

DEXCOM INC  
Form 10-K  
March 09, 2010  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-K**

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

For the fiscal year ended December 31, 2009

OR

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

For the transition period from            to

Commission file number: 000-51222

**DEXCOM, INC.**

(Exact name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)  
**6340 Sequence Drive**  
**San Diego, California**  
(Address of Principal Executive offices)

**33-0857544**  
(I.R.S. Employer  
Identification No.)  
**92121**  
(Zip Code)

Edgar Filing: DEXCOM INC - Form 10-K

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 Market)
Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC  (Nasdaq Global 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  No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.

Yes  No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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).

Yes  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.

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  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

As of June 30, 2009, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately \$244,112,857 based on the closing sales price as reported on the NASDAQ Global Market.

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

## Edgar Filing: DEXCOM INC - Form 10-K

Class	Outstanding at March 3, 2010
Common stock, \$0.001 par value per share	52,755,211 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 2010 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.

---

**Table of Contents****DexCom, Inc.****Table of Contents**

	<b>Page Number</b>
<b>PART I</b>	
ITEM 1. <u>Business</u>	1
ITEM 1A. <u>Risk Factors</u>	23
ITEM 1B. <u>Unresolved Staff Comments</u>	44
ITEM 2. <u>Properties</u>	44
ITEM 3. <u>Legal Proceedings</u>	44
ITEM 4. <u>Submission of Matters to a Vote of Security Holders</u>	45
<b>PART II</b>	
ITEM 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	46
ITEM 6. <u>Selected Financial Data</u>	47
ITEM 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	48
ITEM 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	64
ITEM 8. <u>Consolidated Financial Statements and Supplementary Data</u>	64
ITEM 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	65
ITEM 9A. <u>Controls and Procedures</u>	65
ITEM 9B. <u>Other Information</u>	66
<b>PART III</b>	
ITEM 10. <u>Directors, Executive Officers and Corporate Governance</u>	67
ITEM 11. <u>Executive Compensation</u>	67
ITEM 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters</u>	67
ITEM 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	67
ITEM 14. <u>Principal Accounting Fees and Services</u>	67
<b>PART IV</b>	
ITEM 15. <u>Exhibits, Consolidated Financial Statement Schedules</u>	68

---

**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**

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 both diabetic and non-diabetic patients. 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<sup>®</sup>, and on February 13, 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. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. Our ambulatory product approvals allow for the use of our continuous glucose monitoring systems by adults 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. Our approved ambulatory products must be prescribed by a physician and include a disposable sensor, a transmitter and a small handheld receiver. Our approved ambulatory products 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 patient and is intended to be used continuously for up to seven days after which it is removed by the patient and may be replaced by a new sensor. Our transmitter and receiver are reusable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, and on September 30, 2009, we received CE Mark approval for the SEVEN PLUS. We initiated a limited commercial launch in the European Union and Israel in 2008 and 2009. To address the in-hospital patient population, we entered into an exclusive agreement with Edwards Lifesciences LLC, or 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 blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, but have yet to seek approval for this system from the FDA. In partnership with Edwards we initiated a limited launch of the blood-based, in-vivo automated glucose monitoring system in Europe in 2009. 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, as well as the continued research and clinical development of our technology platform.

The International Diabetes Federation, or IDF, expects the worldwide incidence of diabetes in adults 20 to 79 years of age to reach 284.6 million people in 2010, including 26.8 million people in the United States. IDF

## Table of Contents

estimates that by 2030, the worldwide incidence of people suffering from diabetes will reach 438.0 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 Centers for Disease Control, or CDC, diabetes was the seventh leading cause of death by disease in the United States during 2007, and complications related to diabetes include heart disease, limb amputations, loss of kidney function and blindness.

According to a CDC spokesman cited in a *New York Times* article, one in every three children born in the United States in 2001 was expected to become diabetic in their lifetimes, and every day in the United States, on average, there would be 4,100 people diagnosed with diabetes, 230 people undergoing amputations as a result of diabetes, 120 people who enter end-stage kidney disease programs and 55 people who lose their vision.

According to the American Diabetes Association, or ADA, one in every ten health care dollars was spent on treating diabetes in 2007, and the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated \$174 billion, an increase of \$42 billion since 2002. Of the \$174 billion in overall expenses, the ADA estimates that approximately \$89 billion were costs associated with chronic complications and excess general medical costs, \$27 billion were costs associated with diabetes care and \$58 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.

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 are meeting ADA standards for glucose control (A1c), and only 37% of people with diabetes are 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 diabetes patients 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 both improved A1c levels and reduced the 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 27% of people with Type 2 diabetes who require insulin. Although our initial focus is within the United States, our CE Mark approvals also enable us to commercialize our system in those European, Asian and Latin American countries that recognize the CE Mark.

Close Concerns, Inc., a healthcare information firm exclusively focused on diabetes and obesity, founded dQ&A Market Research Inc., a market research business with over 3,000 panel members that participate in diabetes related surveys. A dQ&A Panel Summary Report from October 2009 estimates that our current share of the continuous glucose monitoring system market in the United States is at 37%. The report analyzed responses from 249 panel members who were asked what brand and model of continuous glucose monitoring system they used. 31% of respondents used our SEVEN PLUS product and 6% used our SEVEN.

## **Table of Contents**

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. To complement our direct sales efforts, we also employ clinical specialists who educate and provide clinical support in the field, and we have entered into a limited number of 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 and have no immediate plans to increase the size of the sales organization. During 2008 and 2009, we also initiated a limited launch of our SEVEN PLUS in the select countries in the European Union and Israel through a network of contracted distributors.

We are leveraging our technology platform to enhance the capabilities of our current products and to develop additional continuous glucose monitoring products. In January 2008, we entered into two separate development agreements, one with Animas Corporation, or Animas, a subsidiary of Johnson & Johnson, and one with Insulet Corporation, or Insulet, 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. In addition, we are continuing clinical development of a fourth generation ambulatory product which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, and will be suited for large scale manufacturing. We also intend to seek approval for a pediatric indication (patients under 18 years of age) and a pregnancy indication (diabetes patients who become pregnant and patients who develop gestational diabetes) for our product platform in the future. To address the hospital market, we entered into an exclusive agreement with Edwards to develop jointly and market a product platform for the in-hospital glucose monitoring market, and are developing, in collaboration with Edwards, a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital.

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, or CMS, released 2008 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 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 patients covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices. As of March 2010, 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 five of those third-party payors for the purchase of our products by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with documentation and other requirements to demonstrate medical necessity under the policy. In addition, patients 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 patients 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 coverage policies with third-party payors during 2009 and expect to continue to do so in 2010. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them on a widespread basis.

We plan to develop a next generation of technologies focused on improved performance and convenience and that will enable intelligent insulin administration. Our next generation of technologies are not yet FDA approved, but in the near term, we plan to introduce a fourth generation sensor platform using advanced membrane technologies that are more scalable and reliable. In the mid term, we expect to introduce networked platforms with open architecture, connectivity and transmitters capable of communicating with other devices.

---

**Table of Contents**

**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, patients 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, diabetes patients risk acute complications, such as loss of consciousness or death. Due to the drastic nature of acute complications associated with hypoglycemia, many patients are reluctant to reduce blood glucose levels. Consequently, these patients 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. We estimate that there are approximately 1.4 million Type 1 diabetes patients in the United States. Type 1 diabetes 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. We estimate that there are approximately 25.4 million people with Type 2 diabetes in the United States, 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 more than 5.0 million Type 2 patients must use insulin to manage their diabetes.

There are various subgroups of diabetic patients, including in-hospital and pediatric 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 non-diabetic hospital patients 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% were diabetic, 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.

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. 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. As of 2002, approximately 16% of children and teens were overweight, about double the number two decades before.

***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. Patients manage their blood glucose levels by administering insulin or ingesting carbohydrates throughout the day in order to maintain blood glucose within normal ranges. Patients frequently



---

## Table of Contents

overcorrect and fluctuate between hyperglycemic and hypoglycemic states, often multiple times during the same day. As a result, many patients with diabetes are routinely outside the normal blood glucose range. Patients 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, patients with diabetes must first measure their blood glucose levels. Often after measuring their blood glucose levels, patients 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 patients with information that can be used to better understand and manage their diabetes. The ADA recommends that patients test their blood glucose levels at least three or four times per day.

Clinical outcomes data support the notion that an important component of effective diabetes management is frequent monitoring of blood glucose levels. The landmark 1993 Diabetes Control and Complications Trial, or DCCT, consisting of patients with Type 1 diabetes, and the 1998 UK Prospective Diabetes Study, consisting of patients with Type 2 diabetes, demonstrated that patients 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 patients 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 patients only have single-point data, they do not gain sufficient information to indicate the direction of change in their blood glucose levels. Without the ability to determine whether their blood glucose level is rising, falling or holding constant, the patient's ability to effectively manage and maintain blood glucose levels within normal ranges is severely limited. In addition, patients cannot test themselves during sleep, when the risk of hypoglycemia is significantly increased.

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 mg/dl, or milligrams per deciliter, for a period of 13.5 hours.

**Table of Contents**

**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. Patients 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, patients 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, patients generally prick one of their fingertips or, occasionally, a forearm with a lancet. Patients 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 patients 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. Patients may also suffer pain when the finger prick site is disturbed during regular activities.

We believe a significant 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 three other companies, Cygnus, Medtronic and Abbott, that have received approval from the FDA for continuous glucose monitors. We believe that one of the products,

---

## **Table of Contents**

originally developed and marketed by Cygnus, is no longer actively marketed. In addition, we believe others are developing invasive and non-invasive continuous glucose monitoring systems. Except for our SEVEN and SEVEN PLUS, we believe that none of the products that have received FDA approval are labeled for more than five 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 approved products offer the following advantages to diabetes patients:

**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 approval support 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 blood sugar control.

**Access to Real-Time Values, Trend Information and Alerts.** By pushing a button, patients 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 patient is often unaware if his or her blood glucose is rising, declining or remaining constant. Access to continuous real-time glucose measurements provides patients with information that may aid in attaining better glucose control. Additionally, our products alert patients when their glucose levels approach inappropriately high or low levels so that they may intervene.

**Intuitive Patient Interface.** We have developed a patient interface that we believe is intuitive and easy to use. Our receiver's ergonomic design includes user-friendly buttons, an easy-to-read display, simple navigation tools, audible alerts and graphical display of trend information.

