DEXCOM INC
Form 10-K
February 20, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-K

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

For the fiscal year ended December 31, 2013

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

For the transition period from to
Commission file number 000-51222
DEXCOM, INC.
(Exact name of Registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	33-0857544 (I.R.S. Employer Identification No.)
6340 Sequence Drive San Diego, California (Address of Principal Executive Offices)	92121 (Zip Code)

Registrant's Telephone Number, including area code: (858) 200-0200
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 Per Share	The NASDAQ Stock Market LLC (Nasdaq Global Select Market)
Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC (Nasdaq Global Select Market)

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 ý 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 ý
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 ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, 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).

1

Yes ý No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Rule 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definite proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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. (Check one)

Large accelerated Filer ý Accelerated Filer ¨ Non-accelerated Filer ¨ 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 ý

As of June 30, 2013, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $1,564,116,891 based on the closing sales price as reported on the NASDAQ Global Select Market.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at February 14, 2014
Common stock, $0.001 par value per share	72,810,396 shares

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the documents listed below have been incorporated by reference into the indicated parts of this report, as specified in the responses to the item numbers involved.

Designated portions of the Proxy Statement relating to the 2014 Annual Meeting of the Stockholders (the "Proxy Statement"): Part III (Items 9, 10, 11, 12, and 13). Except with respect to information specifically incorporated by reference in the Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

DexCom, Inc.
Table of Contents

PART I

Except for historical financial information contained herein, the matters discussed in this Form 10-K may be considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and subject to the safe harbor created by the Securities Litigation Reform Act of 1995. Such statements include declarations regarding our intent, belief, or current expectations and those of our management. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks, uncertainties and other factors, some of which are beyond our control; actual results could differ materially from those indicated by such forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, but are not limited to: (i) that the information is of a preliminary nature and may be subject to further adjustment; (ii) those risks and uncertainties identified under “Risk Factors;” and (iii) the other risks detailed from time-to-time in our reports and registration statements filed with the Securities and Exchange Commission, or SEC. Except as required by law, we undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

ITEM 1. BUSINESS

Overview

DexCom, Inc. is a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems for ambulatory use by people with diabetes and for use by healthcare providers in the hospital for the treatment of patients with and without diabetes. Unless the context requires otherwise, the terms “we,” “us,” “our,” the “company,” or “DexCom” refer to DexCom, Inc. and its subsidiaries.

Ambulatory Product Line: SEVEN® PLUS, DexCom G4® and DexCom G4® PLATINUM

We received approval from the Food and Drug Administration (“FDA”) and commercialized our first product in 2006. In 2007, we received approval and began commercializing our second generation system, the DexCom SEVEN. We no longer market or provide support for the DexCom SEVEN system. In 2009 we received approval for our third generation system, the DexCom SEVEN PLUS, which is designed for up to seven days of continuous use, and we began commercializing this product in the first quarter of 2009. On June 14, 2012, we received Conformité Européene Marking (“CE Mark”) approval for our fourth generation continuous glucose monitoring system, the DexCom G4 system, enabling commercialization of the DexCom G4 system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark. On October 5, 2012, we received approval from the FDA for the DexCom G4 PLATINUM, which is designed for up to seven days of continuous use by adults with diabetes, and we began commercializing this product in the U.S. in the fourth quarter of 2012. On February 14, 2013, we received CE Mark approval for a pediatric indication for our DexCom G4 system, enabling us to market and sell this system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark to persons two years old and older who have diabetes (hereinafter referred to as the "Pediatric Indication"), and we initiated a limited commercial launch in the second quarter of 2013. In connection with our receipt of CE Mark approval for the Pediatric Indication, we changed the name of the DexCom G4 system to the DexCom G4 PLATINUM system. In the first quarter of 2013, we submitted a PMA supplement to the FDA seeking approval of a Pediatric Indication for the DexCom G4 PLATINUM system in the United States and on February 3, 2014, we received approval from the FDA. During the third quarter of 2013, we submitted a PMA supplement to the FDA seeking an expanded indication for the DexCom G4 PLATINUM for professional use. This expanded indication would allow healthcare professionals to purchase DexCom G4 PLATINUM devices for use with multiple patients. Healthcare professionals can use the insights gained from a DexCom G4 PLATINUM professional session to adjust therapy and to educate and motivate patients to modify their behavior after viewing the effects that specific foods, exercise, stress, and medications have on their glucose levels. Unless the context requires otherwise, the term "G4 PLATINUM" shall refer to the DexCom G4 and DexCom G4 PLATINUM systems that are commercialized by us in and outside of the United States.

As compared to the SEVEN PLUS, the G4 PLATINUM offers:

- an improved sensor wire design that allows more scalable manufacturing;

- a smaller, sleeker receiver that is capable of displaying data in color;
- a new transmitter design that offers improved communication range with the receiver that allows for improved data capture;
- additional user interface and algorithm enhancements that are intended to make the user experience more customizable and to make its glucose monitoring function more accurate especially in the hypoglycemic range; and

- the ability to market and sell to an expanded customer population due to the approval by the FDA of, and our obtaining a CE Mark for, a Pediatric Indication,

The approval of the G4 PLATINUM and the Pediatric Indication, by the FDA allows for the use of the G4 PLATINUM by persons two years old and older with diabetes to detect trends and track glucose patterns, to aid in the detection of hypoglycemia and hyperglycemia and to facilitate acute and long-term therapy adjustments. With the approval of the G4 PLATINUM systems in the United States, we have reduced marketing and sales efforts related to SEVEN PLUS.

DexCom SHARE™

During the third quarter of 2013, we submitted a PMA supplement to the FDA seeking approval of the DexCom SHARE remote monitoring system. Through secure wireless connections, DexCom SHARE notifies another person of a user's G4 PLATINUM sensor glucose information when the G4 PLATINUM Receiver is docked in the DexCom SHARE Cradle. DexCom SHARE provides secondary notification and does not replace real time continuous glucose monitoring or standard home blood glucose monitoring.

In-Hospital Product Line: GlucoClear®

To address the in-hospital patient population, we entered into an exclusive agreement with Edwards to develop jointly and market a specific product platform for the in-hospital glucose monitoring market, with an initial focus on the development of an intravenous sensor specifically for the critical care market. On October 30, 2009, we received CE Mark approval for our first generation blood-based in-vivo automated glucose monitoring system, which we have branded the GlucoClear, for use by healthcare providers in the hospital, and in January 2013, Edwards received CE Mark approval for the second generation system. In partnership with Edwards, we initiated a very limited launch of the GlucoClear system in Europe in 2009, and Edwards initiated another limited launch in Europe of the second generation GlucoClear in 2013.

SweetSpot

Through our acquisition of SweetSpot in 2012, we have a software platform that enables our customers to aggregate and analyze data from certain diabetes devices and to share it with their healthcare providers. In November 2011, SweetSpot received 510(k) clearance from the FDA to market to clinics a data management service, which helps healthcare providers and patients see, understand and use blood glucose meter data to diagnose and manage diabetes. SweetSpot’s data transfer service is registered with the FDA as a Medical Device Data System (“MDDS”) and allows researchers to control the transfer of data from certain diabetes devices to research tools and databases according to their own research workflows. SweetSpot’s software provides an advanced cloud-based platform for uploading, processing and delivering health data and transforms raw output from certain medical devices into useful information for healthcare providers, individuals and researchers.

Background

From inception to 2006, we devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. Since 2006, we have devoted considerable resources to the commercialization of our ambulatory continuous glucose monitoring systems, including the SEVEN PLUS and G4 PLATINUM, as well as the continued research and clinical development of our technology platform.

The International Diabetes Federation (“IDF”) estimates that in 2012, 371 million people around the world had diabetes, and the Centers for Disease Control (“CDC”) estimates that in 2010, diabetes affected 25.8 million people in the United States, of which 7.0 million were undiagnosed. IDF estimates that by 2035, the worldwide incidence of people suffering from diabetes will reach 592 million. The increased prevalence of diabetes is believed to be the result of an aging population, unhealthy diets and increasingly sedentary lifestyles. According to the CDC's National Vital Statistics Reports for 2010, diabetes was the seventh leading cause of death by disease in the United States. According to the Congressional Diabetes Caucus, diabetes is the leading cause of kidney failure, adult-onset blindness, lower-limb amputations, and significant cause of heart disease and stroke, high blood pressure and nerve damage. According to the IDF, there were an estimated 4.8 million deaths attributable to diabetes globally in 2012. The American Diabetes Association (“ADA”) Fast Facts, revised in March 2013, states that diabetes is the primary cause of death for more than 71,000 Americans each year, and contributes to the death of more than 231,000 Americans

annually.

According to the Congressional Diabetes Caucus, in the United States, another individual is diagnosed with diabetes every 17 seconds. Each day approximately 5,082 people are diagnosed with diabetes, and about 1.9 million people will be diagnosed this year. In addition to those newly diagnosed, every 24 hours there are: 238 amputations in people with diabetes, 120 people who enter end-stage kidney disease programs, and 48 people who go blind.

According to the ADA one in every five healthcare dollars was spent on treating diabetes in 2012, and the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated $245 billion, an increase of $71 billion, or approximately 41%, since 2007. Of the $245 billion in overall expenses, the ADA estimated that approximately $176 billion were direct costs associated with diabetes care, chronic complications and excess general medical costs, and $69 billion were indirect medical costs. The ADA also found that average medical expenditures among people with diagnosed diabetes were 2.3 times higher than for people without diabetes in 2012. According to the IDF, expenditures attributable to diabetes were an estimated $471 billion globally in 2012. The IDF estimates that expenditures attributable to diabetes will grow to $627 billion globally by 2035.

We believe continuous glucose monitoring has the potential to enable more people with diabetes to achieve and sustain tight glycemic control. The Diabetes Control and Complications Trial ("DCCT") demonstrated that improving blood glucose control lowers the risk of developing diabetes-related complications by up to 50%. The study also demonstrated that people with Type 1 diabetes achieved sustained benefits with intensive management. Yet, according to an article published in the Journal of the American Medical Association ("JAMA") in 2004, less than 50% of diabetes patients were meeting ADA standards for glucose control (A1c), and only 37% of people with diabetes were achieving their glycemic targets. The CDC estimated that as of 2006, 63.4% of all adults with diabetes were monitoring their blood glucose levels on a daily basis, and that 86.7% of insulin-requiring patients with diabetes monitored daily. Various clinical studies also demonstrate the benefits of continuous glucose monitoring and that continuous glucose monitoring is equally effective in patients who administer insulin through multiple daily injections or through use of continuous subcutaneous insulin infusion pumps. Results of a Juvenile Diabetes Research Foundation ("JDRF") study published in the New England Journal of Medicine in 2008, and the extension phase of the study, published in Diabetes Care in 2009, demonstrated that continuous glucose monitoring improved A1c levels and reduced incidence of hypoglycemia for patients over the age of 25 and for all patients of all ages who utilized continuous glucose monitoring regularly.

Our initial target market in the United States consists of an estimated 30% of people with Type 1 diabetes who utilize insulin pump therapy and an estimated 50% of people with Type 1 diabetes who utilize multiple daily insulin injections. Our broader target market in the United States consists of our initial target market plus an estimated 20% of people with Type 1 diabetes using conventional insulin therapy and the estimated 27% of people with Type 2 diabetes who require insulin. Although our initial focus is within the United States, our CE Mark approval also enables us to commercialize our system in those European, Asian and Latin American countries that recognize the CE Mark.

We have built a direct sales organization to call on endocrinologists, physicians and diabetes educators who can educate and influence patient adoption of continuous glucose monitoring. The approval by the FDA of a Pediatric Indication for our G4 PLATINUM system in February 2014 will now allow our sales organization to call on pediatric endocrinologists and pediatricians who can educate and influence adoption of continuous glucose monitoring by parents who have children aged two years or older with diabetes. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy. To complement our direct sales efforts, we have entered into a limited number of U.S. and international distribution arrangements that allow distributors to sell our products. We believe our direct, highly specialized and focused sales organization is sufficient for us to support our sales efforts.

We are leveraging our technology platform to enhance the capabilities of our current products and to develop additional continuous glucose monitoring products. In 2008 and 2012, we entered into development agreements with Animas Corporation ("Animas"), a subsidiary of Johnson & Johnson, and with Tandem Diabetes Care, Inc. ("Tandem"), respectively. The purpose of each of these development relationships is to integrate our technology into the insulin pump product offerings of the respective partner, enabling the partner's insulin pump to receive glucose readings from our transmitter and display this information on the pump's screen. The Animas insulin pump product augmented with our sensor technology has been branded the Vibe®, and received CE Mark approval in May 2011, which allows Animas to market the Vibe in the countries that recognize CE Mark approvals.

On October 5, 2012, we received FDA approval for the G4 PLATINUM system. On June 14, 2012, we received CE Mark approval for the G4 system, enabling commercialization of the DexCom G4 system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark. Our G4 PLATINUM system features improved sensor reliability, stability and accuracy over the useful life of the sensor, and

is suitable for large scale manufacturing. On February 14, 2013, we received CE Mark approval of a Pediatric Indication for the G4 PLATINUM, enabling us to market and sell that system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark to persons two years old and older who have diabetes. On February 3, 2014, we obtained approval from the FDA of a Pediatric Indication for the DexCom G4 PLATINUM system in the United States. We also intend to seek a pregnancy indication (women who develop gestational diabetes during pregnancy) for our product platform in the future.

In March 2012, we acquired SweetSpot and SweetSpot became a wholly-owned subsidiary of DexCom. SweetSpot is a healthcare-focused information technology company with a platform for uploading and processing data from certain diabetes devices to advance the treatment of diabetes. SweetSpot specializes in turning raw output from certain devices into information for healthcare providers, users and researchers. Through our acquisition of SweetSpot, we have a software platform that enables our customers to aggregate and analyze data from certain diabetes devices and share it with their healthcare providers.

Our development timelines are highly dependent on our ability to achieve clinical endpoints and regulatory requirements and to overcome technology challenges, and our development timelines may be delayed due to extended regulatory approval timelines, scheduling issues with patients and investigators, requests from institutional review boards, sensor performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts are successful, the FDA may not approve our products, and even if approved, we may not achieve acceptance in the marketplace by physicians and people with diabetes.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although the Centers for Medicare and Medicaid ("CMS") released 2008 Alpha-Numeric Healthcare Common Procedure Coding System ("HCPCS") codes applicable to each of the three components of our continuous glucose monitoring systems, to date, our approved products are not reimbursed by virtue of a national coverage decision by Medicare. It is not known when, if ever, Medicare will adopt a national coverage decision with respect to continuous glucose monitoring devices. Until any such coverage decision is adopted by Medicare, reimbursement of our products will generally be limited to those customers covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices that includes our devices. As of February 2014, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with six of those third-party payors for the purchase of our SEVEN PLUS and G4 PLATINUM systems by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with extensive documentation and other requirements to demonstrate medical necessity under the policy. 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 currently employ in-house reimbursement expertise to assist customers in obtaining reimbursement from private third-party payors. We also maintain a field-based reimbursement team charged with calling on third-party private payors to obtain coverage decisions and contracts. We have had formal meetings and have increased our efforts to create and liberalize coverage policies with third-party payors and expect to continue to do so in 2014. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, people with diabetes may not use them on a widespread basis.

We plan to develop future generations of technologies focused on improved performance and convenience and that will enable intelligent insulin administration. Over the longer term, we plan to develop networked platforms with open architecture, connectivity and transmitters capable of communicating with other devices. As an example, during the third quarter of 2013, we submitted a PMA supplement to the FDA for the DexCom SHARE System. Through secure wireless connections, DexCom SHARE notifies another person of a user's DexCom G4 PLATINUM sensor glucose information when the G4 PLATINUM Receiver is docked in the DexCom SHARE Cradle.

Market Opportunity

Diabetes

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. This inability prevents the body from adequately regulating blood glucose levels. Glucose, the primary source of energy for cells, must be maintained at certain concentrations in the blood in order to permit optimal cell function and health. Normally, the pancreas provides control of blood glucose levels by secreting the hormone insulin to decrease blood glucose levels when concentrations are too high. In people with diabetes, the body does not produce sufficient levels of insulin, or fails to utilize insulin effectively, causing blood glucose levels to rise above normal. This condition is called hyperglycemia and often results in chronic long-term complications such as heart disease, limb amputations, loss of kidney function and

blindness. When blood glucose levels are high, people with diabetes often administer insulin in an effort to decrease blood glucose levels. Unfortunately, insulin administration can drive blood glucose levels below the normal range, resulting in hypoglycemia. In cases of severe hypoglycemia, people with diabetes risk acute complications, such as loss of consciousness or death. Due to the drastic nature of acute complications associated with hypoglycemia, many people with diabetes are reluctant to reduce blood glucose levels. Consequently, these individuals often remain in a hyperglycemic state, increasing their odds of developing long-term chronic complications.

Diabetes is typically classified into two major groups: Type 1 and Type 2. According to the ADA and JDRF, respectively, there are an estimated 1.3 million to 3.0 million Type 1 diabetes patients in the United States. Type 1 diabetes is an autoimmune

disorder that usually develops during childhood and is characterized by an absence of insulin, resulting from destruction of the insulin producing cells of the pancreas. Individuals with Type 1 diabetes must rely on frequent insulin injections in order to regulate and maintain blood glucose levels. According to the ADA, there are approximately 25.8 million people with diabetes in the United States, of which approximately 24.5 million people have Type 2 diabetes. Type 2 diabetes is a metabolic disorder which results when the body is unable to produce sufficient amounts of insulin or becomes insulin resistant. Depending on the severity of Type 2 diabetes, individuals may require diet and nutrition management, exercise, oral medications or insulin injections to regulate blood glucose levels. We estimate that approximately 3.6 million Type 2 patients must use insulin to manage their diabetes.

