by NEA 9. The shares held by NEA VII are indirectly held by NEA Partners VII, Limited Partnership, or Partners VII, the sole general partner of NEA VII. The individual general partner of Partners VII is Peter J. Barris. Partners VII and Peter J. Barris may be deemed to share voting and dispositive power over, and be the indirect beneficial owners of, the shares held by NEA VII. This information has been obtained from a Schedule 13D filed on April 4, 2016 by NEA 10, NEA 9, NEA VII, Partners 10, Partners 9, Partners VII, M. James Barrett, Peter J. Barris and Scott D. Sandell. The principal business address of NEA 10, NEA 9, NEA VII, NEA Presidents and NEA 1997 is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093.
- (2) Consists of 5,506,773 shares of common stock and 592,663 shares of common stock underlying immediately exercisable warrants held by HealthCare Ventures VI, L.P., or HealthCare VI. The general partner of HealthCare VI is HealthCare Partners VI, L.P. John W. Littlechild, James Cavanaugh, Augustine Lawlor, Christopher Mirabelli and Harold Werner are the general partners of HealthCare Partners VI, L.P., or the HealthCare Partners VI General Partners. HealthCare Partners VI, L.P. and the HealthCare Partners VI General Partners may be deemed to share voting and dispositive power over, and be the indirect beneficial owners of, the shares held by HealthCare VI. This information has been obtained from a Schedule 13G filed on March 28, 2016 by HealthCare VI, HealthCare Partners VI, L.P., Drs. Cavanaugh and Mirabelli and Messrs. Werner, Littlechild and Lawlor. The principal business address of HealthCare VI is 47 Thorndike Street, Suite B1-1, Cambridge, MA 02141.
 - (3) Consists of (a) 10,021,026 shares of common stock held by Delphi Ventures VIII, L.P., or Delphi VIII, and (b) 97,850 shares of common stock held by Delphi BioInvestments VIII, L.P., or Delphi Bio. Delphi Management Partners VIII, L.L.C., or DMP VIII, is the general partner of each of Delphi VIII and Delphi Bio, collectively referred to herein as the Delphi VIII Funds. DMP VIII and each of Douglas A. Roeder, a member of our board of directors, James J. Bochnowski, David L. Douglass and Deepika R. Pakianathan, the Managing Members of DMP VIII, may be deemed to share voting and dispositive power over the shares held by the Delphi VIII Funds. This information has been obtained from a Schedule 13G filed on February 8, 2016 by Delphi VIII, Delphi Bio, DMP VIII, Douglas A. Roeder, James J. Bochnowski, David L. Douglass and Deepika R. Pakianathan. The address of each of the persons and entities affiliated with Delphi Ventures is 160 Bovet Rd., Suite 408, San Mateo, CA 94402.
 - (4) Consists of 7,068,679 shares of common stock and 973,735 shares of common stock underlying immediately exercisable warrants held by Roche Finance Ltd. Roche Finance Ltd is a wholly-owned subsidiary of Roche Holding Ltd, a publicly-held corporation. This information has been obtained from a Schedule 13G filed on February 7, 2017 by Roche Holding Ltd and Roche Finance Ltd. The principal business address of Roche Finance Ltd is Grenzacherstrasse 122, 4070 Basel, Switzerland.
 - (5) Robert L. Smith, the sole Managing Member of Energy Capital, LLC, may be deemed to have voting and dispositive power over the shares held by Energy Capital, LLC. The address of Energy Capital, LLC is 13650 Fiddlesticks Blvd., Suite 202-324, Ft. Myers, FL 33912.
 - (6) Susan Coyne, the sole Managing Member of SBLE, LLC, may be deemed to have voting and dispositive power over the shares held by SBLE, LLC. The address of SBLE, LLC is 15011 Hawks Shadow, Ft. Myers, FL 33905.
 - (7) Consists of (a) 205,725 shares of common stock, (b) 27,928 shares of common stock underlying immediately exercisable warrants and (c) 3,092,516 shares of common stock underlying options that are exercisable within 60 days of December 31, 2016.
 - (8) Consists of shares of common stock underlying options that are exercisable within 60 days of December 31, 2016.
 - (9) Consists of (a) 494,689 shares of common stock held directly by Dr. Barrett, (b) 152,079 shares of common stock held by Dr. Barrett's wife, (c) 14,818,985 shares of common stock held by NEA 10 and (d) 1,079,436 shares of common stock underlying immediately exercisable warrants held by NEA 10.
 - (10) Consists of (a) 3,892 shares of common stock and (b) 2,791 shares of common stock underlying immediately exercisable warrants.
 - (11) Consists of 698,525 shares of common stock.
 - (12) Consists of (a) 26,492,771 shares of common stock, (b) 1,110,155 shares of common stock underlying immediately exercisable warrants and (c) 4,761,629 shares of common stock underlying options that are exercisable within 60 days of December 31, 2016.