**Convenience and Comfort.** Our products provide patients 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 cell phone 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. The SEVEN PLUS enables a patient to check his or her glucose level and trend information at any time with the touch of a button.

While we believe the SEVEN PLUS offers these advantages, patients 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 products will appeal to all types of diabetes patients. The SEVEN PLUS prompts a patient 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 patients have been able to use sensors for periods longer than seven days. Patients could find this process to be uncomfortable or inconvenient. Patients may be unwilling to insert a disposable sensor in their body, especially if their current diabetes management involves no more than two finger

---

## **Table of Contents**

sticks per day. Additionally, the SEVEN PLUS 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. Reimbursement from Medicare and private third-party healthcare payors is an important element of our success. To date, our approved products are not reimbursed by virtue of a national coverage decision by Medicare. As of March 2010, 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. We have negotiated contracted rates with five of those third-party payors for the purchase of our products by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with documentation and other requirements to demonstrate medical necessity under the policy. In addition, patients who are insured by payors that do not offer coverage for our devices will have to bear the financial cost of the products. Unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them widely.

## **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. In addition, we seek to design, develop and commercialize, in collaboration with Edwards, a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital for the treatment of both diabetic and non-diabetic patients. To achieve this objective, 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<sup>®</sup>, and on February 13, 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. 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. We expect to continue to provide performance improvements 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 products through a direct sales and marketing effort.** We have a direct field sales force 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. To complement our sales efforts, we employ clinical specialists who will educate and provide clinical support to patients, and have entered into distribution arrangements that allow distributors to sell our SEVEN PLUS. We currently sell the SEVEN PLUS only in the United States and in portions of Europe and Israel, but plan to expand our sales elsewhere in the future.

**Drive additional adoption through technology integration partnerships.** We have development agreements with Animas and Insulet to develop products that will integrate our technology into the Animas conventional insulin pump and the Insulet OmniPod System PDM, 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 patients who have adopted continuous subcutaneous insulin infusion, or CSII, are patients who more aggressively manage their diabetes and may be more inclined to utilize our continuous glucose monitoring systems.

---

## **Table of Contents**

**Seek broad reimbursement for our products by Medicare, Medicaid and third-party payors.** Although CMS released 2008 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 by virtue of a national coverage decision by Medicare. As of March 2010, 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. We have negotiated contracted rates with five of those third-party payors for the purchase of our products by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with documentation and other requirements to demonstrate medical necessity under the policy. We currently employ in-house reimbursement expertise to assist patients 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 contracts. We have had formal meetings and have increased our efforts to create coverage policies with third-party payors during 2009 and expect to continue these efforts in 2010.

**Expand the use of our products to other patient care settings and patient demographics.** Our products are approved for use at home and in health care facilities by adults (18 years and older) with diabetes. We believe our sensor technology may be beneficial to pediatric diabetes patients and intend to seek approval for use in patients under the age of 18 in the future. We also 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 non-diabetic hospital patients 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 glucose monitoring market, with an initial focus on the development of an intravenous sensor specifically for the critical care 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 to patients, 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 patient 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.

## **Table of Contents**

### ***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 which minimizes inconvenience and discomfort for the patient.

### ***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 patients.

In March 2009, the FCC established a bifurcated 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 through March 2013, which we believe will provide adequate time to design an alternative method of wireless communication.

### ***Other Technology Applications***

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 Products***

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, and on February 13, 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. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. Our approvals allow for the use of our continuous glucose monitoring systems by adults 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. Our approved products must be prescribed by a physician and include a disposable sensor, a transmitter and a small handheld receiver. Our approved products 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 patient and is intended to be used continuously for up to seven days after which it is removed by the patient and may be replaced by a new sensor.

---

**Table of Contents**

Our transmitter and receiver are reusable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, and on September 30, 2009, we received CE Mark approval for the SEVEN PLUS. We initiated a limited commercial launch of the SEVEN PLUS in the European Union and Israel in 2008 and 2009 through a network of contracted distributors. On October 30, 2009, we received CE Mark approval for our blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, but have yet to seek approval for this system from the FDA. 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, as well as the continued research and clinical development of our technology platform.

We are continuing clinical development of products which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, and will be more comfortable for patients to wear. We also intend to seek approval for a pediatric indication (patients under 18 years of age) for our product platform in the future. We are developing products that will integrate our technology into the Animas conventional insulin pump and the Insulet OmniPod System PDM, as applicable, 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 patient 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 patient then disposes of the insertion device and snaps the reusable transmitter to the pod. After a stabilization period of a few hours, the patient 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. Patients 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 is indicated for use as an adjunctive device 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 a future generation sensor as the sole basis for making therapeutic adjustments.

The disposable sensor contained in the SEVEN PLUS is intended to function for up to seven days after which it may be replaced. After seven days, the patient 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 patients have been able to use sensors for periods longer than seven days.

***Handheld Receiver***

Our small handheld receiver is carried by the patient 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 patient 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.

---

## **Table of Contents**

### **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. To complement our direct sales efforts, we employ clinical specialists who help to educate patients on the benefits of continuous glucose monitoring and provide clinical support to endocrinologists, physicians and diabetes educators who prescribe our products. As of December 31, 2009, we employed approximately 45 direct sales personnel and clinical education specialists. We continue to improve 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 patients, have driven and will continue to drive adoption of our SEVEN PLUS. We directly market our products in the United States primarily to endocrinologists, physicians and diabetes educators. Although the number of diabetes patients is significant, the number of physicians and educators influencing these patients is relatively small. As of 2006, 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 commercial launch 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 patients;

providing strong educational and training programs to healthcare providers and patients 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 patients as necessary.

Our sales organization competes with the experienced and well-funded marketing and sales operations of our competitors. We have limited experience developing and managing a direct sales organization and we may be unsuccessful in our attempt to do so. 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 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 Diagnostics, 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.

## Table of Contents

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 three other companies, Cygnus, Medtronic, and Abbott, have received approval from the FDA for continuous glucose monitors. We believe that one of the products, originally developed and marketed by Cygnus, is no longer actively marketed. In addition, we believe that others are developing invasive and non-invasive continuous glucose monitoring systems. Except for our SEVEN and SEVEN PLUS, we believe that none of the products that have received FDA approval are labeled for more than five 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 are developing next generation real-time continuous glucose monitoring or sensing devices and technologies, including several 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 cannot assure you that we will be able to compete effectively against these companies or their products.

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;

## Edgar Filing: DEXCOM INC - Form 10-K

brand awareness and strong acceptance by healthcare professionals and patients;

customer service and support and comprehensive education for patients 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. This facility has more than 10,000 square feet of laboratory space and approximately 5,000 square feet of controlled environment

---

## **Table of Contents**

rooms. In February 2010, our facility was subject to a post-approval inspection by the FDA. After the close of the inspection, the FDA investigator issued a Form 483 identifying several inspectional observations. Based on the results of this inspection, we are acting to address the observations to achieve substantial compliance with the regulatory requirements for a commercial medical device manufacturer.

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 SEVEN PLUS 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 SEVEN PLUS. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished product, which includes 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 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; Flextronics International Ltd., which assembles the printed circuit boards for our transmitters and receivers; 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 CMS released 2008 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 by virtue of a national coverage decision by Medicare. As of March 2010, 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 five of those third-party payors for the purchase of our products by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with documentation and other requirements to demonstrate medical necessity under the policy. In addition, patients 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 patients 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 coverage policies with third-party payors during 2009 and expect to continue to do so in 2010. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them.

---

## **Table of Contents**

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. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Our initial dependence on the commercial success of our SEVEN PLUS 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 2010, we had obtained 37 issued U.S. patents, and had 209 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 2010, we had 14 international applications filed under the Patent Cooperation Treaty, two granted European patents, 13 European patent applications pending, 10 Japanese patent applications pending, 9 registered U.S. trademarks, 11 pending U.S. trademark applications, 5 registered European trademarks, 3 pending European trademark applications, and 4 registered Japanese trademarks.

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 will provide us with sufficient rights to develop, sell and protect our current and proposed commercial products. However, our patent applications may not result in issued patents, and we cannot assure you that any patents that have issued or might issue will protect our intellectual property rights. Furthermore, we cannot assure you that all of our patents will 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. We cannot be certain that the steps we have taken will 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 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 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 materially and adversely affect our business.

On August 11, 2005, Abbott Diabetes Care, Inc., or 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

---

**Table of Contents**

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, or 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.

Each of the seven patents described above have one or more associated reexamination requests in various stages at the Patent Office. 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, and/or seeking to add new claims. With regard to the four patents originally asserted, two of the patents are in the Appeal process and two of the patents have been issued a Certificate of Reexamination. With regard to the two patents in the Appeal process, all of the claims for which reexamination was requested currently stand rejected and Abbott has filed an Appeal Brief in each of the cases. Each of the two Examiner's Answers maintained all rejections. Abbott filed Reply briefs in both cases. We also filed a second and a third reexamination request against each of the two patents in the Appeal process. The Patent Office denied the second requests and ordered reexamination of certain claims raised in the third requests for each of the two patents. With regard to the two patents for which a Certificate of Reexamination has been issued, subsequent reexamination requests have been filed and the determination has been issued ordering reexamination for each of the two patents. With regard to the three patents subsequently asserted, the first patent has recently been issued a Certificate of Reexamination, the second patent has been issued a Notice of Intent to Issue a Reexamination Certificate and the third one is under non-final rejection. A subsequent reexamination request has been granted for the first patent and a subsequent reexamination request has been filed for the second patent. In the non-finally rejected case, 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, and/or seeking to add new claims.

In 2008 and 2009, Abbott 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 an interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also in 2008, Abbott filed reexamination requests seeking to invalidate two of our patents in the Patent Office. In both reexamination requests, the Patent Office ordered the reexamination and issued non-final office actions and we responded to those non-final office actions by seeking claim construction to differentiate certain claims from the prior art, seeking to amend certain claims to overcome the prior art, and canceling certain claims. In each of the proceedings, Abbott has appealed the Examiner's decision to confirm the patentability of our original or amended claims. In one proceeding we have appealed the rejection of certain claims.