There are various subgroups of people with diabetes, including in-hospital patients, who present significant management challenges. According to the ADA, diabetes related hospitalizations totaled 24.3 million days in 2007, an increase of 7.4 million days from 2002. Additionally, studies show that many hospital patients without diabetes suffer episodes of hyperglycemia. According to a Diabetes Care article, as of 1998, as many as 1.5 million hospitalized patients had significant hyperglycemia without a history of diabetes. A November 2001 article in the New England Journal of Medicine summarized a study of over 1,500 hospitalized patients, of which only 13% had diabetes, which concluded that intensive insulin therapy to maintain blood glucose levels within a target range reduced mortality among critically ill patients in the surgical intensive care unit and improved patient outcomes. An August 2010 Healthcare Cost and Utilization Project report on hospital utilization by patients with diabetes in 2008 reported there were over 7.7 million hospital stays for patients with diabetes as a principal or secondary diagnosis and 540,000 hospitals stays for patients with diabetes as a primary diagnosis. The mean length of stay for patients with diabetes was almost one day longer than for patients without diabetes contributing to a 25% increase in the mean cost of hospitalization. Stays involving patients with diabetes contributed almost $83.0 billion of hospital costs in the United States, which represents 23% of the total hospital costs in the United States.

According to the National Diabetes Education Program, about 75% of all newly diagnosed cases of Type 1 diabetes in the United States occur in juveniles younger than 18 years of age. According to JDRF, the incidence of Type 1 diabetes among children under the age of 14 is estimated to increase by approximately 3% annually worldwide. In addition, Type 2 diabetes is occurring with increasing frequency in young people. The increase in prevalence is related to an increase in obesity amongst children. According to the CDC, as of 2010, approximately one-third of children and adolescents in the United States were overweight or obese and childhood obesity has more than doubled in children and tripled in adolescents in the past 30 years.

Importance of Glucose Monitoring

Blood glucose levels can be affected by many factors, including the carbohydrate and fat content of meals, exercise, stress, illness or impending illness, hormonal releases, variability in insulin absorption and changes in the effects of insulin in the body. Given the many factors that affect blood glucose levels, maintaining glucose within a normal range is difficult, resulting in frequent and unpredictable excursions above or below normal blood glucose levels. People with diabetes manage their blood glucose levels by administering insulin or ingesting carbohydrates throughout the day in order to maintain blood glucose within normal ranges. 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. People with diabetes are often unaware that their glucose levels are either too high or too low, and their inability to completely control blood glucose levels and the associated serious complications can be frustrating and, at times, overwhelming.

In an attempt to maintain blood glucose levels within the normal range, people with diabetes must first measure their blood glucose levels. Often after measuring their blood glucose levels, people with diabetes make therapeutic adjustments. As adjustments are made, additional blood glucose measurements may be necessary to gauge the individual’s response to the adjustments. More frequent testing of blood glucose levels provides people with diabetes with information that can be used to better understand and manage their diabetes. The ADA recommends that most people with Type 1 diabetes test their blood glucose levels at least three or more times per day, and that significantly more frequent testing may be required to reach A1c targets safely without hypoglycemia.

Clinical outcomes data support the notion that an important component of effective diabetes management is frequent monitoring of blood glucose levels. The landmark 1993 DCCT consisting of patients with Type 1 diabetes, and the

1998 UK Prospective Diabetes Study, consisting of patients with Type 2 diabetes, demonstrated that people with diabetes who intensely managed blood glucose levels delayed the onset and slowed the progression of diabetes-related complications. In the DCCT, a major component of intensive management was monitoring blood glucose levels at least four times per day using conventional single-point blood glucose meters. The DCCT demonstrated that intensive management reduced the risk of complications by 76% for eye disease, 60% for nerve disease and 50% for kidney disease. However, the DCCT also found that intensive management led to a three-fold increase in the frequency of hypoglycemic events. In the December 2005 edition of the New England Journal of Medicine, the authors of a peer-reviewed study concluded that intensive diabetes therapy has long-term

beneficial effects on the risk of cardiovascular disease in patients with Type 1 diabetes. The study showed that intensive diabetes therapy reduced the risk of cardiovascular disease by 42% and the risk of non-fatal heart attack, stroke or death from cardiovascular disease by 57%.

Limitations of Existing Glucose Monitoring Products

Single-point finger stick devices are the most prevalent devices for glucose monitoring. These devices require taking a blood sample with a finger stick, placing a drop of blood on a test strip and inserting the strip into a glucose meter that yields a single point in time blood glucose measurement. We believe that these devices suffer from several limitations, including:

- Limited Information. Even if people with diabetes test several times each day, each measurement represents a single blood glucose value at a single point in time. Given the many factors that can affect blood glucose levels, excursions above and below the normal range often occur between these discrete measurement points in time. Because people with diabetes only have single-point data, they do not gain sufficient information to indicate the direction or rate of change in their blood glucose levels. Without the ability to determine whether their blood glucose level is rising, falling or holding constant, and the rate at which their blood glucose level is changing, the individual's ability to effectively manage and maintain blood glucose levels within normal ranges is severely limited. Further, people with diabetes cannot test themselves during sleep, when the risk of hypoglycemia is significantly increased. In addition, existing technology generally limits individuals' ability to store their glucose data in servers or systems independent of the blood glucose meter.

The following graph shows the limited information provided by four single-point measurements during a single day using a traditional single-point finger stick device, compared to the data provided by our continuous sensor. The data presented in the graph is from a clinical trial we completed in 2003 with a continuous glucose monitoring system, where the patient was blinded to the continuous glucose data. The continuous data indicates that, even with four finger sticks in one day, the patient's blood glucose levels were above the target range of 80-140 milligrams per deciliter ("mg/dl") for a period of 13.5 hours.

Single Day Continuous Data

- Inconvenience. The process of measuring blood glucose levels with single-point finger stick devices can cause significant disruption in the daily activities of people with diabetes and their families. People with diabetes using single-

point finger stick devices must stop whatever they are doing several times per day, self-inflict a painful prick and draw blood to measure blood glucose levels. To do so, people with diabetes must always carry a fully supplied kit that may include a spring-loaded needle, or lancet, disposable test strips, cleansing wipes, and the meter, and then safely dispose of the used supplies. This process is inconvenient and may cause uneasiness in social situations.

- Difficulty of Use. To obtain a sample with single-point finger stick devices, people with diabetes generally prick one of their fingertips or, occasionally, a forearm with a lancet. They then squeeze the area to produce the blood sample and another prick may be required if a sufficient volume of blood is not obtained the first time. The blood sample is then placed on a disposable test strip that is inserted into a blood glucose meter. This task can be difficult for individuals with decreased tactile sensation and visual acuity, which are common complications of diabetes.
- Pain. Although the fingertips are rich in blood flow and provide a good site to obtain a blood sample, they are also densely populated with highly sensitive nerve endings. This makes the lancing and subsequent manipulation of the finger to draw blood painful. The pain and discomfort are compounded by the fact that fingers offer limited surface area, so tests are often performed on areas that are sore from prior tests. People with diabetes may also suffer pain when the finger prick site is disturbed during regular activities.

We believe a market opportunity exists for a glucose monitoring system that provides continuous glucose information, including trends, and that is convenient and easy to use. Several companies have attempted to address the limitations of single-point finger stick devices by developing continuous glucose monitoring systems. To date, in addition to DexCom, we are aware of two other companies, Medtronic, Inc. (“Medtronic”) and Abbott Diabetes Care, Inc. (“Abbott”), that have received approval from the FDA to market, and actively market, continuous glucose monitors. Abbott has discontinued selling its Freestyle Navigator glucose monitoring system in the United States; however, Abbott filed a clinical study for home use of the Navigator II system in the United States and in October 2012 they initiated a limited launch of the Navigator II system in Europe. In addition, we believe others, including Roche and Becton, Dickinson and Company, are developing invasive and non-invasive continuous glucose monitoring systems. Except for our SEVEN, SEVEN PLUS, and G4 PLATINUM, we believe that none of the products that have received FDA approval are labeled for more than six days of use. We also believe that none of the products that have received FDA approval are labeled for use as a replacement for single-point finger stick devices.

The DexCom Solution

Our G4 PLATINUM system offers the following advantages to people with diabetes:

- Improved Outcomes. Data published in a peer-reviewed article based on our approval support trial for our first system demonstrated that patients using the system showed statistically significant improvements in maintaining their glucose levels within the target range when compared to patients relying solely on single-point finger stick measurements. Additional peer-review published data from our trial for the SEVEN demonstrated that patients with access to seven days of continuous glucose data statistically improved glucose control by further increasing their time spent with glucose levels in the target range, thereby reducing time spent in both hyperglycemic and hypoglycemic ranges. Peer-review published data from our repeated use trial demonstrated a statistically significant reduction in hemoglobin A1c levels, a measure of the average amount of glucose in the blood over the prior three months, in patients using our system compared to patients relying solely on single-point finger stick measurements. Finally, results of a major multicenter clinical trial funded by the Juvenile Diabetes Research Foundation demonstrated that patients with Type 1 diabetes who used continuous glucose monitoring devices to help manage their disease experienced significant improvements in glucose control.
- Access to Real-Time Values, Trend Information and Alerts. At the push of a button, people with diabetes can view their current glucose value, along with a graphical display of one-, three-, six-, twelve- or twenty-four-hour trend information. Without continuous monitoring, the individual is often unaware if his or her glucose is rising, declining or remaining constant. Access to continuous real-time glucose measurements provides people with diabetes information that may aid in attaining better glucose control. Additionally, our G4 PLATINUM alerts people with diabetes when their glucose levels approach inappropriately high or low levels so that they may intervene.
- Intuitive User Interface. We have developed a user interface that we believe is intuitive and easy to use. The G4 PLATINUM receiver’s compact design includes user-friendly buttons, an easy-to-read color display, simple navigation tools, audible alerts and graphical display of trend information.

Convenience and Comfort. Our G4 PLATINUM provides people with diabetes with the benefits of continuous monitoring, without having to perform finger stick tests for every measurement. Additionally, the disposable sensor electrode that is inserted under the skin is a very thin wire, minimizing potential discomfort associated with inserting or wearing the disposable sensor. The external portion of the sensor, including the transmitter, is small, has a low profile and is designed to be easily worn under clothing. The wireless receiver is the size of a small digital music player and

can be carried discreetly in a pocket or purse. We believe that convenience is an important factor in achieving widespread adoption of a continuous glucose monitoring system.

While we believe the G4 PLATINUM offers these advantages, people with diabetes may not perceive the benefits of continuous glucose monitoring and may be unwilling to change their current treatment regimens. Furthermore, we do not expect that our G4 PLATINUM will appeal to all types of people with diabetes. The G4 PLATINUM prompts a person with diabetes to insert a disposable sensor electrode under their skin at least every seven days, although we are aware of reports from the field that some individuals have been able to use sensors for periods longer than seven days. People with diabetes could find this process to be uncomfortable or inconvenient, and may be unwilling to insert a disposable sensor in their body, especially if their current diabetes management involves no more than two finger sticks per day. Additionally, the G4 PLATINUM (and our predecessor products) is not approved as a replacement device for single-point finger stick devices, must be calibrated initially using measurements from two single-point finger stick tests, and thereafter at least every 12 hours using single-point finger stick tests, and may be more costly to use.

Our Strategy

Our objective is to become the leading provider of continuous glucose monitoring systems and related products to enable people with diabetes to more effectively and conveniently manage their disease. We also seek to develop and commercialize products that integrate our continuous glucose monitoring technologies into the insulin pump delivery systems of Animas and Tandem, respectively. In addition, we designed, developed and commercialized, in collaboration with Edwards, the GlucoClear, which is a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital for the treatment of patients with and without diabetes. To achieve these objectives, we are pursuing the following business strategies:

- Establish our technology platform as the leading approach to continuous glucose monitoring and leverage our development expertise to rapidly bring products to market. We have developed proprietary core technology and expertise that provides a broad platform for the development of innovative products for continuous glucose monitoring. We received approval from the FDA and commercialized our first product in 2006. In 2007, we received approval and began commercializing our second generation system, the SEVEN. In 2009 we received approval for our third generation system, the SEVEN PLUS, which is designed for up to seven days of continuous use, and we began commercializing this product in the first quarter of 2009. On October 5, 2012, we received approval from the FDA for our fourth generation system, the DexCom G4 PLATINUM, which is designed for up to seven days of continuous use, and we began commercializing this product in the U.S. in the fourth quarter of 2012. We plan to continue to invest in the development of our technology platform and to obtain additional FDA approvals for our continuous glucose monitoring systems for both the ambulatory and in-hospital markets as well as for our integrated insulin pump delivery systems. We expect to continue to provide performance improvements, expanded indications and introduce new products to establish and maintain a leadership position in the market. In the future, we may develop our technology to support applications beyond glucose sensing.
- Drive the adoption of our ambulatory products through a direct sales and marketing effort. We have a small direct field sales force to call on endocrinologists, physicians and diabetes educators who can educate and influence patient adoption of continuous glucose monitoring. In addition, the FDA's approval of a Pediatric Indication for the G4 PLATINUM in February 2014 will allow our direct field sales force to call on pediatric endocrinologists and pediatricians who can educate and influence parents to adopt continuous glucose monitoring for their children aged two years or older with diabetes. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy. To complement our sales efforts, we have entered into distribution arrangements that allow distributors to sell our G4 PLATINUM. We currently sell the G4 PLATINUM only in the United States, Australia, New Zealand and in portions of Europe, Latin America and the Middle East, but plan to expand our sales elsewhere in the future.
- Drive additional adoption through technology integration partnerships. We have development agreements with Animas and Tandem to develop products that will integrate our ambulatory product technology into the Animas conventional insulin pump, and the Tandem t:slim system, as applicable, enabling the partner's insulin pump to receive glucose readings from our transmitter and display this information on the pump's screen. We believe people with diabetes who have adopted continuous subcutaneous insulin infusion ("CSII") are individuals who more aggressively

manage their diabetes and may be more inclined to utilize our continuous glucose monitoring systems.

- Seek broad coverage policies and reimbursement for our products. Our approved products are not reimbursed by virtue of a national coverage decision by Medicare. As of February 2014, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. Many of these coverage policies, however, are restrictive in nature and require the policy holder to comply with extensive documentation and other requirements to demonstrate medical necessity under the policy. We have

negotiated contracted rates with six of those third-party payors for the purchase of our products by their members. We currently employ in-house reimbursement expertise to assist people with diabetes in obtaining reimbursement from private third-party healthcare payors. We also maintain a field-based reimbursement team charged with calling on third-party private payors to obtain coverage decisions and both durable medical equipment contracts and pharmacy benefit contracts.

- Drive increased utilization and adoption of our products through a cloud-based data repository platform. Through our acquisition of SweetSpot, we hope to develop a software platform that enables people with diabetes to aggregate and analyze data from numerous diabetes devices and share the data with their healthcare providers. We believe that by producing reports detailing metrics such as the individual's glycemic variability that may be shared with physicians and caregivers will lead to better health outcomes, and we expect that as more people with diabetes adopt our system, that utilization of our sensors will increase.
- Expand the use of our products to other patient care settings and patient demographics. On February 3, 2014, the FDA approved a Pediatric Indication for the G4 PLATINUM, enabling us to market and sell that system in the United States to persons two years old and older who have diabetes. We believe our sensor technology may also be beneficial to women who develop gestational diabetes during their pregnancy and we intend to seek approval for a pregnancy indication in the future. We believe there is an unmet medical need for continuous glucose monitoring in the hospital setting. According to the ADA, diabetes related hospitalizations totaled 24.3 million days in 2007, an increase of 7.4 million days from 2002. In addition, studies show that many hospital patients without diabetes suffer episodes of hyperglycemia. As of 1998, as many as 1.5 million hospitalized patients in the United States had significant hyperglycemia without a history of diabetes. A study of over 1,500 hospitalized patients, of which only 13% had a history of diabetes, concluded that intensive insulin therapy to maintain blood glucose levels reduced mortality among critically ill patients in the surgical intensive care unit and improved patient outcomes. To address this patient population, we entered into an exclusive agreement with Edwards to develop jointly and market a specific product platform for the in-hospital critical care glucose monitoring market.
- Provide a high level of customer support, service and education. We support our sales and marketing efforts with a customer service program that includes customer training and support. We provide direct technical support by telephone 24 hours a day in the U.S. and Canada to customers, endocrinologists, physicians and diabetes educators to promote safe and successful use of our products.
- Pursue the highest safety and quality levels for our products. We have established an organization that is highly focused on product quality and customer safety. We have developed in-house engineering, quality assurance, clinical and regulatory expertise, and data analysis capabilities. Additionally, we seek to continue to establish credible and open relationships with regulatory bodies, physician opinion leaders and scientific experts. These capabilities and relationships will assist us in designing products that we believe will meet or exceed expectations for reliable, safe performance.

Our Technology Platform

The development of a continuous glucose monitor requires successful coordination and execution of a wide variety of technology disciplines, including biomaterials, membrane systems, electrochemistry, low power microelectronics, telemetry, software, algorithms, implant tools and sealed protective housings. We have developed in-house expertise in each of these disciplines. We believe we have a broad technology platform that will support the development of multiple products for glucose monitoring.