Equity Compensation Plan Information

The following table provides certain information with respect to our 1997 plan and our 2015 plan, which were our only equity compensation plans in effect as of December 31, 2016.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	17,251,115	\$ 1.86	4,894,146
Equity compensation plans not approved by security holders	—	—	—
Total	17,251,115		4,894,146

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

There have been no transactions since January 1, 2016 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than as set forth below and the compensation arrangements which are described in this Annual Report under “Executive Compensation.”

Participation in Public Offering

Entities affiliated with New Enterprise Associates, Delphi Ventures, HealthCare Ventures, Energy Capital, LLC, and SBLE, LLC, each of which is a holder of more than 5% of our common stock, purchased an aggregate of 2,631,578 shares, 1,228,070 shares, 456,140 shares, 1,578,947 and 877,193 shares, respectively, of our common stock in our public offering. All shares were purchased at the public offering price to the public of \$2.85 per share.

Registration Rights Agreement

We have entered into a registration rights agreement with certain of our 5% stockholders.

The registration rights agreement, among other things grants certain of our stockholders specified registration rights with respect to shares of our common stock issued upon conversion of the shares of Senseonics, Incorporated stock previously held by them.

Letter Agreement with Stephen P. DeFalco

In June 2010, Senseonics, Incorporated entered into a letter agreement with Stephen P. DeFalco, pursuant to which Mr. DeFalco provided Senseonics, Incorporated his services as the chairman of the Senseonics, Incorporated board of directors and, from June 2010 to November 2010, provided Senseonics, Incorporated with consulting services. Pursuant to the letter agreement, for his service as the chairman of the Senseonics, Incorporated board of directors, Mr. DeFalco was entitled to a fee of between 0.75% and 1.25% of the valuation of our company upon the closing of a public offering or a merger or consolidation with another company, a sale, disposition or lease of all or substantially all of their assets.

In December 2015, Senseonics, Incorporated and Mr. DeFalco terminated this agreement and entered into a new agreement that superseded the prior agreement. Under the new agreement, Mr. DeFalco received a restricted stock grant of 190,000 shares of Senseonics, Incorporated common stock, which converted into 398,525 shares of Senseonics Holdings common stock in the Acquisition. One half of the shares covered by this restricted stock grant were fully vested

on grant. The remainder would vest in full upon our completion of a public offering or private placement of our equity securities in which gross proceeds of at least \$40 million are raised, which we refer to as a qualified financing. Additionally, upon a qualified financing, Mr. DeFalco would be entitled to receive a cash payment that, when combined with the value of the restricted stock grant, equals a percentage of our company valuation ranging between 0.75% to 1.25% of our company valuation, with the actual percentage determined based on the company valuation. Upon the completion of our public offering, which was a qualified financing, the remaining unvested shares vested immediately in full.

In June 2016, we entered into a letter agreement with Stephen P. DeFalco. Under the agreement, Mr. DeFalco received a fully vested restricted stock grant of 300,000 shares of our common stock in lieu of the cash payment required by, and in full satisfaction of our remaining obligations under, the December 2015 agreement.

Energy Capital, LLC Borrowing Facility

In connection with the Acquisition, we entered into a Note Purchase Agreement with Energy Capital, LLC, which holds more than five percent of our capital stock, pursuant to which Energy Capital could lend us an aggregate principal amount of up to \$10.0 million, subject to specified conditions. During the year ended December 31, 2016, we borrowed an aggregate of \$2.5 million from Energy Capital, LLC. We repaid these borrowings in full with a portion of the proceeds of our public offering prior to December 31, 2016, and the Note Purchase Agreement was terminated. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness."

Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws provides that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board.

In addition, we have entered into an indemnification agreement with our directors and executive officers.

Related Person Transaction Policy

We have adopted a related party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related party transactions. For purposes of our policy only, a related party transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related party are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related party is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our management must present information regarding the related party transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related parties, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related party transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related party is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related party transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

Director Independence

Our shares are listed on the NYSE-MKT, a national securities exchange system that has requirements that a majority of the board of directors be independent. Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors has determined that Messrs. DeFalco, Fiorentino, Prince and Roeder and Drs. Barrett, Edelman and Klein, representing seven of our eight directors, are "independent directors" as defined under the rules of the NYSE-MKT.

Item 14. Principal Accountant Fees and Services

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2016 and 2015 by our principal accountants. All such fees described below were approved by the audit committee.

	<u>2016</u>	<u>2015</u>
Audit fees	\$ 860,689	\$ 378,752
Tax Fees	18,500 ⁽¹⁾	25,000 ⁽¹⁾
Total	<u>\$ 879,189</u>	<u>\$ 403,752</u>

(1) Tax fees were principally for services related to tax compliance and reporting and analysis services.

Our audit committee has adopted a policy and procedures for the pre-approval of audit and, if applicable, non-audit services rendered by our independent registered public accounting firm. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services, and tax services up to specified amounts. Pre-approval may also be given as part of the audit committee's approval of the scope of the engagement of the independent registered public accounting firm or on an individual explicit case-by-case basis before the independent registered public accounting firm is engaged to provide each service. On a periodic basis, the independent registered public accounting firm reports to the audit committee on the status of actual costs for approved services against the approved amounts.

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

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

(a)(2) Financial Statement Schedules.

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

(a)(3) Exhibits.

The exhibits filed as part of this Annual Report are set forth on the Exhibit Index immediately following the signatures to this report. The Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary.

Not applicable.

EXHIBIT INDEX

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).
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).
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.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+	Transaction Bonus Agreement by and between Senseonics, Incorporated and Stephen DeFalco, dated as of December 4, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.3+	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).
10.4+	Form of Incentive Stock Option Agreement under Senseonics, Incorporated Amended and Restated 1997 Stock Option Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.5+	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).
10.6+	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).
10.6.1+	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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10+	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).
10.11+	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).
10.12+	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).

Exhibit Number	Description of Document
10.13+	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).
10.14	Loan and Security Agreement, by and between Senseonics, Incorporated and Oxford Finance LLC, dated as of July 31, 2014, as amended by the Consent and First Amendment to Loan and Security Agreement, dated as of December 7, 2015 (incorporated by reference to Exhibit 10.14 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on December 10, 2015).
10.14.1	Second Amendment to Loan and Security Agreement, by and among Oxford Finance, LLC, Senseonics, Incorporated and Senseonics Holdings, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 333-198168) filed on February 9, 2016).
10.14.2	Third Amendment to Loan and Security Agreement, by and among Oxford Finance, LLC, Senseonics, Incorporated and Senseonics Holdings, Inc. (incorporated by reference to Exhibit 10.14.2 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-208984) filed on March 14, 2016).
10.15	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).
10.16	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).
10.17	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).
10.18	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).
10.19#	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).
10.20+	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).
10.21+	Non-Employee Director Compensation Policy.
10.22	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).
10.23	Restricted Stock Award Grant Notice and Restricted Stock Award Agreement, by and between the Registrant and Stephen P. DeFalco, dated June 20, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37717) filed on June 21, 2016).
10.24#	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).
10.25	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).
10.26	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).
10.27	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).
10.28*#	Amendment to Distribution Agreement, by and among Senseonics, Incorporated, Roche Diagnostics International AG and Roche Diabetes Care GmbH, dated as of November 28, 2016.

Exhibit Number	Description of Document
10.29*	Employment Agreement by and between the Registrant and Lynne E. Kelley, dated as of April 22, 2016.
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.
23.2*	Consent of PricewaterhouseCoopers 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.