Although it is our position that Abbott's assertions of infringement have no merit, and that the potential interference and reexamination requests have no merit, neither the outcome of the litigation nor the amount and

---

## **Table of Contents**

range of potential fees associated with the litigation, potential interference or reexamination requests can be assessed. No assurances can be given that we will prevail in the lawsuit or that we can successfully defend ourselves against the claims made by Abbott, and we expect to incur significant costs in defending the action, which could have a material adverse effect on our business and our results of operations regardless of the final outcome of such litigation. Subject to the stay, Abbott could immediately seek a preliminary injunction that, if granted, would force us to stop making, using, selling or offering to sell our products. Our SEVEN PLUS is our only ambulatory product that is approved for commercial sale, and if we were forced to stop selling it, or our blood-based in-vivo automated glucose monitoring system for in hospital use, our business and prospects would suffer. We cannot assure you that Abbott will not file for a preliminary injunction, that we would be successful in defending against such an action if filed or that we can successfully defend ourselves against the claim. In addition, defending against this action could have a number of harmful effects on our business regardless of the final outcome of such litigation.

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. 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 could include 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 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 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, or 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 system is classified by the FDA as a PMA medical device. 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, or QSR. Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized

---

**Table of Contents**

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 Quality System Regulation (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 has been classified as a device 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 February 2010, our facility was subject to a post-approval inspection by FDA. After the close of the inspection, the FDA investigator issued a Form 483 identifying several inspectional observations. Based on the results of this inspection, we are acting to address the observations to achieve substantial compliance with the regulatory requirements for a commercial medical device manufacturer.

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.



---

**Table of Contents**

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, or 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;

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.

**Table of Contents**

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, or 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

---

## **Table of Contents**

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 cannot assure you that we will be able to comply with all applicable FDA regulations.

### ***Fraud and Abuse Laws***

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, or 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

## **Table of Contents**

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.

### ***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 environment 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 reengaged our clinical advisory board in 2008.

### ***Employees***

As of December 31, 2009, we had 307 full-time employees and 78 temporary employees. Approximately 84 employees are engaged in research and development, clinical, regulatory and quality assurance, 86 in

---

**Table of Contents**

manufacturing and 137 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](http://www.dexcom.com). We provide free access to various reports that we file with or furnish to the United States Securities and Exchange Commission 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](http://www.sec.gov). Also available on our website are printable versions of DexCom's 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

**ITEM 1A. RISK FACTORS**

**Factors that May Affect our Financial Condition and Results of Operations**

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

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 both diabetic and non-diabetic patients. 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, and on February 13, 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. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. Our ambulatory product approvals allow for the use of our continuous glucose monitoring systems by adults 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. Our approved ambulatory products must be prescribed by a physician and include a disposable sensor, a transmitter and a small handheld receiver. Our approved ambulatory products 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 patient and is intended to be used continuously for up to seven days after which it is removed by the patient and may be replaced by a new sensor. Our transmitter and receiver are reusable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, and on September 30, 2009, we received CE Mark approval for the SEVEN PLUS. We initiated a limited commercial launch in the European Union and Israel in 2008 and 2009. 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 blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, but have yet to seek approval for this system from the FDA. In partnership with Edwards, we initiated a limited launch of the blood-based, in-vivo automated glucose

## Table of Contents

monitoring system in Europe in 2009. 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, as well as the continued research and clinical development of our technology platform.

We expect that sales of our SEVEN PLUS, which consists of a handheld receiver, reusable transmitter and disposable sensor, will account for substantially all of our product revenue for the foreseeable future. From inception through December 31, 2009, product revenues total approximately \$32.9 million. We have limited experience in selling our products and we might be unable to successfully commercialize our products on a wide scale for a number of reasons, including:

market acceptance of our products by physicians and patients will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use;

we may not be able to manufacture our products in commercial quantities or at an acceptable cost;

patients do not generally receive broad reimbursement from third-party payors for their purchase of our products, which may reduce widespread use of our products;

our inexperience in marketing, selling and distributing our products;

we may not have adequate financial or other resources to successfully commercialize our products;

the uncertainties associated with establishing and qualifying new manufacturing facilities;

our SEVEN PLUS is not labeled as a replacement for the information that is obtained from single-point finger stick devices;

patients will need to incur the costs of our SEVEN PLUS in addition to single-point finger stick devices;

the introduction and market acceptance of competing products and technologies;

our inability to obtain sufficient quantities of supplies at appropriate quality levels from our sole 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 is more invasive than current self-monitored glucose testing systems, including single-point finger stick devices, and patients 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, patients 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 long-term clinical evidence to convince them to



## Edgar Filing: DEXCOM INC - Form 10-K

alter their existing treatment methods, (ii) there are recommendations from prominent physicians that our products are effective in monitoring glucose levels and (iii) reimbursement or insurance coverage is widely available. We cannot predict when, if ever, physicians and patients may adopt more widespread use of the SEVEN PLUS. If the SEVEN PLUS does not achieve an adequate level of acceptance by patients, physicians and healthcare payors, we may not generate significant product revenue and we may not become profitable.

## **Table of Contents**

### **Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.**

In March 2007, we issued an aggregate principal amount of \$60 million in 4.75% Convertible Senior Notes due in 2027, or Notes, with \$39.8 million outstanding as of March 5, 2010. The level of our indebtedness, among other things, could:

require us to dedicate a portion of our expected cash flow or our existing cash to service our indebtedness, which would reduce the amount of our cash available for other purposes, including working capital, capital expenditures and research and development expenditures;

make it difficult for us to incur additional debt or obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;

limit our flexibility in planning for or reacting to changes in our business;

limit our ability to sell ourselves or engage in other strategic transactions;

make us more vulnerable in the event of a downturn in our business; or

place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have greater access to capital resources.

If we fail to generate sufficient revenue due to any of the factors described in this section entitled Risk Factors, or otherwise, we could have difficulty paying amounts due on our indebtedness. Although the convertible senior notes mature in 2027, the holders of the convertible senior notes may require us to repurchase their notes prior to maturity under certain circumstances, including specified fundamental changes such as the sale of a majority of the voting power of the company. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of the convertible senior notes, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any other indebtedness that we may have outstanding at such time. Any default under our indebtedness could have a material adverse effect on our business, operating results and financial condition.

### **Conversion of the convertible senior notes will dilute the ownership interests of existing stockholders.**

The terms of the convertible senior notes permit the holders to convert the notes into shares of our common stock. From January 1, 2010 to March 9, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of 2.7 million shares of our common stock, par value \$0.001 per share, in exchange for \$20.3 million in aggregate principal amount of the Notes previously held by the exchanging holders. The convertible senior notes are convertible into our common stock initially at a conversion price of \$7.80 per share, which would result in an aggregate of approximately 5.1 million shares of our common stock being issued upon conversion of Notes outstanding as of March 8, 2010, subject to adjustment upon the occurrence of specified events, provided that the total number of shares of common stock issuable upon conversion, as may be adjusted for fundamental changes or otherwise, may not exceed approximately 6.1 million shares. The conversion of additional Notes will dilute the ownership interest of our existing stockholders. Any sales in the public market of the common stock issuable upon conversion could adversely affect prevailing market prices of our common stock.

### **We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.**

We have incurred net losses in each year since our inception in May 1999, including a net loss of \$53.5 million for the twelve months ended December 31, 2009. As of December 31, 2009, we had an accumulated deficit of \$291.2 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



## **Table of Contents**

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. 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. We also expect that our general and administrative expenses will continue to increase due to the additional operational and regulatory burdens applicable to public companies. As a result, we expect to continue to incur significant operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and may adversely affect our ability to pay interest on, and principal of, the Notes.

### **Current uncertainty in global economic 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 conditions, which have deteriorated significantly in the United States and other countries, and may remain depressed and volatile for the foreseeable future. These conditions may 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. We cannot predict the timing, strength or duration of any economic slowdown or subsequent 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.

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

The U. S. government has in the past considered, is currently considering and 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. 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 U.S. Presidential administration or Congress. It is unclear which, if any, of the various U.S. healthcare reform policies currently being discussed and/or proposed might be enacted by the U.S. Congress and signed into law by the President.

### **If we are unable to develop and maintain 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 SEVEN PLUS and our future products, we must continue to develop and grow our sales and marketing organization and enter into arrangements with others 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 patients throughout the country to initiate sales of our products. Our sales organization competes with the experienced and well-funded marketing and sales operations of our competitors. 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, regional third-party payors that contract exclusively with distributors. Our European distribution partners call directly on healthcare providers to market and sell our products in Europe. Because of the competition for their services, we may be unable to partner with or retain

## **Table of Contents**

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 sales personnel;

effectively train our sales personnel in the benefits of our products;

establish and maintain successful sales and marketing and education programs that encourage endocrinologists, physicians and diabetes educators to recommend our products to their patients; and

manage geographically disbursed sales and marketing operations.

**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. To the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services in the United States or Europe, 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 patients in Europe 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. 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 product revenue and may not become profitable.

**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. 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 going forward. 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. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, materials procurement, 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

---

**Table of Contents**

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, our facilities may have to undergo additional inspections by the FDA and corresponding state agencies. We cannot assure you that we will be able to 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.

Since our commercial launch in 2006, we have experienced periodic field failures, including reports of broken sensors or sensors that become lodged beneath a patient's skin, as well as reports that a sensor fails to provide glucose values for a full seven days. 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 begun to file 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.

**Although many third party payors have adopted some form of coverage policy on continuous glucose monitoring devices, our products do not yet have broad contractual coverage with third party payors and we frequently experience administrative challenges in obtaining reimbursement for our customers. If we are unable to obtain adequate 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. To date, our products are not reimbursed by virtue of a national coverage decision by Medicare. Although CMS released 2008 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 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 patients covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices. As of March 2010, 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 five of those third-party payors for the purchase of our products by their members. However, patients without insurance that covers our products will have to bear the financial cost of them. In the United States, patients 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 patients 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 patients 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

## **Table of Contents**

agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Our initial dependence on the commercial success of the SEVEN PLUS 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, patients 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.

### **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 Flextronics International, Ltd. to manufacture and supply circuit boards for our receiver; we rely on On Semiconductor Corp to manufacture and supply the application specific integrated circuit, or 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 due to 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. 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; 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

## Edgar Filing: DEXCOM INC - Form 10-K

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.



**Table of Contents****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.**

On August 11, 2005, Abbott Diabetes Care, Inc., or 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, or 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.