Sensor Technology

The key enabling technologies for our sensors include biomaterials, membrane systems, electrochemistry and low power microelectronics. Our membrane technology consists of multiple polymer layers configured to selectively allow the appropriate mix of glucose and oxygen to travel through the membrane and react with a glucose specific enzyme to create an extremely low level electrical signal, measured in pico-amperes. This electrical signal is then translated into glucose values. We believe that the capability to measure very low levels of an electrical signal and to accurately translate those measurements into glucose values is also a unique and distinguishing feature of our technology. We have also developed technology to allow sensitive electronics to be packaged in a small, fully contained, lightweight sealed unit that minimizes inconvenience and discomfort for the user.

Receiver and Transmitter Technology

Our ambulatory glucose monitoring systems use radiofrequency telemetry to wirelessly transmit information from the transmitter, which sits in a pod atop the sensor, to our receiver. We have developed the technology for reliable transmission and

reception and have consistently demonstrated a high rate of successful transmissions from sensor to receiver in our clinical trials. Our receiver then processes and displays real-time and trended glucose values, and provides alerts. We have used our extensive database of continuous glucose data from our clinical trials to create software and algorithms for the display of data to customers.

In March 2009, the Federal Communications Commission ("FCC") established a bifurcated Medical Implant Communications System ("MICS") band which requires device manufacturers whose products will operate in the main MICS band to either manufacture their devices using listen-before-transmit technology, or to transmit on a side band outside the main MICS band at lower power. Although the SEVEN PLUS does not comply with existing MICS band listen-before-transmit requirements, the FCC granted a waiver to allow us to continue marketing and operating our SEVEN PLUS. Our G4 PLATINUM system does not operate within the MICS band and does not require a waiver.

Other Technology Applications

Additionally, we have gained our technology expertise by learning to design implants that can withstand the rigors of functioning within the human body for extended periods of time. In addition to the foreign body response, we have overcome other problems related to operating within the human body, such as device sealing, miniaturization, durability and sensor geometry. We believe that, over time, the expertise gained in overcoming these problems may support the development of additional products beyond glucose monitoring.

Our Primary Commercial Products

Ambulatory Product Line: SEVEN PLUS, G4 and DexCom G4 PLATINUM

In 2009 we received approval for our third generation system, the DexCom SEVEN PLUS, which is designed for up to seven days of continuous use, and we began commercializing this product in the first quarter of 2009. On June 14, 2012, we received Conformité Européene Marking ("CE Mark") approval for our fourth generation continuous glucose monitoring system, the DexCom G4 system, enabling commercialization of the DexCom G4 system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark. On October 5, 2012, we received approval from the FDA for the DexCom G4 PLATINUM, which is designed for up to seven days of continuous use by adults with diabetes, and we began commercializing this product in the U.S. in the fourth quarter of 2012. On February 14, 2013, we received CE Mark approval for a Pediatric Indication, and we initiated a limited commercial launch in the second quarter of 2013. In connection with our receipt of CE Mark approval for the Pediatric Indication, we changed the name of the DexCom G4 system to the DexCom G4 PLATINUM system. On February 3, 2014, the FDA approved a Pediatric Indication for the DexCom G4 PLATINUM system in the United States. Unless the context requires otherwise, the term "G4 PLATINUM" shall refer to the DexCom G4 and DexCom G4 PLATINUM systems that are commercialized by us in and outside of the United States.

As compared to the SEVEN PLUS, the G4 PLATINUM offers:

- an improved sensor wire design that allows more scalable manufacturing,
- a smaller, sleeker receiver that is capable of displaying data in color,
- a new transmitter design that offers improved communication range with the receiver which allows for improved data capture,
- additional user interface and algorithm enhancements that are intended to make the user experience more customizable and to make its glucose monitoring function more accurate especially in the hypoglycemic range, and
- the ability to market and sell to an expanded patient population due to the approval by the FDA of, and our obtaining a CE Mark for, a Pediatric Indication.

With the approval of the G4 PLATINUM systems, we have reduced marketing and sales efforts related to SEVEN PLUS. Each of the G4 PLATINUM and SEVEN PLUS systems must be prescribed by a physician and each includes a disposable sensor, a transmitter and a small handheld receiver. The SEVEN PLUS and G4 PLATINUM systems are indicated for use as adjunctive devices to complement, not replace, information obtained from standard home blood glucose monitoring devices and must be calibrated periodically using a standard home blood glucose monitor. The sensor is inserted by the user and is intended to be used continuously for up to seven days after which it is removed by the user and may be replaced by a new sensor. Our transmitter and receiver are reusable.

Products in Development

We are leveraging our technology platform to enhance the capabilities of our current products (including obtaining expanded indications of use) and to develop additional continuous glucose monitoring products. We plan to develop

future

12

generations of technologies focused on improved performance and convenience and that will enable intelligent insulin administration. Over the longer term, we plan to develop networked platforms with open architecture, connectivity and transmitters capable of communicating with other devices. We intend to seek a pregnancy indication for women who develop gestational diabetes during pregnancy in the future.

In 2008 and 2012, we entered into development agreements with Animas and Tandem. The purpose of each of these development relationships is to integrate our technology into the insulin pump product offerings of the respective partner, enabling the partner's insulin pump to receive glucose readings from our transmitter and display this information on the pump's screen.

Continuous Glucose Monitoring Disposable Sensor & Reusable Transmitter

Our sensor includes a tiny wire-like electrode coated with our sensing membrane system. This disposable sensor comes packaged with an integrated insertion device and is contained in a small plastic housing platform, or pod. The base of the pod has adhesive that attaches it to the skin. The sensor is intended to be easily and reliably inserted by the user by exposing the adhesive, placing the pod against the surface of the skin of the abdomen and pushing down on the insertion device. The insertion device first extends a narrow gauge needle containing the sensor into the subcutaneous tissue and then retracts the needle, leaving behind the sensor in the tissue and the pod adhered to the skin. The user then disposes of the insertion device and snaps the reusable transmitter to the pod. After a stabilization period of a few hours, the user is required to calibrate the receiver with two measurements from a single-point finger stick device and the disposable sensor begins wirelessly transmitting the continuous glucose data at specific intervals to the handheld receiver. Users are prompted by the receiver to calibrate the system twice per day with finger stick measurements throughout the seven day usage period to ensure reliable operation, which calibration may be accomplished by using any FDA approved blood glucose meter. Currently, the SEVEN PLUS and G4 PLATINUM are indicated for use as adjunctive devices to complement, not replace, information obtained from standard home blood glucose monitoring devices, although in the future we may seek replacement claim labeling from the FDA for the use of future generation sensors as the sole basis for making therapeutic adjustments.

The disposable sensor contained in the SEVEN PLUS and G4 PLATINUM is intended to function for up to seven days after which it may be replaced. After seven days, the user simply removes the pod and attached sensor from the skin and discards them while retaining the reusable transmitter. A new sensor and pod can then be inserted and used with the same receiver and transmitter for a subsequent seven day period. We are aware of reports from the field, however, that customers have been able to use sensors for periods longer than seven days.

Handheld Receiver

Our small handheld receiver is carried by the user and wirelessly receives continuous glucose values from the sensor. Proprietary algorithms and software, developed from our extensive database of continuous glucose data from clinical trials, are programmed into the receiver to process the glucose data from the sensor and display it on a user-friendly graphical user interface. With a push of a button, the user can access their current glucose value and one-, three-, six-, twelve- and twenty-four-hour trended data. Additionally, when glucose values are inappropriately high or low, the receiver provides an audible alert or vibrates. The receiver is a self-contained, durable unit with a rechargeable battery.

Sales and Marketing

We have built a direct sales organization to call on endocrinologists, physicians and diabetes educators who can educate and influence patient adoption of continuous glucose monitoring. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy. We employ approximately 96 direct sales personnel and continue to add to our sales and marketing organization as necessary to support the commercialization of our products. We believe that referrals by physicians and diabetes educators, together with self-referrals by customers, have driven and will continue to drive adoption of our G4 PLATINUM. We directly market our products in the United States primarily to endocrinologists, physicians and diabetes educators. The approval by the FDA of a Pediatric Indication for our G4 PLATINUM system in February 2014 will also allow our direct sales personnel to call on pediatric endocrinologists and pediatricians who can educate and influence adoption of continuous glucose monitoring by parents who have children aged two years or older with diabetes. Although the number of diabetes patients is significant, the number of physicians and educators influencing these patients is relatively small. As of 2008, there were an estimated 4,000 clinical endocrinologists in the United States. As a result, we believe our direct, highly specialized and focused sales organization is sufficient for us to

support our sales efforts for the foreseeable future.

We use a variety of marketing tools to drive adoption, ensure continued usage and establish brand loyalty for our continuous glucose monitoring systems by:

- creating awareness of the benefits of continuous glucose monitoring and the advantages of our technology with endocrinologists, physicians, diabetes educators and people with diabetes;
- providing strong and simple educational and training programs to healthcare providers and people with diabetes to ensure easy, safe and effective use of our systems; and
- maintaining a readily accessible telephone and web-based technical and customer support infrastructure, which includes clinicians, diabetes educators and reimbursement specialists, to help referring physicians, diabetes educators and people with diabetes as necessary.

Our sales organization competes with the experienced and well-funded marketing and sales operations of our competitors. We have relatively limited experience developing and managing a direct sales organization and we may be unsuccessful in our attempt to manage and expand the sales force. Developing a direct sales organization is a difficult, expensive and time consuming process. To be successful we must:

- recruit and retain adequate numbers of effective sales personnel;
- effectively train our sales personnel in the benefits of our products;
- establish and maintain successful sales, marketing, training and education programs that encourage endocrinologists, physicians and diabetes educators to recommend our products to their patients; and
- manage geographically disbursed operations.

Competition

The market for blood glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions. Four companies, Roche Disetronic, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; the MediSense and TheraSense divisions of Abbott Laboratories; and Bayer Corporation, currently account for substantially all of the worldwide sales of self-monitored glucose testing systems. These competitors' products use a meter and disposable test strips to test blood obtained by pricking the finger or, in some cases, the forearm. In addition, other companies are developing or marketing minimally invasive or noninvasive glucose testing devices and technologies that could compete with our devices. There are also a number of academic and other institutions involved in various phases of our industry's technology development.

Several companies have attempted to address the limitations of single-point finger stick devices by developing continuous glucose monitoring systems. To date, in addition to DexCom, we are aware that two other companies, Medtronic, and Abbott, have received approval from the FDA to market, and actively market, continuous glucose monitors. Abbott has discontinued selling its Freestyle Navigator glucose monitoring system in the United States; however, Abbott filed a clinical study for home use of the Navigator II system in the United States and in October 2012 they initiated a limited launch of the Navigator II system in Europe. Except for our SEVEN, SEVEN PLUS, and G4 PLATINUM, we believe that none of the products that have received FDA approval are labeled for more than six days of use. We also believe that none of the FDA approved products are labeled for use as a replacement for single-point finger stick devices.

A number of companies, including Roche and Becton, Dickinson and Company, are developing next generation real-time continuous glucose monitoring or sensing devices and technologies as well as several other companies that are developing non-invasive continuous glucose monitoring products to measure the patient's glucose level. The majority of these non-invasive technologies do not pierce the skin, but instead typically analyze signatures reflected back from energy that has been directed into the patient's skin, tissue or bodily fluids.

Many of our competitors are either publicly traded or are divisions of publicly traded companies, and they enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we may be unable to compete effectively against these companies or their products.

14

We believe that the principal competitive factors in our market include:

- safe, reliable and high quality performance of products;
- cost of products and eligibility for reimbursement;
- comfort and ease of use;
- effective sales, marketing and distribution;
- brand awareness and strong acceptance by healthcare professionals and people with diabetes;
- customer service and support and comprehensive education for people with diabetes and diabetes care providers;
- speed of product innovation and time to market;
- regulatory expertise; and
- technological leadership and superiority.

Manufacturing

We currently manufacture our devices at our headquarters in San Diego, California. These facilities have more than 13,000 square feet of laboratory space and approximately 10,000 square feet of controlled environment rooms. In July 2012, the FDA completed an inspection of our facilities, and did not identify any observations or require any other types of corrective action. During a routine FDA post-approval facility inspection ending on November 7, 2013, the FDA issued a Form 483 with several observations regarding DexCom Medical Device Reporting (MDR) procedures and complaint reportability determinations. DexCom responded to the observations on November 26, 2013.

There are technical challenges to increasing manufacturing capacity, including equipment design and automation, material procurement, problems with production yields, and quality control and assurance. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts, however there can be no assurances that supply will not be constrained going forward. Additionally, the production of our continuous glucose monitoring systems must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Developing commercial-scale manufacturing facilities has and will continue to require the investment of substantial additional funds and the hiring and retaining of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. Manufacturing is subject to numerous risks and uncertainties described in detail in “Risk Factors” below.

We manufacture our G4 PLATINUM systems with components supplied by outside vendors and with parts manufactured by us internally. Key components that we manufacture internally include our wire-based sensors for our G4 PLATINUM systems. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished G4 PLATINUM systems, which include a reusable transmitter, a receiver, and disposable sensors.

We purchase certain components and materials from single sources due to quality considerations, costs or constraints resulting from regulatory requirements. Currently, those single sources are OnCore Manufacturing Services, which manufactures and supplies circuit boards for our receiver and transmitter; ON Semiconductor Corp, which produces the application specific integrated circuits used in our transmitters; DSM PTG, Inc., which manufactures certain polymers used to synthesize our polymeric membranes for our sensors; and The Tech Group, which produces injection molded components. In some cases, agreements with these and other suppliers can be terminated by either party upon short notice. We may not be able to quickly establish additional or replacement suppliers for our single-source components, especially after our products are commercialized, in part because of the FDA approval process and because of the custom nature of the parts we designed. Any supply interruption from our vendors or failure to obtain alternate vendors for any of the components would limit our ability to manufacture our systems, and could have a material adverse effect on our business.

Third-Party Reimbursement

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although the CMS in 2008 released Alpha-Numeric HCPCS codes applicable to each of the three components of our continuous glucose monitoring systems, to date, our approved products are not reimbursed

due to a national coverage decision by Medicare. It is not known when, if ever, Medicare will adopt a national coverage decision with respect to continuous glucose monitoring devices. Until any such coverage decision is adopted by Medicare, reimbursement of our products will generally be limited to people with diabetes covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices. As of February 2014, the seven largest private third-party payors, in terms of the

number of covered lives, have issued policies for the category of continuous glucose monitoring devices allowing for coverage of these devices if certain conditions are met. In addition, we have negotiated contracted rates with six of those third-party payors for the purchase of our SEVEN PLUS and G4 PLATINUM systems by their members. Many of these coverage policies are restrictive in nature and require the policy holder to comply with extensive documentation and other requirements to demonstrate medical necessity under the policy. In addition, people with diabetes who are insured by payors that do not offer coverage for our devices will have to bear the financial cost of the products. We currently employ in-house reimbursement expertise to assist people with diabetes in obtaining reimbursement from private third-party payors. We also maintain a field-based reimbursement team charged with calling on third-party private payors to obtain coverage decisions and contracts. We have had formal meetings and have increased our efforts to create and liberalize coverage policies with third-party payors and expect to continue to do so throughout 2014. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, people without coverage who have diabetes may not use them 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 initial dependence on the commercial success of our SEVEN PLUS and G4 PLATINUM systems 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, our financial performance may be harmed.

In some foreign markets, pricing and profitability of medical devices are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed healthcare in the United States and proposed legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of healthcare services and products and may result in lower prices for our products or the exclusion of our products from reimbursement programs.

Intellectual Property

Protection of our intellectual property is a strategic priority for our business. We rely on a combination of patent, copyright and other intellectual property laws, trade secrets, nondisclosure agreements and other measures to protect our proprietary rights. As of February 2014, we had obtained 244 issued U.S. patents, and had 239 additional U.S. patent applications pending. We believe it will take up to five years, and possibly longer, for these pending U.S. patent applications to result in issued patents. As of February 2014, we have 20 international applications filed under the Patent Cooperation Treaty, 10 granted European patents, 52 European patent applications pending, 8 granted Japanese patents, 3 Japanese patent applications pending, 15 registered U.S. trademarks, 13 pending U.S. trademark applications, 9 registered European trademarks, 1 pending European trademark application, and 3 registered Japanese trademarks. We also have one pending trademark application in each of a number of countries in Asia, Latin America and the Middle East. In addition, a Madrid Protocol Trademark Registration is pending in each of a number of countries in Asia, Latin America, Europe and the Middle East. Our patents begin expiring in 2017.

Together, our patents and patent applications seek to protect aspects of our core membrane and sensor technologies, and our product concepts for continuous glucose monitoring. We believe that our patent position provides us with sufficient rights to protect our current and proposed commercial products. However, our patent applications may not result in issued patents, and any patents that have been issued or might be issued may not protect our intellectual property rights. Furthermore, our patents may not be upheld. Any patents issued to us may be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents. The steps we have taken may not prevent the misappropriation of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as 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 aspects of our business, including the design and manufacture of continuous glucose monitoring sensors and membranes, as well as methods for continuous glucose monitoring. The owners of each of these patents could assert that the manufacture, use or sale of our continuous glucose monitoring systems infringes one or more claims of their patents. Each of these patents contains multiple claims, any one of which may be independently asserted against us. There may be patents of which we are presently unaware that may relate to aspects of our technology that

could materially and adversely affect our business. In addition, because patent applications can take many years to issue, there may be currently pending applications that are unknown to us, which may later result in issued patents that may materially and adversely affect our business.