AMENDMENT TO DISTRIBUTION AGREEMENT

This Amendment to Distribution Agreement (“ **Amendment** ”) is effective as of November 28, 2016 (the “ **Amendment Effective Date** ”), by and between Roche Diagnostics International AG, Basel Branch Diabetes Care, with offices located at Peter Merian-Weg 4, 4052 Basel, Switzerland (“ **Roche Diagnostics** ”) and Roche Diabetes Care GmbH, with offices located at Sandhofer Strasse 116, 68305 Mannheim, Germany (“ **Roche Diabetes** ” and collectively with Roche Diagnostics, “ **Roche** ”) and Senseonics Incorporated, with offices located at 20451 Seneca Meadows Parkway, Germantown, MD 20876-7005, USA (“ **Senseonics** ”). Roche and Senseonics are sometimes referred to herein individually as a “ **Party** ” and collectively as the “ **Parties.** ”

WHEREAS, Roche and Senseonics are parties to that certain Distribution Agreement dated May 23, 2016 (the “ **Agreement** ”); and

WHEREAS, the Parties desire to amend the Agreement in accordance with Section 11.11 thereof;

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

1. The second and third sentences of Section 10.1 are hereby deleted and replaced with the following:

Unless terminated earlier in accordance with the terms hereof, this Agreement shall expire on December 31, 2018. Upon agreement by the Parties to the Minimum Requirement for 2019 (as described in Exhibit 4), this Agreement shall expire on December 31, 2019.

2. **Exhibit 3** to the Agreement is hereby deleted in its entirety and replaced with the Exhibit 3 attached hereto.
3. **Exhibit 4** to the Agreement is hereby deleted in its entirety and replaced with the **Exhibit 4** attached hereto.
4. Except as expressly amended hereby, the terms and conditions of the Agreement shall remain unchanged and in full force and effect. In the event of any conflict between the terms of this Amendment and the terms of the Agreement, the terms of this Amendment shall govern. The amendments made herein shall be effective as of the Amendment Effective Date. Capitalized terms used in this Amendment that are not otherwise defined herein shall have the same meanings as such terms are given in the Agreement. For clarity, any cross-references to Agreement Sections refer to those Agreement Sections as amended by this Amendment. This Amendment may be executed in counterparts, each of which shall be deemed an original but all of which shall be considered one and the same instrument.

[Signatures are on next page]

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Confidential and Proprietary

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT. THE COPY FILED HERewith OMITTS THE INFORMATION SUBJECT TO A CONFIDENTIALITY REQUEST. OMISSIONS ARE DESIGNATED [***]. A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

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

Senseonics Incorporated

By: /s/ Tim Goodnow
Name: Tim Goodnow
Title: President & CEO

Roche Diagnostic International AG
Basel Branch Diabetes Care

By: /s/ A. Pedrazzetti
Name: A. Pedrazzetti
Title: Head Bus. Dev./Roche Diabetes Care

/s/ Illegible
Illegible
Illegible

Roche Diabetes Care GmbH

By: /s/ Illegible
Name: Illegible
Title: Illegible

/s/ P. Hoffman
P. Hoffmann
Legal Counsel

EXHIBIT 3

Territory

Europe, Middle East and Africa (as listed below), excluding Sweden, Norway, Denmark, Finland and Israel from this amendment.

For clarity, the Parties acknowledge and agree that for all countries listed below, SENSEONICS AND ROCHE must agree in advance of any commitment to enter the market (where and when). ROCHE shall have the exclusive right, but not the obligation, to distribute the Products in the Territory.

EUROPE	MIDDLE EAST	AFRICA
Albania	Bahrain	Algeria
Andorra	Benin	Angola
Austria	Egypt	Benin
Belarus	Iran	Botswana
Belgium	Iraq	Banana Faso
Bosnia and Herzegovina	Jordan	Burundi
Bulgaria	Kuwait	Cameroon
Croatia	Lebanon	Cape Verde
Cyprus	Libya	Central African Republic
Czech Republic	Oman	Chad
Estonia	Palestine	Comoros
Faroe islands	Qatar	Democratic Republic of the Congo
Franca	Saudi Arabia	Djibouti
Georgia	Sudan	Equatorial Guinea
Germany	Syna	Eritrea
Gibraltar	Turkey	Ethiopia
Greece	United Arab Emirates	Gabon
Guernsey	Yemen	Gambia
Hungary		Ghana
Iceland		Guinea
Ireland		Guinea-Bissau
Isle Of Man		Ivory Coast
Italy		Kenya
Jersey		Lesotho
Latvia		Liberia
Liechtenstein		Madagascar
Lithuania		Malawi
Luxembourg		Mali
Macedonia		Mauritania
Malta		Mauritius
Moldova		Morocco
Monaco		Mozambique
Montenegro		Namibia
Netherlands		Niger
Poland		Nigeria
Portugal		Rwanda
Romania		Sao Tome & Principe
San Marino		Senegal