Each of the seven patents described above have one or more associated reexamination requests in various stages at the Patent Office. 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, and/or seeking to add new claims. With regard to the four patents originally asserted, two of the patents are in the Appeal process and two of the patents have been issued a Certificate of Reexamination. With regard to the two patents in the Appeal process, all of the claims for which reexamination was requested currently stand rejected and Abbott has filed an Appeal Brief in each of the cases. Each of the two Examiner's Answers maintained all rejections. Abbott filed Reply briefs in both cases. We also filed a second and a third reexamination request against each of the two patents in the Appeal process. The Patent Office denied the second requests and ordered reexamination of certain claims raised in the third requests for each of the two patents. With regard to the two patents for which a Certificate of Reexamination has been issued, subsequent reexamination requests have been filed and the determination has been issued ordering reexamination for each of the two patents. With regard to the three patents subsequently asserted, the first patent has recently been issued a Certificate of Reexamination, the second patent has been issued a Notice of Intent to Issue a Reexamination Certificate and the third one is under non-final rejection. A subsequent reexamination request has been granted for the first patent and a subsequent reexamination request has been filed for the second patent. In the non-finally rejected case, 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, and/or seeking to add new claims.

In 2008 and 2009, Abbott 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 an interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also in 2008, Abbott filed reexamination requests seeking to invalidate two of our patents in the Patent Office. In both reexamination requests, the Patent Office ordered the reexamination and issued non-final office actions and we responded to those non-final office actions by seeking claim construction to differentiate certain claims from the prior art, seeking to amend certain claims to overcome the prior art, and

---

**Table of Contents**

canceling certain claims. In each of the proceedings, Abbott has appealed the Examiner's decision to confirm the patentability of our original or amended claims. In one proceeding we have appealed the rejection of certain claims.

Although it is our position that Abbott's assertions of infringement have no merit, and that the potential interference and reexamination requests 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. No assurances can be given that we will prevail in the lawsuit or that we can successfully defend ourselves against the claims made by Abbott, and we expect to incur significant costs in defending the action, which could have a material adverse effect on our business and our results of operations regardless of the final outcome of such litigation. Subject to the stay, Abbott could immediately seek a preliminary injunction that, if granted, would force us to stop making, using, selling or offering to sell our products. Our SEVEN PLUS is our only current ambulatory product that is approved for commercial sale, and if we were forced to stop selling it or our blood-based in-vivo automated glucose monitoring system for in-hospital use, our business and prospects would suffer. We cannot assure you that Abbott will not file for a preliminary injunction, that we would be successful in defending against such an action if filed or that we can successfully defend ourselves against the claim. 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.

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. 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 could include 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 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.**

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, could 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

---

**Table of Contents**

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.

**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, proposed regulations may limit our ability to file continuing patent applications and pursue patent claims in the USPTO.

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 SEVEN PLUS, 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 DexCom, three other companies, Cygnus, Medtronic and Abbott, have received approval from the FDA for continuous glucose monitors. We believe that one of the products, originally developed and marketed by Cygnus, is no longer

---

## **Table of Contents**

actively marketed. In addition, we believe that others 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 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 not be able to compete effectively against these companies or their products.

### **We have entered into a Collaboration Agreement with Edwards to develop jointly an in-hospital continuous blood glucose monitoring device that may not result in the development of a commercially viable product or generation of any future revenues.**

On November 10, 2008, we entered into a Collaboration Agreement with Edwards pursuant to which we have agreed to develop jointly and to market a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital. Under the Collaboration Agreement, we expect to 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 commercial sales of the product, or a royalty of 6% of commercial sales of the product. The Collaboration Agreement provides Edwards with an exclusive license to DexCom's intellectual property that relates to blood-based glucose sensors in 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 loss of some or all of our milestone payments and rights to any profit-sharing or royalties. On October 30, 2009, we received CE Mark approval for the first generation blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital that we developed in collaboration with Edwards. Although Edwards commenced market evaluations during 2009, we do not expect this product to generate significant revenue during 2010. We have yet to seek approval from the FDA for this product.

### **We enter into collaborations with third parties related to our SEVEN PLUS 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 Insulet, to integrate our receiver 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 exclusive right to develop and market outside the United States an ambulatory insulin pump that is combined with our continuous glucose monitoring technology. These 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 overcome technology challenges, clinical trials, and may be delayed due to scheduling issues with patients and investigators, institutional review boards, product performance and manufacturing supply constraints, among



## **Table of Contents**

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 if approved, we may not achieve acceptance in the marketplace by physicians and patients.

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

The SEVEN PLUS 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.

**If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support additional PMA or 510(k) applications, we may be unable to commercialize our continuous glucose monitoring systems under development, which could impair our financial position.**

Our SEVEN PLUS systems are classified by the FDA as PMA medical devices. Our blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital has not yet been classified by the FDA. Before submitting any additional PMA or 510(k) applications, such as for our blood-based in-vivo automated glucose monitoring system, we must successfully complete pre-clinical studies, bench-testing, and clinical trials that we believe 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 trial may be inadequate to support approval of a PMA or 510(k) application. While we have in the past obtained, and may in the future obtain, an Investigational Device Exemption, or 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, even if the trial's intended safety and efficacy endpoints are achieved.

**Table of Contents**

**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, 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, or 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 or administrative actions;

the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and

the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

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, we will be unable to obtain regulatory approval to market our products. 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



---

**Table of Contents**

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.

**We may never receive FDA approval or clearance to market our blood-based in-vivo automated glucose monitoring system that is under development, or any other continuous glucose monitoring system under development.**

Pursuant to the Collaboration Agreement entered into with Edwards, we are jointly developing a blood-based in-vivo automated glucose monitoring system, and we will seek to obtain FDA approval for this device. The regulatory approval process for this device, and any other continuous glucose monitoring system in development involves, among other things, successfully completing clinical trials and obtaining either prior 510(k) clearance or prior approval from the FDA through the PMA process. The 510(k) process would require us to establish (including through pre-clinical testing, bench testing, and/or potentially clinical data) that our blood-based in vivo automated glucose monitoring system (or any other devices we may seek to develop) are 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. The PMA process requires us to prove the safety and efficacy of our continuous blood glucose monitoring system to the FDA's satisfaction. This process can be expensive and uncertain, requires detailed and comprehensive scientific and human clinical data, generally takes one to three years after a PMA application is filed and may never result in the FDA granting a PMA. The FDA can refuse to grant us 510(k) clearance or delay, limit or deny approval of a PMA application for many reasons, including:

our systems may not be deemed by the FDA to be substantially equivalent to appropriate predicate devices;

our systems may not satisfy the FDA's safety or efficacy requirements;

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.

Even if approved or cleared by the FDA, our blood-based in-vivo automated blood glucose monitoring 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. Any delay in, or failure to receive or maintain, approval or clearance for our continuous glucose monitoring systems under development could prevent us from generating revenue from these products or achieving profitability.

**We may be unable to continue the commercialization of our SEVEN PLUS or the development and commercialization of our other continuous glucose monitoring systems, including the blood-based in-vivo automated glucose monitoring system, without additional funding.**

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our products, including further development of our direct sales force and expansion of our manufacturing capacity, and on research and development, including conducting clinical trials for our blood-based in-vivo automated blood glucose monitoring system as well as our next generation



**Table of Contents**

continuous glucose monitoring systems. For the twelve months ended December 31, 2009, our net cash used in operating activities was \$39.4 million, compared to \$37.5 million for the same period in 2008, and as of December 31, 2009, we had working capital of \$18.1 million, including \$30.4 million in cash, cash equivalents and short-term marketable securities, which includes \$2.4 million in restricted cash. We expect that our cash used by operations will increase significantly in each of the next several years, and, although we recently completed a follow-on public offering of 4,025,000 shares of our common stock for net proceeds to the company of approximately \$33.1 million, we may need additional funds to continue the commercialization of our products and for the development and commercialization of other continuous glucose monitoring 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 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 and timing of additional regulatory approvals;

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 marketing, customer support or other resources devoted to our products. Any of these factors could harm our financial condition.

**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.**

## Edgar Filing: DEXCOM INC - Form 10-K

Based on our experience, complications from use of our device may include broken or 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 a patient'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, 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.

---

**Table of Contents**

**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, or 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 required to comply with the FDA's Quality System Regulation, or 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 facility in San Diego, California. In this facility we have more than 10,000 square feet of laboratory space and approximately 5,000 square feet of controlled environment rooms. In February 2010, our facility was subject to a post-approval inspection by the FDA. After the close of the inspection, the FDA investigator issued a Form 483 identifying several inspectional observations. Based on the results of this inspection, we are acting to address the observations to achieve substantial compliance with the regulatory requirements for a commercial medical device manufacturer. In March 2009, the FCC established a bifurcated 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 through March 2013, which we believe will provide adequate time to design an alternative method of wireless communication. 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;

fines and civil penalties;

unanticipated expenditures;

delays in approving or refusal to approve our continuous glucose monitoring systems;

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 MDRs are generally underreported and any underlying problems could be of a larger magnitude than suggested by the number or types of MDRs we receive. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

---

**Table of Contents**

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 postmarket 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.

**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 patients, 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 are designed to be used by a patient continuously for up to seven days, but the patient might be able to circumvent the safeguards designed into the SEVEN PLUS and use the product for longer than seven days. Off-label use of products by patients 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.

## **Table of Contents**

**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 federal, state and local laws and regulations 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;

quality of medical equipment and services;

confidentiality, maintenance and security issues associated with medical records and individually identifiable health information;

medical device reporting;

false claims;

professional licensure; and

labeling products.

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.

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 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.

**The majority of our operations are conducted at one facility in San Diego, California. Any disruption at this facility could increase our expenses.**

We take precautions to safeguard our facilities, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural



disasters may not be adequate to cover our losses in any particular case.

---

**Table of Contents**

**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 have begun limited commercial and marketing efforts in Europe and Israel 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 President and Chief Executive Officer, Steven R. Pacelli, our Chief Administrative Officer, Andrew K. Balo, our Senior Vice President of Clinical and Regulatory Affairs and Quality Assurance, and Jorge Valdes, our Senior Vice President of Operations. 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

---

## **Table of Contents**

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.

### **We have incurred and will incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.**

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission, or SEC, will result in increased costs to us as we evaluate the implications of any new rules and regulations and respond to new requirements under such rules and regulations. We are required to comply with many of these rules and regulations, and will be required to comply with additional rules and regulations in the future. As an early commercialization stage company with limited capital and human resources, we will need to divert management's time and attention away from our business in order to ensure compliance with these regulatory requirements. This diversion of management's time and attention may have a material adverse effect on our business, financial condition and results of operations.