We are currently engaged in patent litigation with Abbott as further described in “Item 3. Legal Proceedings” of this Annual Report. In connection with this litigation four of Abbott’s seven patents that are the subject of the litigation have one or more associated reexamination requests in various stages at the U.S. Patent and Trademark Office (the "Patent Office"). The Patent Office’s decisions in the reexamination for two of these four patents were appealed to the Federal Circuit by Abbott. The Federal Circuit issued a decision recently vacating-in-part the Patent Office’s decisions and remanding the case back to the Patent Office for further proceedings. With respect to the remaining three of Abbott’s patents that are subject to the litigation, a Certificate of Reexamination issued for one of the patents in June 2012. We filed an inter partes reexamination request for this patent in September 2012, and the Patent Office has issued a final decision denying our request. Another patent has received a Notice of Intent to Issue a Certificate of Reexamination in September 2012. For the third patent, the Patent Office issued an Advisory Action in September 2012, and Abbott filed an Appeal Brief in January 2013. In many of these reexaminations, Abbott has filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art we have presented, seeking to amend certain claims to overcome the prior art we have presented, canceling claims and/or seeking to add new claims.

Further, on December 31, 2013, Abbott filed a motion with the district court seeking to lift the stay of the two consolidated cases. We filed an opposition to the motion on January 17, 2014, and Abbott filed a reply brief in support of its motion on January 29, 2014. The court has taken the motion under submission, although it is not clear when it will issue a ruling. On December 31, 2013, Abbott filed a new complaint for patent infringement. In that complaint, Abbott alleges that our products, including our SEVEN PLUS and G4 PLATINUM continuous glucose monitoring systems, infringe claims of United States Patent No. 8,175,673. We filed an answer to the complaint on January 23, 2014. On January 28, 2014, we also filed a motion to consolidate the newest case with the first two cases, and to stay the three cases pending conclusion of all pending reexamination proceedings in the Patent Office.

In addition, since 2008, Abbott has copied claims from certain of our applications, and stated that it may seek to provoke an interference with certain of our pending applications in the Patent Office. If interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also since 2008, Abbott has filed 38 reexamination requests seeking to invalidate 31 of our patents. Seven of the 38 reexamination requests are in various stages at the Patent Office, and 30 have been issued a Certificate of Reexamination; one of the Abbott Reexamination Requests was refused by the Patent Office. We have filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented in the reexaminations, seeking to amend certain claims to overcome the prior art presented in the reexaminations, canceling claims and/or seeking to add new claims. It is possible that the Patent Office may determine that some or all of the claims of our patents subject to the reexamination are invalid. Additionally, Abbott has filed an Opposition to six of our European patents, one of which was not defended and one of which was revoked.

Further, we requested reexamination of three other Abbott patents that are not involved in the current patent infringement lawsuit. In April 2012, one of Abbott’s patents received a Certificate of Reexamination. In October 2012, another Abbott patent received a Certificate of Reexamination. An inter partes reexamination request was recently filed on the third Abbott patent, which is awaiting final decision from the Patent Office.

Although it is our position that Abbott’s assertions of infringement have no merit, and that the potential interference, reexamination requests and opposition requests have no merit, the outcome of the litigation, and interference, reexamination or opposition requests cannot be assessed currently with certainty. We may not successfully defend ourselves against the claims made by Abbott, and we may not prevail in the litigation. If Abbott were to successfully seek an injunction, it could force us to stop making, using, selling or offering to sell our products. The technology at issue in our litigation with Abbott is currently used in our products, including our SEVEN PLUS and G4 PLATINUM systems, and the GlucoClear system. If we were forced to stop selling these products either as a result of an unfavorable outcome in the litigation or in connection with the grant of an injunction, our business and prospects would suffer. In addition, defending against this action, including any injunction action, could have a number of harmful effects on our business regardless of the final outcome of such litigation. For example, we have incurred, and

expect to continue to incur significant costs in defending the action.

Any adverse determination in litigation or interference proceedings to which we are or may become a party relating to patents could subject us to significant liabilities to third parties or require us to seek licenses from other third parties. Furthermore, if we are found to willfully infringe third-party patents, we could, in addition to other penalties, be required to pay treble damages and/or attorney fees for the prevailing party. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and would likely require ongoing royalties. 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 and any redesign 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 would have a significant adverse impact on our business. We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by generally requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from bringing the proprietary rights of third parties to us. We also generally require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. We cannot provide any assurance that employees and third parties will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary.

Government Regulation

Our products are medical devices subject to extensive and ongoing regulation by the FDA and regulatory bodies in other countries. The Federal Food, Drug and Cosmetic Act ("FDCA") and the FDA's implementing regulations govern product design and development, pre-clinical and clinical testing, pre-market clearance or approval, establishment registration and product listing, product manufacturing, product labeling, product storage, advertising and promotion, product sales, distribution, recalls and field actions, servicing and post-market clinical surveillance.

FDA Regulation

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior approval from the FDA through the premarket approval ("PMA") process. Our SEVEN PLUS and G4 PLATINUM systems are classified by the FDA as PMA medical devices. 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 Quality System Regulation ("QSR"). Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling, as well as general controls. Some Class I and Class II devices are exempted by regulation from the pre-market notification (i.e., 510(k) clearance) requirement, and/or the requirement of compliance with substantially all of FDA's manufacturing requirements, known as the QSR. Some devices are placed in Class III, which requires approval of a PMA application, if they are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or to be "not substantially equivalent" either to a previously 510(k) cleared device or to a "preamendment" Class III device in commercial distribution before May 28, 1976 for which PMA applications have not been required.

Our SEVEN PLUS and G4 PLATINUM have been classified as devices requiring PMA approval. A PMA application must be supported by valid scientific evidence, which typically requires extensive data, including 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. In July 2012, the FDA completed an inspection of our facilities, and did not identify any observations or require any other types of corrective action. During a routine FDA post-approval facility inspection ending on November 7, 2013, the FDA made several observations regarding DexCom Medical Device Reporting (MDR) procedures and complaint reportability determinations. DexCom responded to the observations on November 26, 2013.

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:

- our systems may not be safe or effective to the FDA's satisfaction;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities we use 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 or manufacturing facilities is favorable, the FDA will either issue an approval letter, or approvable letter, which usually contains a number of conditions which 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 may also determine that additional 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 is 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 clinical data or the convening of an advisory panel.

Clinical trials are almost always 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 investigational device exemption ("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 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, which 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 of our clinical trials 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 we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to our products;
- institutional review boards and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- the company 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 the Company or study that 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 applicable to our trial protocols;

- 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.

In November 2011, SweetSpot received 510(k) clearance from the FDA to market to clinics a data management service, which helps healthcare providers and patients see, understand and use blood glucose meter data to diagnose and manage diabetes. SweetSpot's data transfer service is registered with the FDA as a Medical Device Data System ("MDDS") and allows researchers to control the transfer of data from certain diabetes devices to research tools and databases according to their own research workflows. Additional functions of, or intended uses for, the SweetSpot software platform will require us to obtain either 510(k) clearance or PMA approval from the FDA. To obtain 510(k) clearance, we must submit a pre-market notification demonstrating that the software system is substantially equivalent to a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires a new 510(k) clearance.

After a device is approved and placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- QSR, which requires manufacturers to follow design, testing, control, storage, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or off-label uses or indications and impose other restrictions on labeling, advertising and promotion;
- medical device reporting regulations, which require that manufacturers report to the FDA if a 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 it were to recur;
- voluntary and mandatory device recalls to address problems when a device is defective and/or could be a risk to health; and
- corrections and removal 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 order us to 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, including those applicable to the conduct of our clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

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

We and our contract manufacturers, specification developers, and some suppliers of components or device accessories, are also required to manufacture our products in compliance with current Good Manufacturing Practice ("GMP") 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 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 we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our 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. Any such action by the FDA would have a material adverse effect on our business. We may be unable to comply with all applicable FDA regulations.

Fraud and Abuse Laws and Other Compliance Requirements

The healthcare industry is subject to various federal and state laws pertaining to healthcare fraud and abuse. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid.

Anti-kickback Laws. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration directly or indirectly 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. The definition of "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. The Department of Health and Human Services ("HHS") has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if fully met, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the HHS Office of Inspector General.

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 apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs.

Federal False Claims Act. The federal False Claims Act prohibits the knowing filing of a false claim or the knowing use of false statements to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties of between $5,500 and $11,000 for each separate false claim. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals (known as "relators" or, more commonly, as "whistleblowers") may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act. 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.

HIPAA. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created two new federal crimes: 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.

FCPA. Additionally, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals in many countries. Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or

regulations.

Sunshine Act. Pursuant to the Patient Protection and Affordable Care Act that was signed into law in March 2010, the federal government enacted the Physician Payment Sunshine Act (the “Sunshine Act”). Beginning in 2013 and 2014, we are required to track and publicly report, respectively, gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and failure to comply could result in a range of fines, penalties and/or other sanctions.

International Regulation

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval in a foreign 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, 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. Outside of the European Union, regulatory approval needs to be sought on a country-by-country basis in order for us to market our products.

Environmental Regulation

Our research and development, clinical and manufacturing processes involve the handling of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

Advisory Boards and Consultants

We have relied upon the advice of experts in the development and commercialization of our products. Since 2005, we have used experts in various disciplines on a consulting basis as needed to solve problems or accelerate development pathways. We will continue to engage advisors from the academic, consultancy, governmental or other areas to assist us as necessary. We meet with our clinical advisory board on an annual basis.

Employees

As of December 31, 2013, we had 646 full-time employees and 119 contract and temporary employees. Approximately 123 full-time employees are engaged in research and development, clinical, regulatory and quality assurance, 225 in manufacturing and 298 in selling, general and administrative functions. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our employee relations to be good.

Available Information

Our Internet website address is www.dexcom.com. We provide free access to various reports that we file with or furnish to the SEC through our website, as soon as reasonably practicable after they have been filed or furnished. These reports include, but are not limited to, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports. Our SEC reports can be accessed through the investor relations section of our website, or through www.sec.gov. Also available on our website are printable versions of our Audit Committee charter, Compensation Committee charter, Nominating and Corporate Governance Committee charter, and Business Code of Conduct and Ethics. Information on our website does not constitute part of

this Annual Report on Form 10-K or other report we file or furnish with the SEC. Stockholders may request copies of these documents from:
DexCom, Inc.
6340 Sequence Drive

San Diego, CA 92121
(858) 200-0200

23

ITEM 1A. RISK FACTORS

Factors that May Affect our Financial Condition and Results of Operations

Risks Related to Our Business

We have a limited operating history and our products may never achieve market acceptance.

We expect that sales of our SEVEN PLUS and G4 PLATINUM systems, each of which consist of a handheld receiver, reusable transmitter and disposable sensor, will account for substantially all of our product revenue for the foreseeable future. We have relatively limited experience in selling our products and we might be unable to successfully expand the commercialization of our products on a wide scale for a number of reasons, including:

- the approval to sell our G4 system in the European Union, Australia, New Zealand, and the countries in Asia and Latin America that recognize our CE Mark in June 2012 and approval for our G4 PLATINUM system in the United States in October 2012 means that we have limited experience selling our new G4 system;
- the recent approval for a Pediatric Indication of our G4 PLATINUM system in the United States, European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize our CE Mark means that we have limited experience selling and marketing the DexCom G4 PLATINUM system to persons aged two to 17 years or their legal guardians;
- widespread market acceptance of our products by physicians and people with diabetes will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use;
- the limited size of our sales force and our relative inexperience in marketing, selling and distributing our products;
- we may not have sufficient financial or other resources to adequately expand the commercialization efforts for our products;
- our FDA and other regulatory submissions may be delayed, or approved with limited product labeling;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost;
- people with diabetes do not generally receive broad reimbursement from third-party payors for their purchase of our products since many payors require that a policy holder meet specific medical criteria to qualify for reimbursement, which may reduce widespread use of our products;
- the uncertainties associated with establishing and qualifying new manufacturing facilities;
- our systems are not labeled as a replacement for the information that is obtained from single-point finger stick devices;
- people with diabetes will need to incur the costs of our systems in addition to single-point finger stick devices;
- the relative immaturity of the continuous glucose monitoring market internationally, and the general absence of international reimbursement of continuous glucose monitoring devices by third-party payors and government healthcare providers outside the United States;
- the introduction and market acceptance of competing products and technologies;
- our inability to obtain sufficient quantities of supplies at appropriate quality levels from our single-source and other key suppliers;
- our inability to manufacture products that perform in accordance with expectations of consumers; and
- rapid technological change may make our technology and our products obsolete.

Our SEVEN PLUS and G4 PLATINUM systems are more invasive than current self-monitored glucose testing systems, including single-point finger stick devices, and people with diabetes may be unwilling to insert a sensor in their body, especially if their current diabetes management involves no more than two finger sticks per day. Moreover, people with diabetes may not perceive the benefits of continuous glucose monitoring and may be unwilling to change their current treatment regimens. In addition, physicians tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products. Physicians may not recommend or prescribe our products until (i) there is more long-term clinical evidence to convince them to alter their existing treatment methods, (ii) there are additional recommendations from prominent physicians that our products are effective in monitoring glucose levels and (iii) reimbursement or insurance coverage is more widely available. We cannot predict when, if ever, physicians and people with diabetes may adopt more widespread use of continuous glucose monitoring systems, including the SEVEN PLUS and G4 PLATINUM systems. If the SEVEN PLUS and/or G4 PLATINUM systems do not achieve an adequate level of acceptance by

24

people with diabetes, physicians and healthcare payors, we may not generate significant product revenue and we may not become profitable.

We have incurred losses since inception and anticipate that we will incur continued losses in the future.

We have incurred net losses in each year since our inception in May 1999, including a net loss of $29.8 million for the twelve months ended December 31, 2013. As of December 31, 2013, we had an accumulated deficit of $475.4 million. We have financed our operations primarily through private placements of our equity and debt securities and our public offerings, and have devoted a substantial portion of our resources to research and development relating to our continuous glucose monitoring systems, including our in-hospital product development, and more recently, we have incurred significant sales and marketing and manufacturing expenses associated with the commercialization of the SEVEN PLUS and G4 PLATINUM systems. In addition, we expect our research and development expenses to increase in connection with our clinical trials and other development activities related to our products, including our next generation sensor, and sensor augmented insulin pump collaborations. We also expect that our general and administrative expenses will continue to increase due to the additional operational and regulatory burdens applicable to public healthcare and medical device companies. As a result, we expect to continue to incur operating losses in the future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

Current uncertainty in global economic and political conditions makes it particularly difficult to predict product demand and other related matters and makes it more likely that our actual results could differ materially from expectations.

Our operations and performance depend on worldwide economic and political conditions, which have been adversely impacted by continued global economic uncertainty, concerns over the downgrade of U.S. sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other foreign countries. These conditions have and may continue to make it difficult for our customers and potential customers to afford our products, and could cause our customers to stop using our products or to use them less frequently. If that were to occur, we would experience a decrease in revenue and our performance would be negatively impacted. In addition, the pressure on consumers to absorb more of their own health care costs has resulted in some cases in higher deductibles and limits on durable medical equipment, which may cause seasonality in purchasing patterns. Furthermore, during economic uncertainty, our customers have experienced job losses and may continue to experience issues gaining timely access to sufficient health insurance or credit, which could result in their unwillingness to purchase products or an impairment of their ability to make timely payments to us. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our financial condition and operating results.

We may require additional funding to continue the commercialization of our G4 systems or the development and commercialization of our future generation and other continuous glucose monitoring systems, including our sensor augmented insulin pump systems developed in collaboration with Animas and Tandem.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our products, including growth of our manufacturing capacity, and on research and development, including conducting clinical trials for our next generation ambulatory continuous glucose monitoring sensors and systems. For the twelve months ended December 31, 2013, our operating activities generated $2.4 million in net cash, compared to $33.1 million used for the same period in 2012, and as of December 31, 2013, we had working capital of $61.0 million which included $54.6 million in cash, cash equivalents and short-term marketable securities, and $1.0 million in restricted cash. We expect that our cash used by operations will decrease in each of the next several years, and, although (1) have the ability to borrow up to an additional $28.0 million pursuant to the Loan and Security Agreement we entered into with Silicon Valley Bank and Oxford Finance in November 2012 and (2) we were awarded a $4.0 million grant from the Helmsley Trust in July 2013, we may need additional funds to continue the commercialization of our products and for the development and commercialization of our next generation sensors and systems. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

- the revenue generated by sales of our products and other future products;
- the costs, timing and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- our ability to scale our manufacturing operations to meet demand for our current and any future products;
- the costs to produce our continuous glucose monitoring systems;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technological developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If adequate funds are not available, we may not be able to commercialize our products at the rate we desire and we may have to delay development or commercialization of our other products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce sales, marketing, customer support or other resources devoted to our products. Any of these factors could harm our financial condition.

We may face risks associated with acquisitions of companies, products and technologies and our business could be harmed if we are unable to address these risks.

If we are presented with appropriate opportunities, we intend to acquire or make other investments in complementary companies, products or technologies. In March 2012, we acquired SweetSpot, our only acquisition to date. We may not realize the anticipated benefit of the acquisition of SweetSpot or any future acquisition, or the realization of the anticipated benefits may require greater expenditures than anticipated by us. We will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations and services of any acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired businesses and impairment charges if future acquisitions are not as successful as we originally anticipate. If we fail to successfully integrate companies, products or technologies that we acquire, our business could be harmed. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing shareholders. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets.