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Confidential and Proprietary

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EUROPE	MIDDLE EAST	AFRICA
Serbia		Somalia
Slovakia		South Africa
Slovenia		Swaziland
Spain		Tanzania
Switzerland		Togo
Turkey		Tunisia
Ukraine		Turkey
United Kingdom		Uganda
Vatican City		Western Sahara
		Zambia
		Zimbabwe (Rhodesia)

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Confidential and Proprietary

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EXHIBIT 4

Price:

Eversense® Sensor Pack	
Contains the following: 1 Sensor Insertion Kit — Includes Blunt Dissector, Insertion Tool, Insertion Template, Adhesive Patch 30-Pack (3). Insertion and Removal Instruction Guide 1 Sensor Kit — Includes Sensor Pouch	
Annual Volume	Price
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Eversense® Smart Transmitter Pack	
Contains the following: 1 Smart Transmitter, 1 Power Supply, 1 User Guide, and 1 Quick Reference Guide	
Annual Volume	Price
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Annual Volume Purchased is based on units of the applicable Product purchased by ROCHE in a particular calendar year under the Agreement.

Upon notification by SENSEONICS that a 180 day sensor product is available for inclusion under this Agreement, the Parties shall negotiate in good faith an amendment to this Agreement to include the 180 day sensor product as a Product under this Agreement and the corresponding price for such product and minimum requirements for such product and the other Products under this Agreement. SENSEONICS shall only be entitled to offer the 180 day sensor product to third parties, if ROCHE gives its written consent. For clarity, ROCHE shall be free to order and to distribute the 90 day sensor product even if a sensor with an extended life is available from SENSEONICS.

Minimum Requirement:

	Eversense® Sensor Pack	Eversense® Smart Transmitter Pack
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***

ROCHE shall provide timely written notice to SENSEONICS if it reasonably believes it will not purchase the minimum quantities of each Product in any particular calendar quarter as outlined above. If ROCHE does not order enough Product to meet the Minimum Requirement for 2017, on December 15, 2017 ROCHE shall be deemed to have placed an order for the number of units of Product required to satisfy the remainder of the Minimum Requirement for each Product for 2017 and ROCHE shall pay for such Product in accordance with Section 3.3(b) of the Agreement. For clarity, in case the Minimum Requirement for 2017 is not fulfilled and this is cured by a make-up order from ROCHE, SENSEONICS shall not have the right to terminate the Agreement for material breach based on Section 10.2 of the Agreement.

In September 2017, the Parties will hold a meeting to verify, if — based on the experiences so far—the Minimum Requirement for 2018 is to be confirmed. Factors including but not limited to Product up-take and customer acceptance, the regulatory approvals in the countries, potential adverse reactions to the Product and other unexpected events shall be taken into consideration when reviewing 2017 performance and confirming or adjusting the above Minimum Requirement for 2018.

Starting in September 2018, or such other time period as the Parties may agree, the Parties will negotiate in good faith the Minimum Requirement for 2019 taking into account the Minimum Requirement for 2018, SENSEONICS' product costs, ROCHE'S actual Product sales during the term of this Agreement to date and ROCHE'S anticipated Product sales for 2019.

EXECUTIVE EMPLOYMENT AGREEMENT

This EXECUTIVE EMPLOYMENT AGREEMENT ("*Agreement*") is entered into as of the 22th day of April, 2016 ("*Effective Date*"), by and between E. Lynne Kelley ("*Executive*") and SENSEONICS, INCORPORATED ("*Company*").