### **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 significant 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, 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 GAAP and make it difficult for us to accurately predict the impact 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. Our share-based payments have characteristics significantly different from those of freely traded options, and changes to the subjective input assumptions of our share-based payment valuation models can materially change our estimates of the fair values of our share-based payments. In addition, 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. Moreover, we rely on third parties that supply us with information or help us perform certain calculations that we employ to estimate the fair value of share-based payments. If any of these parties do not perform as expected or make errors, 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

---

**Table of Contents**

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. For example, as a result of changes approved by the Financial Accounting Standards Board, or FASB, on January 1, 2006 we began recording compensation expense in our statements of operations for equity compensation instruments, including employee stock options, using the fair value method. Our reported financial results beginning for the first quarter of 2006 and for all foreseeable future periods will be negatively and materially impacted by this accounting change. Other potential changes in existing taxation rules related to stock options and other forms of equity compensation could also have a significant negative effect on our reported results.

In May 2008, the FASB issued authoritative guidance for accounting for convertible debt instruments that may be settled in cash upon conversion. The authoritative guidance requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability and equity components of the instrument. The debt would be recognized at the present value of its cash flows discounted using our nonconvertible debt borrowing rate. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The authoritative guidance also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The effective date of the authoritative guidance is for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. On January 1, 2009, we adopted the provisions of the authoritative guidance, which resulted in a reduction to the historical carrying value of the 4.75% convertible senior notes due in 2027 on our balance sheet of \$26.6 million, a reduction to the carrying value of the debt issuance costs of \$1.2 million, and a corresponding increase to paid in capital as of the date of issuance. Our estimated non-convertible borrowing rate of 19.5% was applied to the notes and coupon interest using a present value technique to arrive at the fair value of the liability component. The adoption of the authoritative guidance also resulted in an increase in accumulated deficit of \$6.2 million and a corresponding net decrease to the carrying value of the debt discount and issuance costs as of January 1, 2009. We recorded non-cash interest expense relating to the amortization of the debt discount in the amounts of \$4.9 million and \$4.1 million for the twelve months ended December 31, 2009 and 2008, respectively. We recorded interest expense relating to the contractual coupon payments in the amounts of \$2.9 million for the twelve months ended December 31, 2009 and 2008, respectively. The impact of adoption of the authoritative guidance was an increase to loss per share of \$0.09 and \$0.13 for the twelve months ended December 31, 2009 and 2008, respectively.

**Our loan and security agreement contains restrictions that may limit our operating flexibility.**

In March 2006, we entered into our Loan Agreement that provided for a loan to finance various equipment and leasehold improvement expenses. In January 2008, we amended our Loan Agreement to enable us to draw an additional \$3.0 million. We are required to repay this additional amount at intervals through July 2011. As of December 31, 2009, we had a total outstanding loan balance under the Loan Agreement of \$1.4 million. The Loan Agreement requires us to maintain a minimum cash balance with Square 1 Bank, and also imposes certain limitations on us, including limitations on our ability to:

transfer all or any part of our businesses or properties, other than transfers done in the ordinary course of business;

engage in any business other than the businesses in which we are currently engaged;

relocate our chief executive offices or state of incorporation;

change our legal name or fiscal year;

replace our chief executive officer or chief financial officer;

**Table of Contents**

merge or consolidate with or into any other business organizations, with certain exceptions;

permit any person to beneficially own a sufficient number of shares entitling such person to elect a majority of our board of directors;

incur additional indebtedness, with certain exceptions;

incur liens with respect to any of our properties, with certain exceptions;

pay dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock, other than repurchases of the stock of former employees;

directly or indirectly acquire or own, or make any investment in, any persons, with certain exceptions;

directly or indirectly enter into or permit to exist any material transaction with any affiliates except such transactions that are in the ordinary course of business that are done upon fair and reasonable terms that are no less favorable to us than would be obtained in an arm's length transaction with a non-affiliated company;

make any payment in respect of any subordinated debt, or permit any of our U.S. domestic subsidiaries to make any such payment, except in compliance with the terms of such subordinated debt; or

store any equipment or inventory in which the lender has any interest with any bailee, warehousemen or similar third party unless the third party has been notified of the lender's security interest, or

become or be controlled by an investment company.

Complying with these covenants may make it more difficult for us to successfully execute our business strategy and compete against companies who are not subject to such restrictions.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

Not applicable.

**ITEM 2. PROPERTIES**

We maintain our headquarters in San Diego, California in one leased facility of approximately 66,400 square feet, which includes our laboratory, research and development, manufacturing and general administration functions. The lease for this facility expires in 2014. We have the right to extend the term of this lease for one period of five years. During 2009, we also maintained a second facility in San Diego, California, which was located at our former headquarters. The lease for this facility expires in 2011. We have not yet entered into a sublease agreement for our former headquarters facility. In February 2010, our facility was subject to a post-approval inspection by the FDA. After the close of the inspection, the FDA inspector issued a Form 483 identifying several inspectional observations. Based on the results of this inspection, we are acting to address the observations to achieve substantial compliance with the regulatory requirements for a commercial medical device manufacturer. We previously leased a smaller facility of approximately 7,000 square feet near our former headquarters. We entered into a sublease agreement with an unaffiliated third-party to lease this facility from us through the balance of the lease term. We believe that our existing facilities are adequate

to meet our needs for the foreseeable future, and that suitable additional space will be available in the future on commercially reasonable terms as needed.

**ITEM 3. LEGAL PROCEEDINGS.**

On August 11, 2005, Abbott Diabetes Care, Inc., or 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, or the

---

**Table of Contents**

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.

Each of the seven patents described above have one or more associated reexamination requests in various stages at the Patent Office. 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, and/or seeking to add new claims. With regard to the four patents originally asserted, two of the patents are in the Appeal process and two of the patents have been issued a Certificate of Reexamination. With regard to the two patents in the Appeal process, all of the claims for which reexamination was requested currently stand rejected and Abbott has filed an Appeal Brief in each of the cases. Each of the two Examiner's Answers maintained all rejections. Abbott filed Reply briefs in both cases. We also filed a second and a third reexamination request against each of the two patents in the Appeal process. The Patent Office denied the second requests and ordered reexamination of certain claims raised in the third requests for each of the two patents. With regard to the two patents for which a Certificate of Reexamination has been issued, subsequent reexamination requests have been filed and the determination has been issued ordering reexamination for each of the two patents. With regard to the three patents subsequently asserted, the first patent has recently been issued a Certificate of Reexamination, the second patent has been issued a Notice of Intent to Issue a Reexamination Certificate and the third one is under non-final rejection. A subsequent reexamination request has been granted for the first patent and a subsequent reexamination request has been filed for the second patent. In the non-finally rejected case, 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, and/or seeking to add new claims.

In 2008 and 2009, Abbott 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 an interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also in 2008, Abbott filed reexamination requests seeking to invalidate two of our patents in the Patent Office. In both reexamination requests, the Patent Office ordered the reexamination and issued non-final office actions and we responded to those non-final office actions by seeking claim construction to differentiate certain claims from the prior art, seeking to amend certain claims to overcome the prior art, and canceling certain claims. In each of the proceedings, Abbott has appealed the Examiner's decision to confirm the patentability of our original or amended claims. In one proceeding we have appealed the rejection of certain claims.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

Not applicable.

**Table of Contents****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 Market under the symbol DXCM. As of March 8, 2010, there were approximately 110 stockholders of record, excluding stockholders whose shares were held in nominee or street name by brokers. We have not paid any cash dividends and do not currently have plans to do so in the foreseeable future. Additionally, our loan agreement prohibits us from paying cash dividends without the lender's prior written consent.

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

<b>Year Ended December 31, 2009</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 4.72	\$ 2.62
Second Quarter	\$ 7.05	\$ 3.53
Third Quarter	\$ 8.96	\$ 5.25
Fourth Quarter	\$ 8.26	\$ 6.53
<b>Year Ended December 31, 2008</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 10.02	\$ 3.69
Second Quarter	\$ 8.27	\$ 3.94
Third Quarter	\$ 7.90	\$ 5.34
Fourth Quarter	\$ 6.47	\$ 1.36

Neither we nor any affiliated purchaser repurchased any of our equity securities in fiscal year 2009.



**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

The consolidated statements of operations data for the years ended December 31, 2009, 2008, and 2007 and the consolidated balance sheet data as of December 31, 2009 and 2008 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, 2006 and 2005 and the balance sheet data as of December 31, 2007, 2006 and 2005 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.

	2009	Years Ended December 31,			2005
		2008	2007	2006	
(in thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
Product revenue	\$ 18,036	\$ 8,108	\$ 4,627	\$ 2,170	\$
Development grant and other revenue	11,657	1,730			
Total revenue	29,693	9,838	4,627	2,170	
Product cost of sales	18,216	13,383	12,736	10,959	
Development and other cost of sales	7,816	1,984			
Total cost of sales	26,032	15,367	12,736	10,959	
Gross margin (deficit)	3,661	(5,529)	(8,109)	(8,789)	
Operating expenses:					
Research and development <sup>(1)</sup>	14,294	19,629	16,131	19,419	26,770
Selling, general and administrative <sup>(1)</sup>	35,200	27,669	22,436	21,111	5,660
Total operating expenses	49,494	47,298	38,567	40,530	32,430
Operating loss	(45,833)	(52,827)	(46,676)	(49,319)	(32,430)
Other income		34			
Interest income	354	1,220	3,782	2,815	1,662
Interest expense	(8,045)	(7,283)	(5,560)	(95)	
Net loss	(53,524)	(58,856)	(48,454)	(46,599)	(30,768)
Accretion to redemption value of Series B and Series C redeemable convertible preferred stock					(122)
Net loss attributable to common stockholders	\$ (53,524)	\$ (58,856)	\$ (48,454)	\$ (46,599)	\$ (30,890)
Basic and diluted net loss per share attributable to common stockholders <sup>(2)</sup>	\$ (1.21)	\$ (2.00)	\$ (1.71)	\$ (1.71)	\$ (1.63)
Shares used to compute basic and diluted net loss per share attributable to common stockholders <sup>(2)</sup>	44,347	29,487	28,313	27,236	18,944
As of December 31,					
	2009	2008	2007	2006	2005
(in thousands)					
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents, and marketable securities	\$ 28,016	\$ 27,068	\$ 64,323	\$ 54,508	\$ 50,525
Working capital	18,124	17,062	58,844	52,126	43,939

## Edgar Filing: DEXCOM INC - Form 10-K

Total assets	46,948	43,882	76,388	64,553	56,726
Long term obligations	46,597	48,354	38,009	2,118	
Total stockholders' equity (deficit)	(18,445)	(19,468)	29,932	56,828	49,412

- (1) For the year ended December 31, 2005, certain prior period amounts have been reclassified to conform to current period presentation. The separate display of stock-based compensation expenses associated with research and development and selling, general, and administrative have been reclassified as components of research and development and selling, general, and administrative expenses.
- (2) 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.