If we are unable to continue the development of an adequate sales and marketing organization, or if our direct sales organization is not successful, we may have difficulty achieving market awareness and selling our products.

To achieve commercial success for the G4 PLATINUM system and our future products, we must continue to develop and grow our sales and marketing organization and enter into partnerships or other arrangements to market and sell our products. We currently employ a small direct sales force to market our products in the United States. In the United States, our sales force calls directly on healthcare providers and people with diabetes throughout the country to initiate sales of our products. Our sales organization competes with the experienced, larger and well-funded marketing and sales operations of our competitors. We may not be able to successfully manage our dispersed sales force, or increase our product sales in the new territories. We have also entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. Our U.S. distribution partnerships are focused on accessing underrepresented regions and, in some instances, third-party payors that contract exclusively with distributors. Our European and other international distribution partners call directly on healthcare providers to market and sell our products in Europe, Australia, New Zealand, the Middle East and Latin America. Because of the competition for their services, we may be unable to partner with or retain additional qualified distributors. Further, we may not be able to enter into agreements with distributors on commercially reasonable terms, if at all.

Additionally, to aid our efforts to obtain timely and comprehensive reimbursement of our products for our customers, we must continue to improve our customer service processes and scale our information technology systems.

Developing and managing a direct sales organization is a difficult, expensive and time consuming process. To be successful we must:

- recruit and retain adequate numbers of effective and experienced sales personnel;
- effectively train our sales personnel in the benefits and risks of our products;
- establish and maintain successful sales, marketing and education programs that educate endocrinologists, physicians and diabetes educators so they can appropriately inform their patients about our products; and
- manage geographically disbursed sales and marketing operations.

26

If we are unable to establish adequate sales, marketing and distribution capabilities or enter into and maintain arrangements with third parties to sell, market and distribute our products, our business may be harmed.

We have entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. We have distribution agreements with Byram Healthcare and their subsidiaries ("Byram") and RGH Enterprises, Inc. (“Edgepark”), pursuant to which we generated approximately 15% and 14%, respectively, of our total revenue during the twelve months ended December 31, 2013. There can be no assurances that these relationships will continue or that we will be able to maintain this volume of sales from these relationships in the future. A substantial decrease or loss of these sales could have a material adverse effect on our operating performance. Additionally, to the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services in the United States, Europe or other countries, our product margins could be lower than if we directly marketed and sold our products. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we cannot predict whether these efforts will be successful. In addition, market acceptance of our products by physicians and people with diabetes in Europe or other countries will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use. If we are unable to do so, we may not be able to generate product revenue from our sales efforts in Europe or other countries. Finally, if we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate adequate product revenue and may not become profitable.

Although many third-party payors have adopted some form of coverage policy on continuous glucose monitoring devices, our products do not yet have broad-based contractual coverage with third-party payors and we frequently experience administrative challenges in obtaining reimbursement for our customers. If we are unable to obtain adequately broad reimbursement at acceptable prices for our products or any future products from third-party payors, we will be unable to generate significant revenue.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although the Centers for Medicare & Medicaid Services (“CMS”) in 2008 released Alpha-Numeric Healthcare Common Procedure Coding System (“HCPCS”) codes applicable to each of the three components of our continuous glucose monitoring systems, to date, our approved products are not reimbursed by virtue of a national coverage decision by Medicare. It is not known when, if ever, Medicare will adopt a national coverage decision with respect to continuous glucose monitoring devices. Until any such coverage decision is adopted by Medicare, reimbursement of our products will generally be limited to those people with diabetes covered by third-party payors that have adopted policies for continuous glucose monitoring devices allowing for coverage of these devices if certain conditions are met. As of February 2014, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with six of those third-party payors for the purchase of our products by their members. However, people with diabetes without insurance that covers our products will have to bear the financial cost of them. In the United States, people with diabetes using existing single-point finger stick devices are generally reimbursed all or part of the product cost by Medicare or other third-party payors. The commercial success of our products in both domestic and international markets will be substantially dependent on whether third-party reimbursement is widely available for individuals that use them. While many third-party payors have adopted some form of coverage policy on continuous glucose monitoring devices, those coverage policies frequently require significant medical documentation in order for policy holders to obtain reimbursement, and as a result, we have experienced difficulty in improving the efficiency of our customer service group. In addition, 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, they may not cover or provide adequate payment for our products. In order to obtain additional 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. Furthermore, we are unable to predict what effect the current or any future healthcare reform will have on our business, or the effect these matters

will have on our customers. Our initial dependence on the commercial success of the SEVEN PLUS and G4 PLATINUM systems 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 the SEVEN PLUS and G4 PLATINUM systems, people without coverage who have diabetes may not use our products.

In some foreign markets, pricing and profitability of medical devices are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed healthcare in the United States and proposed legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of healthcare services and products and may result in lower prices for our products or the exclusion of our products from reimbursement programs.

We may never receive approval or clearance from the FDA and other governmental agencies to market our next generation ambulatory system, expanded indications for use of current and future generation ambulatory systems, the DexCom SHARE and SweetSpot software platforms or the GlucoClear system, our blood-based in-vivo automated glucose monitoring system, or any other continuous glucose monitoring system under development.

Our SEVEN PLUS and G4 PLATINUM systems are classified by the FDA as premarket approval ("PMA") medical devices. The PMA process requires us to prove the safety and efficacy of our ambulatory system to the FDA's satisfaction. This process can be expensive, prolonged and uncertain, requires detailed and comprehensive scientific and human clinical data, and may never result in the FDA granting a PMA. On June 14, 2012, we received CE Mark approval for our fourth generation continuous glucose monitoring system, initially marketed under the name "DexCom G4 system," enabling commercialization of the DexCom G4 system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark. On October 5, 2012, we obtained FDA approval for the DexCom G4 PLATINUM system. On February 14, 2013, we received CE Mark approval of a Pediatric Indication for the DexCom G4 system, enabling us to market and sell the system in the European Union, Australia, New Zealand and the countries in Asia and Latin America that recognize the CE Mark to persons two years old and older who have diabetes. In connection with our receipt of CE Mark approval for the Pediatric Indication, we changed the name of the DexCom G4 system to the DexCom G4 PLATINUM system. On February 3, 2014, the Pediatric Indication was approved in the United States by the FDA. During the third quarter of 2013, we submitted a PMA supplement to the FDA seeking an expanded indication for G4 PLATINUM for professional use. This expanded indication would allow health care professionals to purchase G4 PLATINUM devices for use with multiple patients. Animas has submitted an application to the FDA seeking approval of the VIBE system. Tandem intends to seek approval for the product that integrates our continuous glucose monitoring technology into Tandem's insulin delivery system. We cannot predict when, if ever, those products will be approved in the United States. We intend to seek either 510(k) clearances or PMA approvals for certain changes and modifications to SweetSpot's existing software platform, but cannot predict when, if ever, those changes and modifications will be approved.

In addition, we have completed the development of the second generation GlucoClear product with Edwards and they continue to develop regulatory pathways for the system. The 510(k) process would require us to establish (including through pre-clinical testing, bench testing, and/or potentially clinical data) that the GlucoClear system is substantially equivalent in terms of indication, technological characteristics, and performance to one or more legally marketed devices eligible to be cited as predicates in the 510(k) process. We cannot predict whether the FDA will classify the GlucoClear as a 510(k) product, nor can we predict when, if ever, the GlucoClear system will obtain FDA clearance or approval.

The FDA can refuse to grant the GlucoClear system 510(k) clearance or delay, limit or deny approval of a PMA application or supplement for many reasons, including:

- the system may not be deemed by the FDA to be substantially equivalent to appropriate predicate devices;
- the system may not satisfy the FDA's safety or efficacy requirements;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities used may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

Even if approved or cleared by the FDA, future generations of our ambulatory system, expanded indications for use of current and future generation ambulatory systems, SHARE, SweetSpot, the GlucoClear system, or any other continuous glucose monitoring system under development, may not be approved or cleared for the indications that are necessary or desirable for successful commercialization. We may not obtain the necessary regulatory approvals or clearances to market these continuous glucose monitoring systems in the United States or outside of the United States. Any delay in, or failure to receive or maintain, approval or clearance for the next generation of our ambulatory system or the GlucoClear system, could prevent us from generating revenue from these products or achieving profitability.

If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support additional PMA or 510(k) applications or supplements, we may be unable to commercialize our continuous glucose monitoring systems under development, including future generations of our ambulatory system, ambulatory systems with expanded indications for use, DexCom SHARE, the GlucoClear system or our systems developed in collaboration with Animas and Tandem, which could impair our financial position.

Animas has submitted an application to the FDA seeking approval of the VIBE system, and Tandem intends to seek approval for the product that integrates our continuous glucose monitoring technology into Tandem's insulin delivery system . In addition, together with Edwards we continue to develop regulatory pathways for the GlucoClear system. The GlucoClear

system may ultimately be classified by the FDA as either a 510(k) or PMA product, and we may consequently be requested to provide additional data in support of any GlucoClear application.

To support these and any future additional PMA or 510(k) applications or supplements, we, together with our partners, must successfully complete pre-clinical studies, bench-testing, and clinical trials that will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the studies and trials may be inadequate to support approval of a PMA or 510(k) application and the FDA may request additional clinical data in support of those applications, which may result in significant additional clinical expenses and may delay product approvals. While we have in the past obtained, and may in the future obtain, an Investigational Device Exemption ("IDE") prior to commencing clinical trials for our continuous glucose monitoring systems, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial to be sufficient to support approval of a PMA or 510(k) application or supplement, even if the trial's intended safety and efficacy endpoints are achieved. Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations, including 510(k) and PMA submissions, by hiring new investigators and increasing the frequency and scope of its inspections of manufacturing facilities. The FDA's Center for Devices and Radiological Health ("CDRH") is contemplating significant changes to the 510(k) process, which could complicate the product approval process for certain of our and our partner's products, although we cannot predict the effect of such procedural changes and cannot ascertain if such changes will have a substantive impact on the approval of our products or our partners' products. If we fail to adequately respond to any changes to the 510(k) submission process and associated matters, our business may be adversely impacted. Unexpected changes to the FDA or foreign regulatory approval processes could also delay or prevent the approval of our products submitted for review. The data contained in our submission, including data drawn from our clinical trials, may not be sufficient to support approval of our products or additional or expanded indications. Medical device company stock prices have declined significantly in certain circumstances where companies have failed to meet expectations in regards to the timing of regulatory approval. If the FDA's response causes product approval delays, or is not favorable for any of our products, our stock price could decline substantially.

The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA or 510(k) application or supplement, 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 we expect;
- patients do not comply with trial protocols;
- patient follow-up does not occur at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to our products;
- institutional review boards ("IRBs") and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the investigator agreements, clinical trial protocol, good clinical practices or other FDA or IRB requirements;
- the company 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 the company or study that 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 may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations, policies or administrative actions applicable to our trial protocols;
- 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.

The results of pre-clinical studies do not necessarily predict future clinical trial results, and prior clinical trial results might not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or

efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the approval of our products. If we are unable to demonstrate the safety and efficacy of our products in our clinical trials to the FDA's satisfaction, we will be unable to obtain regulatory approval to market our products in the United States. In addition, the data we collect from our current clinical trials, our pre-clinical studies and other clinical trials may not be sufficient to support FDA approval, even if our endpoints are met.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

We rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trial and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to ensure compliance by patients with clinical protocols or fail to comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our products. Our agreements with clinical investigators and clinical sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our products.

Healthcare reforms, changes in healthcare policies and changes to third-party reimbursements for our products may affect demand for our products.

Comprehensive healthcare legislation, signed into law in March 2010, imposes stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, with which we may need to comply, and enhanced penalties for non-compliance with the new healthcare regulations. The impact of this legislation remains unclear, and costs of compliance with this legislation, or any future amendments thereto, could result in certain risks and expenses that we may have to assume.

Other political and regulatory influences are also subjecting our industry to significant changes, and we cannot predict whether new regulations will emerge at the federal or state level, or abroad. The U.S. government may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect reimbursement for healthcare products such as the SEVEN PLUS and G4 PLATINUM systems. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current or future U.S. Presidential administration or Congress.

In addition, the comprehensive healthcare reform legislation included an annual excise tax on the sale of medical devices equal to 2.3% of the price of the device starting on January 1, 2013, which does not include, under Internal Revenue Service (“IRS”) guidance, our existing SEVEN PLUS and G4 PLATINUM systems as they are deemed to be retail medical devices under such legislation. As a result, as of December 31, 2013, we believed that our current products were exempt from the excise tax. Notwithstanding our belief, if the IRS determined that this tax is applicable to our current or future products, our future operating results could be harmed, which in turn could cause the price of our stock to decline, Additionally, because of the uncertainty surrounding these issues, the impact of this tax has not been reflected in our forward guidance.

We conduct business in a heavily regulated industry and if we fail to comply with these laws and government regulations, we could suffer penalties or be required to make significant changes to our operations.

The healthcare industry is subject to extensive foreign, federal, state and local laws and regulations, including those relating to:

- billing for services;
- financial relationships with physicians and other referral sources;
- inducements and courtesies given to physicians and other health care providers and patients;
- labeling products;

- quality of medical equipment and services;
- confidentiality, maintenance and security issues associated with medical records and individually identifiable health information;
- medical device reporting;
- anti-kickback:
- any scheme to defraud any healthcare benefit program;
- physician payment disclosure requirements;
- false claims; and
- professional licensure.

These laws and regulations are extremely complex and, in some cases, still evolving. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations. If our operations are found to be in violation of any of the federal, state or local laws and regulations which govern our activities, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines or curtailment of our operations. The risk of being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business.

The FDA, the Office of Inspector General for the Department of Health and Human Services, the Department of Justice, states' attorneys general and other governmental authorities actively enforce the laws and regulations discussed above. In the U.S., medical device manufacturers have been the target of numerous government prosecutions and investigations alleging violations of law, including claims asserting impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state healthcare business, and submission of false claims for government reimbursement. As part of our compliance program, we have reviewed our sales contracts and marketing materials and practices to assure compliance with these federal and state laws, and inform employees and marketing representatives of the anti-kickback statute and their obligations thereunder. However, we cannot rule out the possibility that the government or other third parties could interpret these laws differently and challenge our practices under one or more of these laws.

In addition, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the healthcare regulatory environment may change in a way that restricts or adversely impacts our operations.

We are not aware of any governmental healthcare investigations involving our executives or us. However, any future healthcare investigations of our executives, our managers or us could result in significant liabilities or penalties to us, as well as adverse publicity.

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing capabilities are insufficient to produce an adequate supply of product at appropriate quality levels, our growth could be limited and our business could be harmed.

We currently have limited resources, facilities and experience in commercially manufacturing sufficient quantities of product to meet expected demand. In the past, we have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support our commercialization efforts. From time to time, we have also experienced brief periods of backorder and, at times, have had to limit the efforts of our sales force to introduce our products to new customers. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts; however, there can be no assurances that supply will not be constrained in the future. In order to produce our products in the quantities we anticipate will be necessary to meet market demand, we will need to increase our manufacturing capacity by a significant factor over the current level. In addition, we will have to modify our manufacturing design, reliability and process if and when our next generation sensor technologies are approved and commercialized. There are technical challenges to

increasing manufacturing capacity, including equipment design and automation, materials procurement, manufacturing site expansion, problems with production yields and quality control and assurance. Developing commercial-scale manufacturing facilities will require the investment of substantial additional funds and the hiring and retention of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. Also, the scaling of manufacturing capacity is subject to numerous risks and uncertainties, and may lead to variability in product quality or reliability, increased construction timelines, as well as resources required to design, install and

maintain manufacturing equipment, among others, all of which can lead to unexpected delays in manufacturing output. In addition, any changes to our manufacturing processes may require FDA submission and approval and our facilities may have to undergo additional inspections by the FDA and corresponding state agencies. We may be unable to adequately maintain, develop and expand our manufacturing process and operations or obtain FDA and state agency approval of our facilities in a timely manner or at all. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand and our business will suffer.

Additionally, the production of our products must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products. If we are not able to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and our results of operations.

In the future, if our products experience a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Such defects or errors could also prompt us to amend certain warning labels or narrow the scope of the use of our products, either of which could hinder our success in the market.

Since our commercial launch in 2006, we have experienced periodic field failures related to our products, including reports of sensor errors, sensor failures, broken sensors, receiver malfunctions and transmitter failures. We do not believe these failures necessitated device explant, other procedures, or non-standard clinical treatment or intervention. To comply with the FDA's medical device reporting requirements, we have filed reports of all such broken or lodged sensors. Although we believe we have taken and are taking appropriate actions aimed at reducing or eliminating field failures, there can be no assurances that we will not experience additional failures going forward.

Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.