WHEREAS, the Company wishes to continue to employ Executive and Executive wishes to continue to be its employee, subject to the terms and conditions of this Agreement;

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

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

1. Employment by the Company.

1.1 Position. Subject to the terms set forth herein, the Company agrees to continue to employ Executive in the position of Chief Medical Officer, and Executive hereby accepts such continued employment on the terms and conditions set forth in this Agreement.

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

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

2. Compensation.

2.1 Salary. Executive shall receive for Executive's services to be rendered under this Agreement an initial base salary of \$365,000 on an annualized basis, subject to review and adjustment by the Company in its sole discretion, payable subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices ("**Base Salary**").

2.2 Bonus. During the period Executive is employed with the Company, Executive shall be eligible to earn for Executive's services to be rendered under this Agreement a discretionary annual cash bonus of up to 35% of Base Salary ("**Target Amount**"), subject to review and adjustment by the Company in its sole discretion, payable subject to standard federal and state payroll withholding requirements. Whether or not Executive earns any bonus will be dependent upon (a) Executive's continuous performance of services to the Company through the date any bonus is paid; and (b) the actual achievement by Executive and the Company of the applicable performance targets and goals set by the CEO. The annual period over which performance is measured for purposes of this bonus is January 1 through December 31. The Board will determine in its sole discretion the extent to which Executive and the Company have achieved the performance goals upon which the bonus is based and the amount of the bonus, which could be above or below the Target Amount (and may be zero). Any bonus shall be subject to the terms of any applicable incentive compensation plan adopted by the Company. Any bonus, if earned, will be paid to Executive within the time period set forth in the incentive compensation plan.

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

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

4. Outside Activities during Employment. Except with the prior written consent of the Company's Board of Directors, including consent given to Executive prior to the signing of this Agreement, Executive will not, while employed by the Company, undertake or engage in any other employment, occupation or business enterprise that would interfere with Executive's responsibilities and the performance of Executive's duties hereunder except for (i) reasonable

time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Executive may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties; and (iii) such other activities as may be specifically approved by the CEO. This restriction shall not, however, preclude Executive (x) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (y) from employment or service in any capacity with Affiliates of the Company. As used in this Agreement, "Affiliates" means an entity under common management or control with the Company.

5. No Conflict with Existing Obligations. Executive represents that Executive's performance of all the terms of this Agreement does not and will not breach any agreement or obligation of any kind made prior to Executive's employment by the Company, including agreements or obligations Executive may have with prior employers or entities for which Executive has provided services. Executive has not entered into, and Executive agrees that Executive will not enter into, any agreement or obligation, either written or oral, in conflict herewith.

6. Termination of Employment. The parties acknowledge that Executive's employment relationship with the Company is at-will, meaning either the Company or Executive may terminate Executive's employment at any time, with or without cause or advanced notice. The provisions in this Section govern the amount of compensation, if any, to be provided to Executive upon termination of employment and do not alter this at-wills tat us.

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

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

(b) If the Company terminates Executive's employment at any time without Cause or Executive terminates Executive's employment with the Company for Good Reason and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "*Separation from Service*"), then Executive shall be entitled to receive the Accrued Obligations (defined below). If Executive complies with the obligations in Section 6.1(c) below, Executive shall also be eligible to receive the following severance benefits: (1) an amount equal to Executive's then current Base Salary for nine (9) months, less all applicable withholdings and deductions ("*Severance*"), paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date (as defined in Section 6.1(c) below), with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter and (2) a pro rata portion of Executive's Target Amount for the performance year in which Executive's termination occurs, with such pro rata portion calculated based upon the number of days that Executive was employed during such performance year divided by the

total number of days in such performance year, payable as a lump sum payment on the Release Effective Date (as defined below) ("*Bonus Severance*").