**Table of Contents****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 comparable 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 patients, the inability to manufacture products in commercial quantities at an acceptable cost, possible delays in our research and development programs, the inability of patients to receive reimbursements from third-party payors, 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 both diabetic and non-diabetic patients. 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, and on February 13, 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. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. Our ambulatory product approvals allow for the use of our continuous glucose monitoring systems by adults 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. Our approved ambulatory products must be prescribed by a physician and include a disposable sensor, a transmitter and a small handheld receiver. Our approved ambulatory products 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 patient and is intended to be used continuously for up to seven days after which it is removed by the patient and may be replaced by a new sensor. Our transmitter and receiver are reusable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, and on September 30, 2009, we received CE Mark approval for the SEVEN PLUS. We initiated a limited commercial launch in the European Union and Israel in 2008 and 2009. 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 blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, but have yet to seek approval for this system from the FDA. In partnership with Edwards, we initiated a limited launch of the blood-based, in-vivo automated glucose monitoring system in Europe in 2009. 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, as well as the continued research and clinical development of our technology platform.

---

**Table of Contents**

The International Diabetes Federation, or IDF, expects the worldwide incidence of diabetes in adults 20 to 79 years of age to reach 284.6 million people in 2010, including 26.8 million people in the United States. IDF estimates that by 2030, the worldwide incidence of people suffering from diabetes will reach 438.0 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 Centers for Disease Control, or CDC, diabetes was the seventh leading cause of death by disease in the United States during 2007, and complications related to diabetes include heart disease, limb amputations, loss of kidney function and blindness.

According to a CDC spokesman cited in a *New York Times* article, one in every three children born in the United States in 2001 was expected to become diabetic in their lifetimes, and every day in the United States, on average, there would be 4,100 people diagnosed with diabetes, 230 people undergoing amputations as a result of diabetes, 120 people who enter end-stage kidney disease programs and 55 people who lose their vision.

According to the American Diabetes Association, or ADA, one in every ten health care dollars was spent on treating diabetes in 2007, and the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated \$174 billion, an increase of \$42 billion since 2002. Of the \$174 billion in overall expenses, the ADA estimates that approximately \$89 billion were costs associated with chronic complications and excess general medical costs, \$27 billion were costs associated with diabetes care and \$58 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.

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 are meeting ADA standards for glucose control (A1c), and only 37% of people with diabetes are 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 diabetes patients 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 both 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 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.

Close Concerns, Inc., a healthcare information firm exclusively focused on diabetes and obesity, founded dQ&A Market Research Inc., a market research business with over 3,000 panel members that participate in diabetes related surveys. A dQ&A Panel Summary Report from October 2009 estimates that our current share of the continuous glucose monitoring system market in the United States is at 37%. The report analyzed responses from 249 panel members who were asked what brand and model of continuous glucose monitoring system they used. 31% of respondents used our SEVEN PLUS product and 6% used our SEVEN.

---

**Table of Contents**

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. To complement our direct sales efforts, we also employ clinical specialists who educate and provide clinical support in the field, and we have entered into a limited number of 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 and have no immediate plans to increase the size of the sales organization.

We are leveraging our technology platform to enhance the capabilities of our current products and to develop additional continuous glucose monitoring products. In January 2008, we entered into two separate development agreements, one with Animas Corporation, or Animas, a subsidiary of Johnson & Johnson, and one with Insulet Corporation, or Insulet, 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. In addition, we are continuing clinical development of a fourth generation ambulatory product which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, and will be suited for large scale manufacturing. We also intend to seek approval for a pediatric indication (patients under 18 years of age) and a pregnancy indication (diabetes patients who become pregnant and patients who develop gestational diabetes) for our product platform in the future. In addition, we are developing, in collaboration with Edwards, a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital. Our development timelines are highly dependent on our ability to overcome technology challenges, clinical trials, and may be delayed due to scheduling issues with patients and investigators, 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 if approved, we may not achieve acceptance in the marketplace by physicians and patients.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although CMS released 2008 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 patients covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices. As of March 2010, 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 five of those third-party payors for the purchase of our products by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with documentation and other requirements to demonstrate medical necessity under the policy. In addition, patients 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 patients 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 coverage policies with third-party payors during 2009 and expect to continue to do so in 2010. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them on a widespread basis.

We plan to develop a next generation of technologies focused on improved performance and convenience and that will enable intelligent insulin administration. Our next generation of technologies are not yet FDA approved, but in the near term, we plan to introduce a fourth generation sensor platform using advanced

---

## **Table of Contents**

membrane technologies that are more scalable and reliable. In the mid term, we expect to introduce networked platforms with open architecture, connectivity and transmitters capable of communicating with other devices.

We currently manufacture our devices at our headquarters in San Diego, California. In this facility we have more than 10,000 square feet of laboratory space and approximately 5,000 square feet of controlled environment rooms. In February 2010, our facility was subject to a post-approval inspection by the FDA. After the close of the inspection, the FDA inspector issued a Form 483 identifying several inspectional observations. Based on the results of this inspection, we are acting to address the observations to achieve substantial compliance with the regulatory requirements for a commercial medical device manufacturer. We manufacture our SEVEN PLUS with components supplied by outside vendors and with parts manufactured internally. Key components that we manufacture internally include the wire-based sensor for our SEVEN PLUS. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished product, which includes a reusable transmitter, a receiver and a disposable sensor. We are expanding our manufacturing capacity in our facility in San Diego, California. Our capacity expansion could be constrained by the lack of material availability, equipment design, production and validation, regulatory approval of any required additional facilities, personnel staffing and other factors.

Product revenues are generated from the sale of durable continuous glucose monitoring systems (receivers and transmitters) and disposable sensors through a direct sales force in the United States as well as through distribution arrangements in the United States and in portions of Europe. The sensor is inserted by the patient and is intended to be used continuously for up to seven days, after which it may be replaced with a new disposable sensor. Our transmitter and receiver are reusable. In the event we establish an installed base of patients using our products, we expect to generate an increasing portion of our revenues through recurring sales of our disposable sensors. We recognize product revenue upon shipment and our sales terms provide for customer payment at the time of order, payment due within negotiated contractual terms with insurance payors, or with the issuance of a purchase order or letter of credit for certain distributors and institutions.

From inception through December 31, 2009, we had generated \$46.3 million of product and development grant and services (non-product) revenue, and we have incurred net losses in each year since our inception in May 1999. From inception through December 31, 2009, we had an accumulated deficit of \$291.2 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 convertible debt. In April 2005, we completed our initial public offering in which we sold 4,700,000 shares of common stock for net proceeds of \$50.5 million. In March 2006, we entered into a Loan Agreement, which was subsequently amended in January 2008. As of December 31, 2009, we had an outstanding balance of \$1.4 million under the Loan Agreement. In May 2006, we completed a follow-on public offering of 2,117,375 shares of our common stock for net proceeds of \$47.0 million. In March 2007, we issued an aggregate principal amount of \$60.0 million of 4.75% Convertible Senior Notes due in 2027. In February 2009, we completed a public follow-on offering of 15,994,000 shares of our common stock for net proceeds of approximately \$45.6 million. In January 2010, we completed a public follow-on offering of 4,025,000 shares of our common stock for net proceeds of approximately \$33.1 million.

## **Financial Operations**

### ***Revenue***

From inception through December 31, 2009, we generated \$32.9 million in product revenue from the sale of our continuous glucose monitoring systems. We expect that revenues we generate from the sales of our products will fluctuate from quarter to quarter. During the first quarter of 2008, we entered into a joint development agreement with Animas and we recognize development grant revenue received pursuant to that agreement ratably over the term of the development period. During the fourth quarter of 2008, we entered into a collaboration agreement with Edwards and we recognize development grant revenue received pursuant to that agreement ratably over the term of the development period. From inception through December 31, 2009, we recognized \$13.4 million in development grant and other revenue, which includes milestones and services.

---

## **Table of Contents**

### ***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. The majority of our costs are currently fixed due to our relatively low production volumes compared to our potential capacity. All of our manufacturing costs are included in product cost of sales. Development 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, materials and products for clinical trials. Until December 31, 2005 our manufacturing costs were included in research and development expense. 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 and consulting expenses.

## **Results of Operations**

### ***Fiscal year ended December 31, 2009 Compared to December 31, 2008***

#### ***Revenue, Cost of Sales and Gross Margin***

Product revenues increased \$9.9 million to \$18.0 million for the twelve months ended December 31, 2009 compared to \$8.1 million for the twelve months ended December 31, 2008 based primarily on increased sales volume and higher average per unit selling prices. Product cost of sales increased \$4.8 million to \$18.2 million for the twelve months ended December 31, 2009 compared to \$13.4 million for the twelve months ended December 31, 2008. The increased product cost of sales associated with additional product sales was offset primarily by increased manufacturing absorption for the twelve months ended December 31, 2009 as compared to the same period in 2008. The product gross margin loss of \$180,000 for the twelve months ended December 31, 2009 decreased \$5.1 million compared to \$5.3 million for the same period in 2008, primarily due to increased revenue and better direct labor utilization.

Development grant and other revenues increased \$10.0 million to \$11.7 million for the twelve months ended December 31, 2009 compared to \$1.7 million for the twelve months ended December 31, 2008. Development and other cost of sales increased \$5.8 million to \$7.8 million for the twelve months ended December 31, 2009 compared to \$2.0 million for the twelve months ended December 31, 2008. The increase in both revenues and costs associated with development was primarily due to our continuing performance obligations under a joint development agreement with Animas originally signed in the first quarter of 2008 and our continuing performance obligations under a collaboration agreement with Edwards originally signed in the fourth quarter of 2008.