We rely on OnCore Manufacturing Services to manufacture and supply circuit boards for our receiver and transmitter; we rely on ON Semiconductor Corp. to manufacture and supply the application specific integrated circuit (“ASIC”) that is incorporated into the transmitter; we rely on DSM PTG, Inc. to manufacture certain polymers used to synthesize our polymeric biointerface membranes for our products; and we rely on The Tech Group to supply our injection molded components. Each of these suppliers is a single-source supplier. In some cases, our agreements with these and our other suppliers can be terminated by either party upon short notice. Our contract manufacturers also rely on single-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. If our single-source suppliers shift their manufacturing and assembly sites to other locations, these new sites may require additional FDA approval and inspection. Should any such FDA approval be delayed, or such inspection requires corrective action, our supply of critical components may be constrained or unavailable. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our products are technologically complex and it is difficult to develop alternative supply sources;
- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- our suppliers may make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products;
- we may have difficulty locating and qualifying alternative suppliers for our single-source supplies;
- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;
-

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner;

- our suppliers may make obsolete components that are critical to our products; and
- our suppliers may encounter financial hardships unrelated to our demand for components, including those related to changes in global economic conditions, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or replacement suppliers, particularly for our single-source components, in part because of the FDA approval process and because of the custom nature of various parts we design. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

Potential long-term complications from our products or other continuous glucose monitoring systems under development may not be revealed by our clinical experience to date.

Based on our experience, complications from use of our products may include sensor errors, sensor failures, broken sensors, lodged sensors or skin irritation under the adhesive dressing of the sensor. 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 long-term side-effects result from the use of our products or other glucose monitoring systems under development, we could be subject to liability and our systems would not be widely adopted. With respect to our SEVEN PLUS and G4 PLATINUM systems, our clinical trials have been limited to seven days of continuous use. Additionally, we have limited clinical experience with repeated use of our products in the same patient. We cannot assure you that long-term use would not result in unanticipated complications. Furthermore, the interim results from our current pre-clinical studies and clinical trials may not be indicative of the clinical results obtained when we examine the patients at later dates. It is possible that repeated use of our products may result in unanticipated adverse effects, potentially even after the device is removed.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval will be subject to continual review and periodic inspections by the FDA and other regulatory bodies, which may include inspection of our manufacturing processes, post-approval clinical data and promotional activities for such product. The FDA's medical device reporting (“MDR”) regulations require that we 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, it would likely cause or contribute to a death or serious injury. We and our suppliers are also required to comply with the FDA's Quality System Regulation (“QSR”) and other regulations, which cover the methods and documentation of the design, testing, production, control, selection and oversight of suppliers or contractors, quality assurance, labeling, packaging, storage, complaint handling, shipping and servicing of our products. The FDA enforces the QSR through unannounced inspections. We currently manufacture our devices at our headquarters facilities in San Diego, California. In these facilities we have more than 13,000 square feet of laboratory space and approximately 10,000 square feet of controlled environment rooms. In July 2012, the FDA completed an inspection of our facilities and did not identify any observations or require any other types of corrective action. In February 2010, the FDA inspected our facility and issued a Form 483 identifying several inspectional observations. Subsequent to the inspection, we also received a warning letter from the FDA requiring us to file MDRs in accordance with the MDR regulations for complaints involving sensor wire fractures underneath a patient's skin. In response to the warning letter and the Form 483 inspectional observations, we took corrective action to address the observations to achieve substantial compliance with the FDA regulatory requirements applicable to a commercial medical device manufacturer and received written notification dated November 1, 2010 from the FDA that we adequately addressed all issues cited in the warning letter. During a routine FDA post-approval facility inspection ending on November 7, 2013, the FDA issued a Form 483 with several observations regarding DexCom Medical Device Reporting (MDR) procedures and complaint reportability determinations. DexCom responded to the observations on November 26, 2013.

In March 2009, the Federal Communications Commission (“FCC”) established a bifurcated Medical Implant Communications System (“MICS”) band which requires device manufacturers whose products will operate in the main MICS band to either manufacture their devices using listen-before-transmit technology, or to transmit on a side band outside the main MICS band at lower power. Although the SEVEN PLUS does not comply with existing MICS band listen-before-transmit requirements, the FCC granted a waiver to allow continued operation of the SEVEN PLUS. Our G4 PLATINUM system does not operate within the MICS band and does not require a waiver.

Compliance with ongoing regulatory requirements can be complex, expensive and time-consuming. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or

failure to take adequate response to any observations, could result in, among other things, any of the following actions:

- warning letters or untitled letters that require corrective action;
- delays in approving or refusal to approve our continuous glucose monitoring systems;
- fines and civil penalties;
- unanticipated expenditures;
- FDA refusal to issue certificates to foreign governments needed to export our products for sale in other countries;

- suspension or withdrawal of approval by the FDA or other regulatory bodies;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer. In addition, we believe events that could be classified as reportable events pursuant to MDR regulations are generally underreported by physicians and users, and any underlying problems could be of a larger magnitude than suggested by the number or types of MDRs filed by us. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

Even if regulatory approval or clearance of a product is granted, the approval or clearance may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing or surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including software bugs, unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, MDR reporting, or other post-market requirements may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Abbott Diabetes Care, Inc. has filed a patent infringement lawsuit against us. If we are not successful in defending against its claims, our business could be materially impaired.

As further described in Part I, Item 3 “Legal Proceedings” of this annual report, Abbott has filed certain patent infringement lawsuits against us, claiming that our continuous glucose monitor infringes certain patents held by Abbott. We requested, and the Patent Office granted, reexamination of each of the patents cited in this lawsuit. On September 30, 2007, the court granted our motion to stay the case pending conclusion of the reexamination proceedings in the Patent Office relating to all seven patents asserted against us.

In connection with this litigation, two of the seven patents that are the subject of the litigation have reexamination requests on appeal at the Patent Office. Certificates of Reexamination were issued for five of the seven patents. In many of these reexamination proceedings, Abbott filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art we presented, seeking to amend certain claims to overcome the prior art we presented, canceling claims and/or seeking to add new claims. In addition, since 2008, Abbott has copied claims from certain of our applications, and stated that it may seek to provoke an interference with certain of our pending applications in the Patent Office. If interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also since 2008, Abbott has filed 38 reexamination requests seeking to invalidate 31 of our patents. Three of the 38 reexamination requests are in various stages at the Patent Office, and 34 have been issued a Certificate of Reexamination (one Reexamination Request was denied). We have filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented in the reexaminations, seeking to amend certain claims to overcome the prior art presented in the reexaminations, canceling claims and/or seeking to add new claims.

On December 31, 2013, Abbott filed a motion with the district court seeking to lift the stay of the two consolidated cases. We filed an opposition to the motion on January 17, 2014, and Abbott filed a reply brief in support of its motion on January 29, 2014. The court has taken the motion under submission, although it is not clear when it will issue a ruling. On December 31, 2013, Abbott filed a new complaint for patent infringement. In that complaint, Abbott alleges that our products, including our Seven Plus and G4 PLATINUM continuous glucose monitoring systems, infringe claims of United States Patent No. 8,175,673. We filed an answer to the complaint on January 23, 2014. On January 28, 2014, we also filed a motion to consolidate the newest case with the first two cases, and to stay the three cases pending conclusion of all pending reexamination proceedings in the Patent Office. It is possible that the Patent Office may determine that some or all of the claims of our patents subject to the reexamination are invalid. Additionally, Abbott has filed an Opposition to six of our European patents, one of which was not defended and one of which was revoked.

Although it is our position that Abbott's assertions of infringement have no merit, and that the potential interference, reexamination and opposition requests have no merit, the outcome of the litigation and interference, reexamination or opposition requests cannot be assessed currently with any certainty. We may not successfully defend ourselves against the

claims made by Abbott or prevail in the litigation. Subject to the stay of litigation, if Abbott were to seek and obtain a preliminary or permanent injunction, it could force us to stop making, using, selling or offering to sell our products. The technology at issue in our litigation with Abbott is currently used in our products, including SEVEN PLUS and G4 PLATINUM ambulatory products, and our GlucoClear system for in-hospital use. If we were forced to stop selling these products, our business and prospects would suffer. In addition, defending against this action could have a number of harmful effects on our business, including those discussed in the following risk factor, regardless of the final outcome of such litigation. For example, we have incurred, and expect to continue to incur, significant costs in defending the action.

Any adverse determination in litigation or interference proceedings to which we are or may become a party relating to patents could subject us to significant liabilities to third parties or require us to seek licenses from other third parties. Furthermore, if we are found to willfully infringe third-party patents, we could, in addition to other penalties, be required to pay treble damages and/or attorneys' fees for the prevailing party. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and would likely include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement and any redesign may not receive FDA approval in a timely manner if at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a significant adverse impact on our business.

We are subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief. We may also be subject to other claims or suits.

Other companies, including Abbott, could, in the future, assert infringement or misappropriation claims against us with respect to our current or future products. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our continuous glucose monitoring systems or the methods we employ in the use of our systems are covered by U.S. or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications relating to self-monitored glucose testing systems in the medical technology field. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe. There could also be existing patents of which we are unaware that one or more components of our system may inadvertently infringe. As the number of competitors in the market for continuous glucose monitoring systems grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases.

Any infringement or misappropriation claim, including the claim brought by Abbott, could cause us to incur significant costs, place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign our products to avoid infringement. Even if we are able to redesign our products to avoid an infringement claim, we may not receive FDA approval for such changes in a timely manner or at all. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling or offering to sell one or more of our products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

In addition, from time to time, we are subject to various claims and suits arising out of the ordinary course of business, including commercial or employment related matters. Although individually we do not expect these claims or suits to have a material adverse effect on the Company, in the aggregate they may divert significant time and resources from our staff.

Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.

Our success and our ability to compete are dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright and trademark law, and trade secrets and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a

competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the Patent Office, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the U.S. from a "first-to-invent" system to a "first to file" system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our financial condition and results of operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, invalid or unenforceable, and could award attorney fees.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology or other information that we regard as proprietary. Additionally, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States.

We operate in a highly competitive market and face competition from large, well-established medical device manufacturers with significant resources, and, as a result, we may not be able to compete effectively.

The market for glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. In selling the SEVEN PLUS and G4 systems, we compete directly with Roche Diabetes Care, a division of Roche Diagnostics, LifeScan, Inc., a division of Johnson & Johnson, the MediSense and TheraSense divisions of Abbott Laboratories, and Bayer Corporation, each of which manufactures and markets products for the single-point finger stick device market. Collectively, these companies currently account for substantially all of the worldwide sales of self-monitored glucose testing systems.

Several companies are developing or marketing short-term continuous glucose monitoring products that will compete directly with our products. To date, in addition to us, two other companies, Medtronic and Abbott, have received approval from the FDA to market, and actively market, continuous glucose monitors. Abbott has discontinued selling its Freestyle Navigator glucose monitoring system in the United States; however, Abbott filed a clinical study for home use of the Navigator II system in the United States and in October 2012, Abbott initiated a limited launch of the Navigator II system in Europe. In addition, we believe that others, including Roche and Becton, Dickinson and Company, are developing invasive and non-invasive continuous glucose monitoring systems. Most of the companies developing or marketing competing devices are publicly traded or divisions of publicly traded companies, and these companies possess several competitive advantages, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we may not be able to compete effectively against these companies or their products, which may adversely impact our business.

We have entered into a Collaboration Agreement with Edwards to develop jointly an in-hospital critical care automated blood glucose monitoring device, branded as the GlucoClear system, which may not result in a

commercially viable product in the United States or generate of any future revenues.

On November 10, 2008, we entered into a Collaboration Agreement with Edwards pursuant to which we agreed to develop jointly and to market the GlucoClear system, a blood-based in-vivo automated glucose monitoring system for use by

healthcare providers in the hospital critical care sector. Under the Collaboration Agreement, we may receive payments for various milestones related to regulatory approvals and commercial readiness of the product. In addition, we also expect to receive either a profit-sharing payment of 10% of the products' gross profits, or a royalty of 6% of commercial sales of the product. The Collaboration Agreement provides Edwards with an exclusive license to our intellectual property that relates to blood-based glucose sensors in the critical care sector of the hospital market. However, this collaboration may not result in the development of products that achieve regulatory approval in the United States or commercial success, which would result in various penalties to us under the Collaboration Agreement, up to and including delay or loss of some or all of our milestone payments and rights to any profit-sharing or royalties. In October 2009, we received CE Mark approval for the first generation of the GlucoClear system that we developed in collaboration with Edwards. Although Edwards commenced market evaluations during 2009, this product has never generated significant revenue and we do not expect this product to generate significant revenue during 2014. In January 2013, Edwards received CE Mark approval for the second generation system and Edwards initiated another limited launch in Europe of the second generation GlucoClear system in 2013. We cannot predict whether the FDA will classify the GlucoClear as a 510(k) or PMA product, nor can we predict when, if ever, the GlucoClear will obtain FDA clearance or approval.

We enter into collaborations 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 enter into collaborative arrangements to develop new products and to pursue new markets, such as our agreements with Animas and Tandem, to integrate our continuous glucose monitoring technology into their respective insulin delivery systems. We have also entered into an OUS Commercialization Agreement, as amended, with Animas pursuant to which Animas retains the right to develop and market outside the United States an ambulatory insulin pump that is combined with our continuous glucose monitoring technology which has been branded the Vibe. In May 2011, we, together with Animas, received CE Mark certification for the Vibe, allowing it to be marketed in the countries that recognize CE Mark approval. Animas has also recently submitted an application to the FDA seeking approval of the VIBE system.

We also previously entered into collaborative agreements with Insulet and Roche neither of which resulted in the successful development of a commercially viable product or result in significant additional future revenues.

Many of the companies that we collaborate with are also competitors or potential competitors who may decide to terminate our collaborative arrangement. In the event of such a termination, we may be required to devote additional resources to product development and commercialization, we may need to cancel some development programs and we may face increased competition. Additionally, similar to the agreements with Insulet and Roche, collaborations may not result in the development of products that achieve commercial success and could be terminated prior to developing any products. Accordingly, we cannot assure you that any of our collaborations will result in the successful development of a commercially viable product or result in significant additional future revenues. In addition, our development timelines are highly dependent on our ability to achieve clinical endpoints and regulatory requirements and to overcome technology challenges, and may be delayed due to scheduling issues with patients and investigators, requests from institutional review boards, product performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts are successful, the FDA may not approve the combined products or may require additional product testing and clinical trials before approving the combined products, which would result in product launch delays and additional expense. If approved by the FDA, the combined products may not achieve acceptance in the marketplace by physicians and people with diabetes.

To date, no continuous glucose monitoring system, including our G4 PLATINUM system, has received FDA clearance as a replacement for single-point finger stick devices, and our G4 PLATINUM and future generations may never be approved for that indication.

The G4 PLATINUM system does not eliminate the need for single-point finger stick devices and our future products may not be approved for that indication. No precedent for FDA approval of continuous glucose monitoring systems as a replacement for single-point finger stick devices has been established. Accordingly, there is no established study design or agreement regarding performance requirements or measurements in clinical trials for continuous glucose

monitoring systems. We have not yet filed for FDA approval for therapeutic or replacement claim labeling and we cannot assure you that we will not experience delays if we do file. If any of our competitors were to obtain replacement claim labeling for a continuous glucose monitoring system, our products may not be able to compete effectively against that system and our business would suffer.

Technological breakthroughs in the glucose monitoring market could render our products obsolete.

The glucose monitoring market is subject to rapid technological change and product innovation. Our products are based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies for the monitoring of glucose levels. FDA approval of a commercially viable continuous glucose monitor or sensor produced by one of our competitors could significantly reduce market acceptance of our systems. Several of our competitors are in various stages of developing continuous glucose monitors or sensors, including non-invasive and invasive devices, and the FDA has approved several of these competing products. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve treatment of diabetes. Therefore, our products may be rendered obsolete by technological breakthroughs in diabetes monitoring, treatment, prevention or cure.

We face the risk of product liability claims and may not be able to maintain or obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. Claims may be made by customers, healthcare providers or others selling our products.

Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. Further, if additional products are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

We may be subject to claims against us even if the apparent injury is due to the actions of others or misuse of the device. Our customers, either on their own or following the advice of their physicians, may use our products in a manner not described in the products' labeling and that differs from the manner in which it was used in clinical studies and approved by the FDA. For example, our SEVEN PLUS and G4 PLATINUM systems are designed to be used by an individual continuously for up to seven days, but the individual might be able to circumvent the safeguards designed into the SEVEN PLUS and G4 PLATINUM systems and use the products for longer than seven days.

Off-label use of products by customers is common, and any such off-label use of our products could subject us to additional liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

We may be subject to fines, penalties and injunctions if we are determined to be promoting the use of our products for unapproved off-label uses.

Although we believe our promotional materials and training methods are conducted in compliance with FDA and other regulations, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, the FDA could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of 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 promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures

of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

The majority of our operations are conducted at two facilities in San Diego, California. Any disruption at these facilities could increase our expenses.

We take precautions to safeguard our facilities, which include manufacturing protocols, insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a fire, flood, earthquake, an act of terrorism, cyber attack or other disruptive event could cause substantial delays in our operations, damage or destroy our manufacturing equipment, inventory, or records and cause us to incur additional expenses. Earthquakes are of particular significance since our primary manufacturing facilities in California are located in an earthquake-prone area. In the event our existing manufacturing facilities or equipment are affected by man-made or natural disasters, we may be unable to manufacture products for sale or meet customer demands or sales projections. If our manufacturing operations were curtailed or ceased, it would seriously harm our business. The insurance we maintain against fires, floods, earthquakes and other natural disasters and similar events may not be adequate to cover our losses in any particular case.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may significantly suffer.

We may be liable for contamination or other harm caused by materials that we handle, and changes in environmental regulations could cause us to incur additional expense.

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

We conduct limited commercial and marketing efforts in Europe, Australia, New Zealand, the Middle East, Latin America and Asia with respect to our G4 PLATINUM system and may seek to market our products in other regions in the future. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one

foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States on a timely basis, or at all.