(c) Executive will be paid all of the Accrued Obligations on the Company's first payroll date after Executive's date of termination from employment or earlier if required by law. Executive shall receive the Severance and Bonus Severance pursuant to Section 6.1(b) of this Agreement and the payments pursuant to Section 6.1(d) if: (i) by the 60th day following the date of Executive's Separation from Service, Executive has signed and delivered to the Company a separation agreement containing an effective, general release of claims in favor of the Company and its affiliates and representatives, in a form acceptable to the Company (the "*Release*"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "*Release Effective Date*"); and (ii) if Executive holds any other positions with the Company, Executive resigns such position(s) to be effective no later than the date of Executive's termination date (or such other date as requested by the Board); (iii) Executive returns all Company property; (iv) Executive complies with Executive's post-termination obligations under this Agreement and the Proprietary Information Agreement; and (v) Executive complies with the terms of the Release, including without limitation any non-disparagement and confidentiality provisions contained in Release. To the extent that any severance payments are deferred compensation under Section 409A of the Code, and are not otherwise exempt from the application of Section 409A, then, if the period during which Executive may consider and sign the Release spans two calendar years, the payment of Severance will not be made or begin until the later calendar year.

(d) If Executive timely elects continued coverage under COBRA for Executive and Executive's covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Executive's and Executive's covered dependents' health insurance coverage in effect for Executive (and Executive's covered dependents) on the termination date until the earliest of: (i) nine (9) months following the termination date (the "*COBRA Severance Period*"); (ii) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (iii) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (i)-(iii), (the "*COBRA Payment Period*"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Executive's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding (such amount, the "*Special Severance Payment*"), such Special Severance Payment to be made without regard to the COBRA period prior to the end of the COBRA Payment Period. Nothing in this Agreement shall deprive Executive of Executive's rights under COBRA or ERISA for benefits under plans and policies arising under Executive's employment by the Company.

(e) For purposes of this Agreement, "*Accrued Obligations*" are (i) Executive's accrued but unpaid salary through the date of termination, (ii) any unreimbursed business expenses incurred by Executive payable in accordance with the Company's standard expense reimbursement policies, and (iii) benefits owed to Executive under any

qualified retirement plan or health and welfare benefit plan in which Executive was a participant in accordance with applicable law and the provisions of such plan.

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

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

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

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

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

(a) If Executive's employment by the Company is terminated by the Company without "Cause" (and not due to Disability or death) or by Executive for Good Reason coincident with a Change in Control (as defined below), then the Company shall pay or provide Executive with the Accrued Obligations and all of the benefits described in **Section 6.1** above, subject to compliance with **Section 6.1(c)**; *provided that*: (i) in lieu of the bonus described in **Section 6.1(b)**, the Company shall pay Executive the larger of a pro-rata amount as described in **Section 6.1(b)** or 75% of the Target Amount for the performance year in which Executive's termination occurs, payable as a lump sum payment on the Release Effective Date; and (ii) if Executive's employment by the Company or any successor entity is terminated by the Company or the successor entity without "Cause" (and not due to Disability or death) within twelve (12) months following a Change in Control, 100% of the then unvested portion of the

equity awards granted to Executive shall become fully vested.

(b) For purposes of this Agreement, a "*Change in Control*" means (a) any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, continue to hold a majority of the voting power of the surviving entity (or, if the surviving entity is a wholly owned subsidiary, its parent) immediately after such consolidation, merger or reorganization; (b) any transaction or series of related transactions to which the Company is a party in which in excess of fifty percent (50%) of the Company's voting power is transferred; provided that the foregoing shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or indebtedness of the Company is cancelled or converted or a combination thereof; or (c) a sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company. In the event of any interpretation of this definition, the Board of Directors of the Company, upon advice of legal counsel, shall have final and conclusive authority, so long as such authority is exercised in good faith. Notwithstanding the foregoing, a Change in Control will only be deemed to occur for purposes of this Agreement if it also meets the definition used for purposes of Treasury Regulation Section 1.409A-3(a)(5), that is, as defined under Treasury Regulation Section 1.409A-3(i)(5).

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

6.2 Termination by the Company for Cause.

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

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

or (vii) breach of fiduciary duty.

6.4 Resignation by Executive.

- (a) Executive may resign from Executive's employment with the Company at any time, in accordance with **Section 6.6**, by giving notice as described in **Section 8.1**.
- (b) In the event Executive resigns from Executive's employment with the Company for any reason, Executive will not receive Severance, a Severance Bonus or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Executive the Accrued Obligations.