---

**Table of Contents**

**Research and Development.** Research and development expense decreased \$5.3 million to \$14.3 million for the twelve months ended December 31, 2009, compared to \$19.6 million for the twelve months ended December 31, 2008. The decrease in research and development expense was primarily due to the joint development and collaboration agreements originally entered into with Animas and Edwards in 2008, and the corresponding allocation of expenses to development cost of sales for the ongoing delivery of these agreements. Changes in research and development expense include \$3.8 million in lower development costs and \$1.6 million in lower clinical and regulatory and quality assurance costs. Major elements of decreased research and development costs include \$2.3 million in lower salaries and payroll related costs, \$1.1 million in lower facilities costs, and \$509,000 in lower consulting costs.

**Selling, General and Administrative.** Selling, general and administrative expense increased \$7.5 million to \$35.2 million for the twelve months ended December 31, 2009, compared to \$27.7 million for the twelve months ended December 31, 2008. The increase was primarily due to higher selling, marketing, and international development costs to support revenue growth and the continued commercialization of our products. Major elements of increased selling, general, and administrative expenses include \$4.3 million in higher salaries, bonus, and payroll related costs, \$839,000 in higher commissions, and \$722,000 in higher share-based compensation.

**Interest Income.** Interest income decreased \$866,000 to \$354,000 for the twelve months ended December 31, 2009, compared to \$1.2 million for the twelve months ended December 31, 2008. The decrease in interest income was primarily due to lower average interest bearing cash and marketable securities balances and lower yields earned on those balances during the twelve months ended December 31, 2009 as compared to the same period of 2008.

**Interest Expense.** Interest expense increased \$762,000 to \$8.0 million for the twelve months ended December 31, 2009, compared to \$7.3 million for the twelve months ended December 31, 2008. The increase in interest expense was primarily due to additional non-cash interest expense relating to the 4.75% convertible notes issued in March of 2007 and the accretion of the debt discount to interest expense over the instrument's expected life using the effective interest method.

***Fiscal year ended December 31, 2008 Compared to December 31, 2007***

***Revenue, Cost of Sales and Gross Margin***

Product revenues increased \$3.5 million to \$8.1 million for the twelve months ended December 31, 2008 compared to \$4.6 million for the twelve months ended December 31, 2007 based primarily on increased sales volume and higher average per unit selling prices. Product cost of sales increased \$647,000 to \$13.4 million for the twelve months ended December 31, 2008 compared to \$12.7 million for the twelve months ended December 31, 2007. The increased product cost of sales associated with additional product sales was offset primarily by increased manufacturing absorption for the twelve months ended December 31, 2008 as compared to the same period in 2007. The product gross margin loss of \$5.3 million for the twelve months ended December 31, 2008 decreased \$2.8 million compared to \$8.1 million for the same period in 2007, primarily due to increased revenue and better direct labor utilization.

Development grant revenues totaled \$1.7 million for the twelve months ended December 31, 2008 and development cost of sales totaled \$2.0 million. There were no development grant revenues or development cost of sales generated during 2007. The increase in both revenues and costs associated with development was primarily due to our continuing performance obligations under a joint development agreement with Animas originally signed in the first quarter of 2008 and our continuing performance obligations under a collaboration agreement with Edwards originally signed in the fourth quarter of 2008.

**Research and Development.** Research and development expense increased \$3.5 million to \$19.6 million for the twelve months ended December 31, 2008, compared to \$16.1 million for the twelve months ended December 31, 2007. Changes in research and development expense include \$2.1 million in higher development



---

**Table of Contents**

costs and \$1.4 million in higher clinical and regulatory and quality assurance costs. Major elements of increased research and development costs include \$1.2 million in additional consulting fees, \$1.2 million in increased facilities costs, and \$415,000 in additional supplies.

**Selling, General and Administrative.** Selling, general and administrative expense increased \$5.2 million to \$27.7 million for the twelve months ended December 31, 2008, compared to \$22.4 million for the twelve months ended December 31, 2007. The increase was primarily due to higher selling, legal and marketing costs. Major elements of increased selling, general, and administrative expenses include \$1.4 million in higher share-based compensation, \$852,000 in increased facilities costs, and \$824,000 in higher salaries.

**Interest Income.** Interest income decreased \$2.6 million to \$1.2 million for the twelve months ended December 31, 2008, compared to \$3.8 million for the twelve months ended December 31, 2007. The decrease in interest income was primarily due to lower average interest bearing cash and marketable securities balances and lower yields earned on those balances during the twelve months ended December 31, 2008 as compared to the same period of 2007.

**Interest Expense.** Interest expense increased \$1.7 million to \$7.3 million for the twelve months ended December 31, 2008, compared to \$5.6 million for the twelve months ended December 31, 2007. The increase in interest expense was primarily due to our \$60.0 million in Convertible Senior Notes outstanding for the entire twelve months ended December 31, 2008 compared to a shorter period of time during the twelve months ended December 31, 2007 following the issuance in March of 2007, and the accretion of the debt discount to interest expense over the instrument's expected life using the effective interest method.

**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, 2009, we had an accumulated deficit of \$291.2 million and had working capital of \$18.1 million. Our cash, cash equivalents and short-term marketable securities totaled \$28.0 million, excluding \$2.4 million in restricted cash. We have funded our operations primarily from the sale of equity and debt securities and our bank line, raising aggregate net proceeds of \$215.7 million from equity sales and \$46.3 million from debt sales through December 31, 2009. As of December 31, 2009 we had a total of \$1.4 million outstanding under our amended bank equipment loan that we are required to repay through July 2011. In January 2010, we completed a public follow-on offering of 4,025,000 shares of our common stock for net proceeds of approximately \$33.1 million.

**Net Cash Used in Operating Activities.** Net cash used in operating activities increased \$1.9 million to \$39.4 million for the twelve months ended December 31, 2009, compared to \$37.5 million net cash used for the same period in 2008. The increase in cash used in operations was primarily due to \$8.4 million in changes in operating assets and liabilities offset by \$5.3 million in lower net loss, and \$1.1 million in additional non-cash charges primarily comprised of share-based compensation. Of the \$8.4 million in changes in operating assets and liabilities, \$16.3 million was due to less deferred revenue and \$5.2 million was due to less restricted cash requirements.

**Net Cash Provided By Investing Activities.** Net cash used in investing activities was \$14.1 million for the twelve months ended December 31, 2009, compared to \$24.3 million provided for the same period of 2008. The decrease in cash provided by investing activities was primarily due to \$28.3 million increase in cash used to purchase available-for-sale marketable securities and by \$10.0 million decrease in proceeds from the maturities of short-term marketable securities for the twelve months ended December 31, 2009 as compared to the same period in 2008. For the twelve months ended December 31, 2009, we invested \$3.0 million in equipment to support manufacturing improvements compared to \$2.5 million during the same period in 2008.

**Net Cash Provided by Financing Activities.** Net cash provided by financing activities increased \$41.7 million to \$44.4 million for the twelve months ended December 31, 2009, compared to \$2.7 million for the same

## **Table of Contents**

period of 2008. The increase was primarily due to the \$45.6 million in net proceeds generated by the sale of common stock in the follow on public offering completed in February 2009 for the twelve months ending December 31, 2009 compared to none in the same period of 2008, offset by a decrease of \$3.0 million of net proceeds from equipment loans for the twelve months ended December 31, 2009 compared to the same period of 2008.

### ***Operating Capital and Capital Expenditure Requirements***

We anticipate that we will continue to incur net losses for the foreseeable future as we incur expenses to commercialize 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, net proceeds from our January 2010 offering, and projected cash contributions from existing partnership arrangements will be sufficient to meet our anticipated cash requirements with respect to the 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 for at least the next twelve months. 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. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

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 and timing 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, although we currently have no commitments or agreements relating to any of these types of transactions.

---

**Table of Contents**

***Contractual Obligations***

In March 2007, we issued \$60.0 million aggregate principal amount of Convertible Senior Notes due 2027 in a private offering. The notes are convertible into shares of common stock based on an initial conversion rate of 128.2051 shares of common stock per \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$7.80 per share. Interest on the notes is due semiannually on March 15 and September 15 of each year at a rate of 4.75% per year. The notes will be redeemable by us beginning March 20, 2010 at a price equal to 100% of the principal amount to be redeemed plus accrued and unpaid interest. Holders of the notes may require us to repurchase the notes for cash equal to 100% of the principal amount to be repurchased plus accrued and unpaid interest upon the occurrence of certain designated events, including a change of control. In addition, we will have the right to automatically convert the notes if the closing price of our common stock exceeds 150% of the conversion price or \$11.70 per share, for at least 20 trading days during any 30-day period. If such an automatic conversion occurs before March 15, 2010, we are required to pay additional interest in cash or, at our option, in shares of our common stock. The holders of the notes may require us to repurchase the notes for cash on March 15, 2012, March 15, 2017 and March 15, 2022 at a repurchase price equal to 100% of the principal amount, plus accrued and unpaid interest. From January 1, 2010 to March 9, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of 2.7 million shares of our common stock, par value \$0.001 per share, in exchange for \$20.3 million in aggregate principal amount of the Notes previously held by the exchanging holders.

On January 31, 2008, we amended our bank equipment loan to enable us to draw an additional \$3.0 million. Beginning April 2008, this additional amount requires monthly amortized payments through the maturity date of July 2011. As of December 31, 2009, we had an outstanding balance of \$1.4 million due on this bank equipment loan.

In April 2006, we entered into an office lease agreement for approximately 66,400 square feet of additional facilities located in San Diego, California. The initial term of this lease is eight years and we have a five-year option to renew the lease upon the expiration of the initial term. In connection with the lease, we entered into a \$664,000 letter of credit to secure future payments under the lease and paid a security deposit in the amount of \$89,640 in April 2006. We also currently maintain a second lease for approximately 23,000 square feet which expires in 2011 for our former headquarters facility. In January 2007, we entered into a sublease agreement to sublet an existing facility near our corporate headquarters to a third party. Under the terms of the agreement, we sublet approximately 7,000 square feet of facilities space at terms and conditions, including real estate taxes and operating costs, which mirror the original lease agreement. We retain obligations per the original lease which expires in May 2011. These facility leases have annual rental escalation clauses and are expensed on a straight-line basis. In November 2007, we entered into a one year lease for approximately 1,200 square feet of storage. In November 2008, we renewed the lease of the storage facility for an additional year. In September 2008, our subsidiary in Sweden entered into a three year lease for a small shared office space, which has a quarterly adjustment clause for rent to increase or decrease in proportion to changes in consumer prices. Excluding real estate taxes and operating costs, we are required to make total future monthly payments for all of our real estate obligations for the period from December 2009 through April 2014 totaling \$6.4 million.