Our success will depend on our ability to attract and retain our personnel.

We are highly dependent on our senior management, especially Terrance H. Gregg, our Chief Executive Officer, Kevin Sayer, our President and Chief Operating Officer, Steven R. Pacelli, our Executive Vice President of Strategy and Corporate

Development, Jorge Valdes, our Chief Technical Officer, and Andrew K. Balo, our Senior Vice President of Clinical and Regulatory Affairs. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including sales persons, scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as sales persons, scientists, clinicians and engineers, is intense and we may not be able to retain our personnel. The loss of the services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the commercialization of our current products and the development and introduction of additional products. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement. Each of our officers may terminate their employment at any time without notice and without cause or good reason. Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees.

We expect to continue to expand our operations and grow our research and development, manufacturing, sales and marketing, product development and administrative operations. This expansion is expected to place a significant strain on our management and will require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

New regulations related to "conflict minerals" may cause us to incur additional expenses and could limit the supply and increase the cost of certain metals used in manufacturing our products.

On August 22, 2012, the SEC adopted a new rule requiring disclosures by public companies of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured. The new rule, which is effective for 2013 and requires a disclosure report to be filed by May 31, 2014, will require companies to perform due diligence, disclose and report whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The new rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of our products, including tantalum, tin, gold and tungsten. The number of suppliers who provide conflict-free minerals may be limited. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities. Within our supply chain, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement, which may harm our reputation. We are currently investigating the use of conflict materials within our supply chain.

Compliance with regulations relating to public company corporate governance matters and reporting is time consuming and expensive.

Many laws and regulations, notably those adopted in connection with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and the NASDAQ Stock Market, impose obligations on public companies, such as ours, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Compliance with these laws and regulations, including enhanced new disclosures has required and will continue to require substantial management time and oversight and requires us to incur significant additional accounting and legal costs. The effects of new laws and regulations remain unclear and will likely require substantial management time and oversight and require us to incur significant additional accounting and legal costs. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards (“IFRS”), may adversely impact our reported financial results and business, and may further require us to incur greater accounting fees.

If we are unable to successfully maintain effective internal control over financial reporting, investors may lose confidence in our reported financial information and our stock price and our business may be adversely impacted.

As a public company, we are required to maintain internal control over financial reporting and our management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Additionally, we are required to disclose in our Annual Reports on Form 10-K our management's assessment of the effectiveness of our internal control over financial reporting and a registered public accounting firm's attestation report on this assessment. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the SEC. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our

internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets or cause our stock to be delisted from The NASDAQ Global Select Market or any other securities exchange on which it is then listed.

Valuation of share-based payments, which we are required to perform for purposes of recording compensation expense under authoritative guidance for share-based payment, involves assumptions that are subject to change and difficult to predict.

We record compensation expense in the consolidated statement of operations for share-based payments, such as employee stock options, restricted stock units and employee stock purchase plan shares, using the fair value method. The requirements of the authoritative guidance for share-based payment have and will continue to have a material effect on our future financial results reported under U.S. generally accepted accounting principles ("U.S. GAAP") and make it difficult for us to accurately predict the impact on our future financial results.

For instance, estimating the fair value of share-based payments is highly dependent on assumptions regarding the future exercise behavior of our employees and changes in our stock price. The actual values realized upon the exercise, expiration, early termination or forfeiture of share-based payments might be significantly different than our estimates of the fair values of those awards as determined at the date of grant. If there are errors in our input assumptions for our valuations models, we may inaccurately calculate actual or estimated compensation expense for share-based payments.

The authoritative guidance for share-based payment could also adversely impact our ability to provide accurate guidance on our future financial results as assumptions that are used to estimate the fair value of share-based payments are based on estimates and judgments that may differ from period to period. We may also be unable to accurately predict the amount and timing of the recognition of tax benefits associated with share-based payments as they are highly dependent on the exercise behavior of our employees and the price of our stock relative to the exercise price of each outstanding stock option.

For those reasons, among others, the authoritative guidance for share-based payment may create variability and uncertainty in the share-based compensation expense we will record in future periods, which could adversely impact our stock price and increase our expected stock price volatility as compared to prior periods.

Changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected revenue and/or expense fluctuations and affect our reported results of operations.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. The method in which we market and sell our products may have an impact on the manner in which we recognize revenue. In addition, changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards, may adversely impact our reported financial results and business, and may further require us to incur greater accounting fees.

Risks Related to Our Common Stock

Our stock price is highly volatile and investing in our stock involves a high degree of risk, which could result in substantial losses for investors.

Historically, the market price of our common stock, like the securities of many other medical products companies, fluctuates and could continue to be volatile in the future. Since January 1, 2013, the closing price of our common stock on the NASDAQ Global Select Market has been as high as $44.53 per share and as low as $13.85 per share. The market price of our common stock is influenced by many factors that are beyond our control, including the following:

•

securities analyst coverage or lack of coverage of our common stock or changes in their estimates of our financial performance;

- variations in quarterly operating results;
- future sales of our common stock by our stockholders;

- investor perception of us and our industry;
- announcements by us or our competitors of significant agreements, acquisitions or capital commitments;
- changes in market valuation or earnings of our competitors;
- general economic conditions;
- regulatory actions;
- legislation and political conditions; and
- terrorist acts.

Please also refer to the factors described above in this “Risk Factors” section. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated and disproportionate to the operating performance of companies in our industry. These broad market and industry factors may materially reduce the market price of our common stock, regardless of our operating performance.

Further, securities class action litigation has often been brought against public companies that experience periods of volatility in the market prices of their securities. Securities class action litigation could result in substantial costs and a diversion of our management's attention and resources.

If our financial performance fails to meet the expectations of investors and public market analysts, the market price of our common stock could decline.

Our revenues and operating results may fluctuate significantly from quarter to quarter. We believe that period-to-period comparisons of our operating results may not be meaningful and should not be relied on as an indication of our future performance. If quarterly revenues or operating results fall below the expectations of investors or public market analysts, the trading price of our common stock could decline substantially. Factors that might cause quarterly fluctuations in our operating results include:

- our inability to manufacture an adequate supply of product at appropriate quality levels and acceptable costs;
- possible delays in our research and development programs or in the completion of any clinical trials;
- a lack of acceptance of our products in the marketplace by physicians and people with diabetes;
- the inability of customers to receive reimbursements from third-party payors;
- failures to comply with regulatory requirements, which could lead to withdrawal of products from the market;
- our failure to continue the commercialization of any of our continuous glucose monitoring systems;
- competition;
- inadequate financial and other resources; and
- global economic conditions.

Failure to comply with covenants in our loan agreement with Silicon Valley Bank and Oxford Finance LLC could result in our inability to borrow additional funds and adversely impact our business.

We have entered into a loan and security agreement with the Silicon Valley Bank and Oxford Finance LLC to fund our business operations. This loan and security agreement imposes numerous financial and other restrictive covenants on our operations, including covenants relating to our general profitability and our liquidity. As of December 31, 2013, we were in compliance with the covenants imposed by the loan and security agreement. If we violate these or any other covenants, any outstanding amounts under these agreements could become due and payable prior to their stated maturity dates, each lender could proceed against any collateral in our operating accounts and our ability to borrow funds in the future may be restricted or eliminated. These restrictions may also limit our ability to borrow additional funds and pursue other business opportunities or strategies that we would otherwise consider to be in our best interests.

The issuance of shares by us in the future or sales of shares by our stockholders may cause the market price of our common stock to drop significantly, even if our business is doing well.

This issuance of shares by us in the future or sales of shares by our stockholders may cause the market price of our common stock to decline, perhaps significantly, even if our business is doing well. The market price of our common stock could also decline if there is a perception that sales of our shares are likely to occur in the future. This might also make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Also, we may issue securities in connection with future financings and acquisitions, and those shares could dilute the holdings of other stockholders. For example, pursuant to the terms of our acquisition of SweetSpot, we may be obligated to issue up to 267,880

42

shares of our common stock to the former security holders of SweetSpot following the achievement of certain performance milestones. We have not issued any shares of common stock for milestone payments in 2013.

We do not intend to pay dividends for the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future and the terms of our loan and security agreement restrict our ability to declare or pay any dividends. As a result, stockholders may only receive a return on their investment in our common stock if the market price of our common stock increases.

Anti-takeover effects of our rights agreement, charter documents and Delaware law could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

We have a stockholder rights agreement in place, under which our stockholders have special rights, in the form of additional voting and beneficial ownership, in the event that a person or group not approved by our Board of Directors were to acquire, or to announce the intention to acquire 15% or more of our outstanding shares. This plan is designed to have the effect of discouraging, delaying or rendering more difficult an acquisition of us that has not been approved by our Board of Directors.

In addition, there are provisions in our certificate of incorporation and bylaws, as well as provisions in the Delaware General Corporation Law, that may discourage, delay or prevent a change of control that might otherwise be beneficial to stockholders. For example:

- our Board of Directors may, without stockholder approval, issue shares of preferred stock with special voting or economic rights;
- our stockholders do not have cumulative voting rights and, therefore, each of our directors can only be elected by holders of a majority of our outstanding common stock;
- a special meeting of stockholders may only be called by a majority of our Board of Directors, the Chairman of our Board of Directors, or our Chief Executive Officer;
- our stockholders may not take action by written consent;
- our Board of Directors is divided into three classes, only one of which is elected each year; and
- we require advance notice for nominations for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We maintain our headquarters in San Diego, California in two leased facilities of approximately 128,815 square feet, which includes our laboratory, research and development, manufacturing and general administration functions. The lease for these facilities expires in 2016. We have the right to extend the term of this lease for one period of five years. In July 2012, the FDA completed an inspection of our facilities and did not identify any observations or require any other types of corrective action. During a routine FDA post-approval facility inspection ending on November 7, 2013, the FDA made several observations regarding Dexcom Medical Device Reporting (MDR) procedures and complaint reportability determinations. Dexcom responded to the observations on November 26, 2013. In September 2008, our subsidiary in Sweden entered into a three-year lease for a small shared office space, which was renewed for a three-year term and has a quarterly adjustment clause for rent to increase or decrease in proportion to changes in consumer prices. In July 2012, our subsidiary SweetSpot entered into a five-year lease for a small office space in a multi-tenant commercial building in Portland, Oregon.

ITEM 3. LEGAL PROCEEDINGS

On August 11, 2005, Abbott Diabetes Care, Inc. (“Abbott”) filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware, seeking a declaratory judgment that our continuous glucose monitor

infringes certain patents held by Abbott. In August 2005, we moved to dismiss these claims and filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office (the “Patent Office”) and by March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against us in the litigation. On June 27, 2006, Abbott

amended its complaint to include three additional patents owned or licensed by Abbott which are allegedly infringed by our continuous glucose monitor. On August 18, 2006, the court granted our motion to stay the lawsuit pending reexamination by the Patent Office of each of the four patents originally asserted by Abbott, and the court dismissed one significant infringement claim. In approving the stay, the court also granted our motion to strike, or disallow, Abbott's amended complaint in which Abbott had sought to add three additional patents to the litigation. Subsequent to the court's August 18, 2006 order striking Abbott's amended complaint, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of the three additional patents it had sought to include in the litigation discussed above. On September 7, 2006, we filed a motion to strike Abbott's new complaint on the grounds that it is redundant of claims Abbott already improperly attempted to inject into the original case, and because the original case is now stayed, Abbott must wait until the court lifts that stay before it can properly ask the court to consider these claims. Alternatively, we asked the court to consolidate the new case with the original case and thereby stay the entirety of the case pending conclusion of the reexamination proceedings in the Patent Office. In February 2007, the Patent Office ordered reexamination of each of the three patents cited in this new lawsuit. On September 30, 2007, the court granted our motion to consolidate the cases and stay the entirety of the case pending conclusion of the reexamination proceedings in the Patent Office relating to all seven patents asserted against us.
On December 31, 2013, Abbott filed a motion with the district court seeking to lift the stay of the two consolidated cases. We filed an opposition to the motion on January 17, 2014, and Abbott filed a reply brief in support of its motion on January 29, 2014. The court has taken the motion under submission, although it is not clear when it will issue a ruling. On December 31, 2013, Abbott filed a new complaint for patent infringement. In that complaint, Abbott alleges that our products, including our SEVEN PLUS and G4 PLATINUM continuous glucose monitoring systems, infringe claims of United States Patent No. 8,175,673. We filed an answer to the complaint on January 23, 2014. On January 28, 2014, we also filed a motion to consolidate the newest case (case no. 1-13-cv-02105-GMS) with the first two cases (case nos.1:05-cv-00509-GMS and 1:06-cv-00514-GMS), and to stay the three cases pending conclusion of all pending reexamination proceedings in the Patent Office.
In connection with this litigation, two of the seven patents that are the subject of the litigation have reexamination requests on appeal at the Patent Office. Certificates of Reexamination were issued for five of the seven patents. In many of these reexamination proceedings, Abbott filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art we presented, seeking to amend certain claims to overcome the prior art we presented, canceling claims and/or seeking to add new claims.
In addition, since 2008, Abbott has copied claims from certain of our applications, and stated that it may seek to provoke an interference with certain of our pending applications in the Patent Office. If interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also since 2008, Abbott has filed 38 reexamination requests seeking to invalidate 31 of our patents. Three of the 38 reexamination requests are in various stages at the Patent Office, and 34 have been issued a Certificate of Reexamination (one Reexamination Request was denied). We have filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented in the reexaminations, seeking to amend certain claims to overcome the prior art presented in the reexaminations, canceling claims and/or seeking to add new claims. It is possible that the Patent Office may determine that some or all of the claims of our patents subject to the reexamination are invalid. Additionally, Abbott has filed an Opposition to six of our European patents, one of which was not defended and one of which was revoked.
Although it is our position that Abbott's assertions of infringement have no merit, and that the potential interference and reexamination requests by Abbott have no merit, neither the outcome of the litigation nor the amount and range of potential fees associated with the litigation, potential interference or reexamination requests can be assessed, and as of December 31, 2013, no amounts have been accrued.
We may be subject to additional various claims, complaints and legal actions that arise from time to time in the normal course of business. Other than as described above, we do not believe we are party to any currently pending legal proceedings, the outcome of which could have a material adverse effect on our operations or financial position. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, consolidated financial position, results of operations or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES
Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

DexCom's common stock is traded on the NASDAQ Global Select Market under the symbol "DXCM." As of February 17, 2014, there were approximately 60 stockholders of record, excluding stockholders whose shares were held in nominee or street name by brokers. We have not paid any cash dividends, do not currently have plans to do so in the foreseeable future and the terms of our loan and security agreement restrict our ability to declare or pay any dividends.

The following table sets forth the high and low intraday sales price per share for DexCom's common stock for the periods indicated:

	High	Low
Year Ended December 31, 2013		
First Quarter	$17.16	$13.69
Second Quarter	$22.97	$15.04
Third Quarter	$29.24	$21.76
Fourth Quarter	$35.97	$26.68
	High	Low
Year Ended December 31, 2012		
First Quarter	$11.90	$8.64
Second Quarter	$13.20	$9.36
Third Quarter	$15.08	$10.65
Fourth Quarter	$15.48	$12.03

Neither we nor any affiliated purchaser repurchased any of our equity securities in fiscal year 2013.

The information required by this Item concerning shares reserved for issuance under our equity compensation plans is incorporated by reference to information set forth in the Proxy Statement.

In connection with our acquisition of SweetSpot, we issued 384,483 shares of our common stock to the security holders of SweetSpot. Following the issuance, the resale of these shares was registered on a Registration Statement on Form S-3 filed by us with the SEC on March 28, 2012. On June 27, 2012, we issued an additional 89,296 shares of our common stock to the former security holders of SweetSpot following the achievement of certain milestone objectives. Following the issuance, the resale of these shares of common stock was registered on a Registration Statement on Form S-3 filed by us with the SEC on June 29, 2012.

ITEM 6. SELECTED FINANCIAL DATA

The consolidated statements of operations data for the years ended December 31, 2013, 2012, and 2011 and the consolidated balance sheet data as of December 31, 2013 and 2012 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report. The statements of operations data for the years ended December 31, 2010 and 2009 and the consolidated balance sheet data as of December 31, 2011, 2010 and 2009 have been derived from our audited financial statements not included in this Annual Report. The following selected financial data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and consolidated financial statements and related notes to those statements included elsewhere in this Annual Report.