6.5 Termination by Virtue of Death or Disability of Executive.

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

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

6.6 Notice; Effective Date of Termination.

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

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

(ii) immediately upon the Executive's death;

(iii) ten (10) days after the Company gives notice to Executive of Executive's termination on account of Executive's Disability, unless the

Company specifies a later date, in which case, termination shall be effective as of such later date, *provided* that Executive has not returned to the full time performance of Executive's duties prior to such date;

(iv) ten (10) days after the Executive gives written notice to the Company of Executive's resignation, *provided* that the Company may set a termination date at any time between the date of notice and the date of resignation, in which case the Executive's resignation shall be effective as of such other date. Executive will receive compensation through any required notice period; or

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

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

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

6.8 Application of Section 409A. It is intended that all of the severance payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively, "**Section 409A** ") provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9), and this Agreement will be construed in a manner that complies with Section 409A. If not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A, and incorporates by reference all required definitions and

payment terms. No severance payments will be made under this Agreement unless Executive's termination of employment constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1 (h)). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b) (2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. If the Company determines that the severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A and if Executive is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i) of the Code at the time of Executive's Separation from Service, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance will be delayed as follows: on the earlier to occur of (a) the date that is six months and one day after Executive's Separation from Service, and (b) the date of Executive's death (such earlier date, the "*Delayed Initial Payment Date*"), the Company will (i) pay to Executive a lump sum amount equal to the sum of the severance benefits that Executive would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the severance benefits had not been delayed pursuant to this Section 6.8 and (ii) commence paying the balance of the severance benefits in accordance with the applicable payment schedule set forth in Section 6. No interest shall be due on any amounts deferred pursuant to this Section 6.8.

7. Section 280G.

7.1 Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 2800 of the Code and the applicable regulations thereunder (the "*Aggregate Payments*"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be \$1.00 less than the amount at which Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in Executive receiving a higher After Tax Amount (as defined below) than Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 2800 of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.2800-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.2800-1, Q&A-24(b) or (c).

7.2 For purposes of this Section 5, the "*After Tax Amount*" means the

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

8. General Provisions.

8.1 Notices. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Executive at either Executive's address as listed on the Company payroll, or Company-issued email address, or at such other address as the Company or Executive may designate by ten (10) days advance written notice to the other.

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

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

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

8.5 Complete Agreement. This Agreement constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof. This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements, including the Employment Offer Letter from with the Company dated July 13, 2015. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by

Executive and an authorized officer of the Company. The parties have entered into a separate Proprietary Information Agreement and have or may enter into separate agreements related to equity. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of Executive's employment under this Agreement, may be amended or superseded by the parties without regard to this Agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

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

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

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

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

8.10 Dispute Resolution. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Executive's employment with the Company or out of this Agreement, or the Executive's termination of employment or termination of this Agreement, may not be in the best interests of either the Executive or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Executive Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided however*, that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the Washington, DC metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment

upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the *Company*; *provided however*, that at the Executive's option, Executive may voluntarily pay up to one-half the costs and fees. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Executive and the Company. The parties each further agree that the arbitration provisions of this Agreement shall provide each party with its exclusive remedy, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. By election arbitration as the means for final settlement of all claims, the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.

[SIGNATURES TO FOLLOW ON NEXT PAGE]

IN WITNESS **WHEREOF**, the parties have duly executed this Agreement as of the date first above written.

SENSEONICS INCORPORATED

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

EXECUTIVE

/s/ E. Lynne Kelley
E. Lynne Kelley

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 001-37717) pertaining to the Amended and Restated 1997 Stock Option Plan, as amended, Amended and Restated 2015 Equity Incentive Plan and 2016 Employee Stock Purchase Plan of Senseonics Holdings, Inc. of our report dated February 23, 2017, with respect to the consolidated financial statements of Senseonics Holdings, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM.

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-210586) of Senseonics Holdings, Inc. of our report dated July 10, 2015, except with respect to our opinion on the financial statements insofar as it relates to the effects of the recapitalization described in Note 1 as to which the date is January 13, 2016, relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Baltimore, Maryland
February 23, 2017

**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: February 23, 2017

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

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

I, R. Don Elsey, 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: February 23, 2017

/s/ R. Don Elsey
R. Don Elsey
Chief Financial Officer
(principal financial officer)

**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 R. Don Elsey, 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, 2016 (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 23rd day of February, 2017.

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

/s/ R. Don Elsey

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

R. Don Elsey
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.