	Years Ended December 31,				
	2013	2012	2011	2010	2009
	(in millions, except per share data)				
Consolidated Statements of Operations Data:					
Product revenue	$157.1	$93.0	$65.9	$40.2	$18.0
Development grant and other revenue	2.9	6.9	10.4	8.4	11.7
Total revenue	160.0	99.9	76.3	48.6	29.7
Product cost of sales	58.1	48.3	36.6	26.1	18.2
Development and other cost of sales	1.8	5.0	3.8	4.1	7.8
Total cost of sales	59.9	53.3	40.4	30.2	26.0
Gross profit (deficit)	100.1	46.6	35.9	18.4	3.7
Operating expenses:					
Research and development	44.8	38.3	29.6	22.0	13.3
Selling, general and administrative	84.2	64.0	51.1	41.7	36.2
Total operating expenses	129.0	102.3	80.7	63.7	49.5
Operating loss	(28.9)	(55.7)	(44.8)	(45.3)	(45.8)
Interest and other income	—	0.1	0.1	0.1	0.3
Interest expense	(0.9)	(0.2)	—	(1.5)	(8.0)
Loss on debt extinguishment upon conversion of convertible debt	—	—	—	(8.5)	—
Loss before income taxes	(29.8)	(55.8)	(44.7)	(55.2)	(53.5)
Income tax expense (benefit)	—	(1.3)	—	—	—
Net loss	$(29.8)	$(54.5)	$(44.7)	$(55.2)	$(53.5)
Basic and diluted net loss per share attributable to common stockholders[1]	$(0.42)	$(0.79)	$(0.68)	$(0.97)	$(1.21)
Shares used to compute basic and diluted net loss per share attributable to common stockholders[1]	71.1	68.7	65.6	56.9	44.3

	As of December 31,				
	2013	2012	2011	2010	2009
	(in millions)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents, and marketable securities	$54.6	$48.7	$82.0	$47.1	$28.0
Working capital	61.0	58.1	89.8	50.2	18.1
Total assets	122.5	106.0	120.5	77.2	46.9
Long term obligations	6.3	9.5	1.3	1.0	46.6
Total stockholders' equity (deficit)	84.1	77.0	104.5	61.0	(18.4)

(1) See Note 2 of the notes to our consolidated financial statements for a description of the method used to compute basic and diluted net loss per share attributable to common stockholders.

46

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document, including the following Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that are based upon current expectations. These forward-looking statements fall within the meaning of the federal securities laws that relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "expect," "plan," "anticipate," "believe," "estimate," "intend," "potential" or "continue" or the negative of these terms or other comparab terminology. Forward-looking statements involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in our forward-looking statements as a result of many factors, including product performance, a lack of acceptance in the marketplace by physicians and customers, insufficient customer demand, the inability to manufacture products in commercial quantities at an acceptable cost, possible delays in our research and development programs, the inability of customers to receive reimbursements from third-party payors, the impact of competitive products and pricing, our ability to obtain regulatory approvals and introduce new products, other uncertainties related to regulatory processes, our ability to respond to changing laws and regulations affecting our industry and changing enforcement practices related thereto, inadequate financial and other resources, global economic conditions, and the other risks set forth below under "Risk Factors" and elsewhere in this report. We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results.

Overview

We are a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems for ambulatory use by people with diabetes and for use by healthcare providers in the hospital for the treatment of people with and without diabetes. The majority of our product revenue comes from sales of our G4 PLATINUM ambulatory continuous glucose monitoring system, which we began commercializing in the fourth quarter of 2012. We also have received CE Mark approval for the GlucoClear in-hospital system, and in partnership with Edwards, we initiated a very limited launch of the first generation GlucoClear system in Europe in 2009 and Edwards initiated another limited launch in Europe of the second generation GlucoClear system in 2013.

From inception to 2006, we devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. Since 2006, we have devoted considerable resources to the commercialization of our ambulatory continuous glucose monitoring systems, including the SEVEN PLUS and G4 PLATINUM, as well as the continued research and clinical development of our technology platform.

As of December 31, 2013, we generated $431.1 million of product and development grant and other (non-product) revenue, and we have incurred net losses in each year since our inception in May 1999. As of December 31, 2013, we had an accumulated deficit of $475.4 million. We expect our losses to continue as we proceed with our commercialization and research and development activities. We have financed our operations primarily through offerings of equity securities and debt. In November 2012, we entered into a loan and security agreement that provides for up to $35.0 million in credit facilities and term loans, with $28.0 million currently available. In July 2013, we were awarded a $4.0 million grant from the Helmsley Trust to accelerate the development of the sixth generation of our advanced glucose-sensing technologies.

Financial Operations

Revenue

We expect that revenues we generate from the sales of our products will fluctuate from quarter to quarter. Between 2008 and 2012, we entered into joint development and collaboration agreements with Animas and Tandem, as well as other third parties under agreements that have since expired, under which we recognized development grant and other revenue received pursuant to that agreement ratably over the term of the development period. We recognize development milestones associated with each agreement as revenue upon achievement of each milestone if the milestone is considered substantive.

Cost of Sales

Product cost of sales includes direct labor and materials costs related to each product sold or produced, including assembly, test labor and scrap, as well as factory overhead supporting our manufacturing operations. Factory overhead includes facilities, material procurement and control, manufacturing engineering, quality assurance, supervision and management. These costs are primarily salary, fringe benefits, share-based compensation, facility expense, supplies and purchased services. A large portion of our costs are currently fixed due to our moderate level of production volumes compared to our potential capacity. All

of our manufacturing costs are included in product cost of sales. Development and other cost of sales consists primarily of salaries, fringe, facilities, and supplies directly attributable to our development contracts.

Research and Development

Our research and development expenses primarily consist of engineering and research expenses related to our continuous glucose monitoring technology, clinical trials, regulatory expenses, quality assurance programs, materials and products for clinical trials. Research and development expenses are primarily related to employee compensation, including salary, fringe benefits, share-based compensation, and temporary employee expenses. We also incur significant expenses to operate our clinical trials including clinical site reimbursement, clinical trial product and associated travel expenses. Our research and development expenses also include fees for design services, contractors and development materials.

Selling, General and Administrative

Our selling, general and administrative expenses primarily consist of salary, fringe benefits and share-based compensation for our executive, financial, sales, marketing and administrative functions. Other significant expenses include trade show expenses, sales samples, insurance, professional fees for our outside legal counsel and independent auditors, litigation expenses, patent application expenses and consulting expenses.

Results of Operations

Fiscal year ended December 31, 2013 Compared to December 31, 2012

Revenue, Cost of Sales and Gross Profit

Product revenue increased $64.1 million to $157.1 million for the twelve months ended December 31, 2013, compared to $93.0 million for the twelve months ended December 31, 2012 based primarily on increased sales volume, due, in part, to the commercial launch in October 2012 of the G4 PLATINUM system. Product cost of sales increased $9.8 million to $58.1 million for the twelve months ended December 31, 2013, compared to $48.3 million for the twelve months ended December 31, 2012 primarily due to increased sales volume. The product gross profit of $99.0 million for the twelve months ended December 31, 2013 increased $54.3 million compared to $44.7 million for the same period in 2012, primarily due to increased revenue, and the greater sales mix of our higher margin G4 PLATINUM system compared to our SEVEN PLUS system.

Development grant and other revenues decreased $4.0 million to $2.9 million for the twelve months ended December 31, 2013, compared to $6.9 million for the twelve months ended December 31, 2012. Development and other cost of sales decreased $3.2 million to $1.8 million for the twelve months ended December 31, 2013, compared to $5.0 million for the twelve months ended December 31, 2012. The decrease in revenues associated with development was primarily due to the termination of the Roche Agreement in February 2013, and the completion of development activities under the Collaboration Agreement with Edwards in the fourth quarter of 2012. The decrease in costs associated with development was primarily due to fewer development obligations during the period with respect to our collaboration and development arrangements.

Research and Development. Research and development expense increased $6.5 million to $44.8 million for the twelve months ended December 31, 2013, compared to $38.3 million for the twelve months ended December 31, 2012. The increase in research and development expense was primarily due to increased development efforts for our ambulatory products. Significant elements of increased research and development expense included $3.0 million in additional salaries, bonus, and payroll related costs and $2.5 million in additional share-based compensation.

Selling, General and Administrative. Selling, general and administrative expense increased $20.2 million to $84.2 million for the twelve months ended December 31, 2013, compared to $64.0 million for the twelve months ended December 31, 2012. The increase was primarily due to higher selling and information technology costs to support revenue growth and the continued commercialization of our products. Significant elements of increased selling, general, and administrative expenses included $7.3 million in additional salaries, bonus, and payroll related costs, $3.4 million in additional share-based compensation costs, $3.2 million in additional sales commissions, and $1.5 million in additional bad debt expense.

Interest Expense. Interest expense increased to $0.9 million for the twelve months ended December 31, 2013, compared to $0.2 million for the twelve months ended December 31, 2012. The increase in interest expense was primarily due to increased debt obligations under the loan and security agreement we entered into in November 2012.

Income Tax Benefit. Income tax benefit was $12,000 for the twelve months ended December 31, 2013, compared to $1.3 million for the twelve months ended December 31, 2012. The decrease in income tax benefit was due to the acquisition of SweetSpot during the first quarter of 2012 and the release of the valuation allowance against some of our deferred tax assets.

Fiscal year ended December 31, 2012 Compared to December 31, 2011

Revenue, Cost of Sales and Gross Profit

Product revenues increased $27.1 million to $93.0 million for the twelve months ended December 31, 2012 compared to $65.9 million for the twelve months ended December 31, 2011 based primarily on increased sales volume of our durable systems and disposable sensors, due in part to the launch of the G4 PLATINUM system in the fourth quarter of 2012. Product cost of sales increased $11.7 million to $48.3 million for the twelve months ended December 31, 2012 compared to $36.6 million for the twelve months ended December 31, 2011. The product gross profit of $44.7 million for the twelve months ended December 31, 2012 increased $15.4 million compared to $29.3 million for the same period in 2011, primarily due to increased revenue.

Development grant and other revenues decreased $3.5 million to $6.9 million for the twelve months ended December 31, 2012 compared to $10.4 million for the twelve months ended December 31, 2011. Development and other cost of sales increased $1.2 million to $5.0 million for the twelve months ended December 31, 2012 compared to $3.8 million for the twelve months ended December 31, 2011. The decrease in development grant and other revenues during the twelve months ended December 31, 2012 was due to the $4.0 million milestone payment received from Animas for CE Mark approval in June 2011 and by extended revenue recognition timelines related to longer than expected development and regulatory review timelines under our collaboration arrangements with Edwards. The increase in costs associated with development was primarily due to additional development obligations during the year with respect to our collaboration arrangements.

Research and Development. Research and development expense increased $8.7 million to $38.3 million for the twelve months ended December 31, 2012, compared to $29.6 million for the twelve months ended December 31, 2011. The increase in research and development expense was primarily due to increased development efforts for our future generation ambulatory products and by decreased activity with respect to our development and collaboration agreements. Major elements of increased research and development costs include $3.2 million in additional salaries, bonus, and payroll related costs, $1.8 million in additional share-based compensation and $1.6 million in additional consulting costs.

Selling, General and Administrative. Selling, general and administrative expense increased $12.9 million to $64.0 million for the twelve months ended December 31, 2012, compared to $51.1 million for the twelve months ended December 31, 2011. The increase was primarily due to higher selling, marketing, and information technology costs to support revenue growth and the continued commercialization of our products. Major elements of increased selling, general, and administrative expenses include $3.7 million in higher salaries, bonus, and payroll related costs, $2.7 million in higher share-based compensation, and $1.8 million in higher sales commissions.

Interest and Other Income. Interest and other income was $0.1 million for each of the twelve months ended December 31, 2012 and 2011.

Interest Expense. Interest expense increased to $0.2 million for the twelve months ended December 31, 2012, compared to $11,000 for the twelve months ended December 31, 2011. The increase in interest expense was primarily due to the loan and security agreement we entered into in November 2012.

Income Tax Benefit. Income tax benefit was $1.3 million for the twelve months ended December 31, 2012, compared to none for the twelve months ended December 31, 2011. The increase in income tax benefit was primarily due to the acquisition of SweetSpot and the release of the valuation allowance against some of our deferred tax assets.

Liquidity and Capital Resources

We are in the early commercialization stage and have incurred losses since our inception in May 1999. As of December 31, 2013, we had an accumulated deficit of $475.4 million and had working capital of $61.0 million. Our cash, cash equivalents and short-term marketable securities totaled $54.6 million, excluding $1.0 million in restricted cash. To date, we have funded our operations primarily through offerings of equity securities and debt.

In July 2013, we were awarded a $4.0 million grant (the "Helmsley Grant") from the Leona M. and Harry B. Helmsley Charitable Trust (the "Helmsley Trust") to accelerate the development of the sixth generation of our advanced glucose-sensing technologies (the "Gen 6 Sensor"). The funding is milestone based and is contingent upon our meeting specific development milestones related to the Gen 6 Sensor over the next several years. Upon the successful commercialization of the Gen 6 Sensor, we are obligated to either (1) make royalty payments of up to $2.0 million per

year for four years, or (2) at our sole election, make a one-time $6.0 million royalty payment.

Net Cash Provided by/Used in Operating Activities. Net cash used in operating activities decreased $35.5 million to $2.4 million provided for the twelve months ended December 31, 2013, compared to $33.1 million used for the same period in 2012.

The decrease in cash used in operations was primarily due to $24.7 million in lower net loss, and $8.4 million in higher non-cash charges primarily comprised of share-based compensation, partially offset by a one-time non-cash tax benefit of $1.3 million for the twelve months ended December 31, 2012.

Net cash used in operating activities increased $3.0 million to $33.1 million for the twelve months ended December 31, 2012, compared to $30.1 million for the same period in 2011. The increase in cash used in operating activities was primarily due to $9.8 million in higher net loss, offset by $8.4 million in higher non-cash charges primarily comprised of share-based compensation and depreciation and amortization. Higher non-cash charges were offset by a one-time non-cash tax benefit of $1.3 million. Also included in net loss were $3.0 million of non-cash charges for excess and obsolete inventory and accelerated depreciation on manufacturing equipment related to the approval and launch of our next generation G4 PLATINUM system.

Net Cash Provided by Investing Activities. Net cash provided by investing activities decreased $7.5 million to $20.9 million for the twelve months ended December 31, 2013, compared to $28.4 million for the same period of 2012. The decrease in cash provided by investing activities was due to a $59.2 million decrease in proceeds from the maturity of short-term marketable securities, offset by a $50.1 million decrease in cash used to purchase short-term marketable securities.

Net cash provided by investing activities was $28.4 million for the twelve months ended December 31, 2012, compared to $46.4 million used in investing activities for the same period of 2011. The increase in cash provided by investing activities was primarily due to $36.3 million decrease in cash used to purchase available-for-sale marketable securities and by $40.0 million increase in proceeds from the maturity of available-for-sale marketable securities for the twelve months ended December 31, 2012 as compared to the same period in 2011.

For the twelve months ended December 31, 2013, 2012 and 2011, we invested $7.9 million, $9.5 million and $8.0 million, respectively, to purchase equipment to support manufacturing improvements.

Net Cash Provided by Financing Activities. Net cash provided by financing activities increased $1.6 million to $11.8 million for the twelve months ended December 31, 2013, compared to $10.2 million for the same period of 2012. The increase was due to increased proceeds from the issuance of common stock pursuant to the exercise of then-outstanding stock options for the twelve months ended December 31, 2013 compared to the same period of 2012.

Net cash provided by financing activities decreased $64.0 million to $10.2 million for the twelve months ended December 31, 2012, compared to $74.2 million for the same period of 2011. The decrease was primarily due to the approximately $3.6 million in net proceeds generated by the sale of common stock for the twelve months ending December 31, 2012 compared to approximately $74.7 million in the same period of 2011, offset by net proceeds of $6.6 million from the loan and security agreement entered into during the twelve months ending December 31, 2012 compared to none in the same period of 2011.

Operating Capital and Capital Expenditure Requirements

We anticipate that we will continue to incur net losses as we incur expenses and expand the commercialization of our approved products, develop additional continuous glucose monitoring products, and expand our marketing, manufacturing and corporate infrastructure.

We believe that our cash, cash equivalents, short-term marketable securities balances, and projected cash contributions from existing partnership arrangements will be sufficient to meet our anticipated cash requirements with respect to the continued scale-up of our commercialization activities, research and development activities, including clinical trials, the expansion of our marketing, manufacturing and corporate infrastructure, and to meet our other anticipated cash needs through at least December 31, 2014. If our available cash, cash equivalents and short-term marketable securities are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. Additionally, there can be no assurance that we will be successful in obtaining additional cash contributions from future partnership arrangements. Our ability to transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. If events or circumstances occur such that we do

not meet our operating plan as expected, or if we are unable to obtain additional financing, we may be required to reduce planned increases in compensation related expenses or other operating expenses related to research, development, and commercialization activities, which could have an adverse impact on our ability to achieve our intended business objectives.

Because of the numerous risks and uncertainties associated with the development of continuous glucose monitoring technologies, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including, but not limited to:

- the revenue generated by sales of our approved products and other future products;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- the quality levels of our products and services;
- the third-party reimbursement of our products for our customers;
- our ability to efficiently scale our manufacturing operations to meet demand for our current and any future products;
- the costs, timing and risks of delays of additional regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including, but not limited to, defending the patent infringement lawsuit filed against us by Abbott;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the emergence of competing or complementary technological developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- the acquisition of businesses, products and technologies.

On March 6, 2012, we acquired SweetSpot. Through our acquisition of SweetSpot, we have a software platform that enables our customers to aggregate and analyze data from certain diabetes devices and to share it with their healthcare providers. In November 2011, SweetSpot received 510(k) clearance from the FDA to market to clinics a data management service, which helps healthcare providers and patients see, understand and use blood glucose meter data to diagnose and manage diabetes. SweetSpot’s data transfer service is registered with the FDA as a MDDS and allows researchers to control the transfer of data from certain diabetes devices to research tools and databases according to their own research workflows. SweetSpot’s software provides an advanced cloud-based platform for uploading, processing and delivering health data and transforms raw output from certain medical devices into useful information for healthcare providers, users and researchers.

Contractual Obligations

In November 2012, we entered into a loan and security agreement (the “Loan Agreement”) that provides for (i) a $15.0 million revolving line of credit and (ii) a total term loan