We are party to various purchase arrangements related to components used in production and research and development activities. As of December 31, 2009, we had purchase commitments with certain vendors totaling approximately \$3.8 million due within one year. There are no purchase commitments due beyond one year.

**Table of Contents**

The following table summarizes our outstanding contractual obligations as of December 31, 2009 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

		Less than	1-3	3-5	More than
Contractual Obligations	Total	1 Year	Years	Years	5 Years
Notes payable	\$ 61,425	\$ 900	\$ 60,525	\$	
Operating leases	6,365	1,731	2,783	1,851	
Purchase commitments	3,834	3,834			
Total	\$ 71,624	\$ 6,465	\$ 63,308	\$ 1,851	\$

**Off-Balance Sheet Arrangements**

We have not engaged in any off-balance sheet activities.

**Related Party Transactions**

Our Chairman is a director of Oracle Corporation. We incurred costs totaling \$94,000, \$105,000, and \$96,000 relating to an Oracle ERP system for the years ended December 31, 2009, 2008 and 2007, respectively. The Chairman was not involved in the selection of our ERP system. We believe that the aforementioned arrangement was at no less favorable rates to us than those that could have been obtained from unrelated third parties based on review of price quotations with third parties.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our annual report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

**Revenue Recognition**

We sell durable systems and disposable units through a direct sales force in the United States as well as through distribution arrangements in the United States and in portions of Europe. Components are individually priced and can be purchased separately or together. The SEVEN PLUS durable system includes a transmitter, a receiver, a power cord, data management software and a USB cable. Disposable sensors for use with the SEVEN PLUS system are sold separately in packages of four. The initial SEVEN PLUS durable system price is not dependent upon the purchase of any amount of disposable sensors. We discontinued sales of our SEVEN system in the United States in the first quarter of 2009, although we continue to sell disposable sensors for use with both the SEVEN and SEVEN PLUS durable systems.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Revenue on

---

**Table of Contents**

product sales is recognized upon shipment, which is when title and the risk of loss have been transferred to the customer and there are no other post-shipment obligations. With respect to customers who directly pay for the products, the products are generally paid for at the time of shipment using a customer's credit card and do not include customer acceptance provisions. We recognize revenue from contracted insurance payors based on the contracted rate. For non-contracted insurance payors, we obtain a prior authorization from the payor and recognize revenue based on the estimated collectible amount and historical experience. We also receive a prescription or statement of medical necessity and, for insurance reimbursement customers, an assignment of benefits prior to shipment.

We provide a 30-day money back guarantee program whereby customers who purchase the SEVEN PLUS durable system and a package of four disposable sensors may return the SEVEN PLUS durable system for any reason within thirty days of purchase and receive a full refund of their purchase price. At December 31, 2009, we maintained a reserve balance of \$20,000 relating to this program. We accrue for estimated returns and/or refunds by reducing revenues and establishing a liability account at the time of shipment based on historical experience.

During 2008 and 2009, we entered into distribution agreements with RGH Enterprises, Inc., or Edgepark, and other distributors that allow the distributors to sell our durable systems and disposable units. Revenue on product sales to distributors is recognized at the time of shipment, which is when title and risk of loss have been transferred to the distributor and there are no other post-shipment obligations. Revenue is recognized based on contracted prices and invoices are either paid by check following the issuance of a purchase order or letter of credit, or they are paid by wire at the time of placing the order. Terms of distributor orders are FOB shipping point (FCA shipping point for international orders). Distributors do not have rights of return per their distribution agreement outside of our standard warranty. We accrue for estimated returns, refunds and rebates by reducing revenues and establishing a liability account at the time of shipment based on historical experience. Our distributors typically have a limited time frame to notify us of any missing, damaged, defective or non-conforming products. For any such products, we shall either, at our option, replace the portion of defective or non-conforming product at no additional cost to the distributor or cancel the order and refund any portion of the price paid to us at that time for the sale in question. We have no intention of refunding or unwinding a prior sale and view any potential product non-conformity solely as a warranty issue.

We shipped product directly to Edgepark's customers and recognized \$4.5 million and \$1.2 million in revenue, which represents 15% and 12% of our revenues, respectively, for the twelve months ended December 31, 2009 and 2008. With respect to other distributors which stock inventory of our product and fulfill orders from their inventory, we shipped product to these distributors and recognized \$1.4 million in revenue from these arrangements for the twelve months ended December 31, 2009. We monitor shipments to, and on-hand inventory levels of, these distributors, and at December 31, 2009 these distributors had limited amounts of our product in their year-ending inventory.

During 2008, we entered into collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing our technologies. The terms of these agreements typically include multiple deliverables by us (for example, license rights, provision of research and development services, and manufacture of clinical materials) in exchange for consideration to us of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of development milestones and royalties in the form of a designated percentage of product sales or profits. With the exception of royalties, these types of consideration are classified as development grant and other revenue in our consolidated statements of operations when revenue recognition is appropriate.

Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license, development and other multiple element service arrangements, are analyzed to determine how the arrangement consideration should be allocated among the separate units of accounting, or

## **Table of Contents**

whether they must be accounted for as a single unit of accounting. We recognize deliverables as revenue upon delivery only if the deliverable has stand-alone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting. We use judgment in estimating the value allocable to product revenues or development grant and other revenue based on our estimate of the fair value attributable to the related deliverables.

For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement are recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. The cumulative amount of revenue earned is limited to the cumulative amount of payments received as of the period ending date.

If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance. Deferred revenue amounts are classified as current liabilities to the extent that revenue is expected to be recognized within one year.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

During the first quarter of 2008, we entered into a development agreement with Animas, as amended on January 12, 2009 and July 30, 2009, which provided us with a development grant. During the fourth quarter of 2008, we entered into a collaboration agreement with Edwards, as amended on May 5, 2009, which provided us with a development grant. We recognized \$11.7 million in development and other revenue for the twelve months ended December 31, 2009. As of December 31, 2009, we had \$7.7 million in deferred revenue relating to our development and other agreements.

### ***Share-Based Compensation***

Our share-based employee compensation plans are described in the notes to our consolidated financial statements. We measure and recognize compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants including employee stock options and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values. Share-based compensation expense for the years ended December 31, 2009, 2008 and 2007 was \$8.4 million, \$7.7 million, and \$6.1 million, respectively. As of December 31, 2009, there was \$13.5 million of unrecognized compensation cost related to outstanding options that is expected to be recognized as a component of our operating expenses through 2013. Compensation costs will be adjusted for future changes in estimated forfeitures.

We estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods as share-based compensation expense in our consolidated statement of operations. For the years ended December 31, 2009, 2008 and 2007, the consolidated statement of operations included compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated. In conjunction with the adoption of the guidance, we changed our method of attributing the value of share-based compensation to expense from the accelerated multiple-option approach to the straight-line single option method. Compensation expense for all share-based payment awards granted on or prior to December 31, 2005 will continue to be

---

## **Table of Contents**

recognized using the accelerated multiple-option approach while compensation expense for all share-based payment awards granted subsequent to December 31, 2005 is recognized using the straight-line single-option method. As share-based compensation expense recognized in the statement of operations in fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

We utilize the Black-Scholes option-pricing model as our method of valuation for share-based awards granted. The Black-Scholes model was previously utilized for our pro forma information. Our determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because our employee stock options have certain characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, the existing valuation models may not provide an accurate measure of the fair value of the our employee stock options. Although the fair value of employee stock options is determined using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

### ***Inventory***

Inventories are valued at the lower of cost or market value. We make adjustments to reduce the cost of inventory to its net realizable value, if required, for estimated excess, obsolete and potential scrapped inventories. We estimate excess and obsolete inventories by identifying the amount of on hand and on order materials and comparing those to expected future sales for the next twelve months, taking into account clinical trial and development usage along with new product introductions on a part-by-part basis. Once written down the adjustments are considered permanent and are not reversed until the related inventory is sold or disposed. We utilize a standard cost system to track inventories on a part-by-part basis that approximates first in, first out. If necessary, adjustments are made to the standard materials, standard labor and standard overhead costs to approximate actual labor and actual overhead costs. The labor and overhead elements of our inventory are based on full utilization of our manufacturing capacity.

### ***Clinical Trial Accounting***

We record accruals for estimated clinical study expenses, comprising payments for work performed by contract research organizations, physicians and participating hospitals. These expenses can be a significant component of research and development expenses. We accrue expenses for clinical studies performed by contract research organizations based on estimates of work performed under the contracts. Expenses for setting up clinical trial sites and study initiation are accrued immediately. Clinical expenses related to patient enrollment and ongoing monitoring are accrued as the trials progress.

### ***Warranty Accrual***

We accrue for estimated warranty costs at the time of shipment. We estimate warranty accruals by analyzing the timing, cost and amount of returned product. We evaluate assumptions and historical warranty experience on at least a quarterly basis to determine the continued appropriateness of such assumptions.

### ***Bonus Accrual***

For the 2009 bonus plan, the Compensation Committee authorized an amount of up to 55% of salary and wages for non sales employees to be awarded from the pool based on the weighted average achievement measured against certain objectives. As various targets were met, bonuses were paid under the 2009 bonus plan totaling \$1.9 million.



**Table of Contents****Foreign Currency**

The consolidated financial statements of our non-U.S. subsidiary, whose functional currency is the Swedish Krona, is translated into U.S. dollars for financial reporting purposes. Assets and liabilities are translated at period-end exchange rates, and revenue and expense transactions are translated at average exchange rates for the period. Cumulative translation adjustments are recognized as part of comprehensive income and are included in accumulated other comprehensive income in the consolidated balance sheet. Gains and losses on transactions denominated in other than the functional currency are reflected in operations.

**Income Taxes**

In July 2006, the Financial Accounting Standards Board ( FASB ) issued authoritative guidance for accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, the authoritative guidance provides detail on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. Only tax positions that meet the more likely than not recognition threshold at the effective date may be recognized upon adoption of the authoritative guidance.

We adopted the guidance as of January 1, 2007. Due to the valuation allowance, the adoption of the guidance did not impact our financial condition, results of operations or cash flows. As a result of the adoption, we recorded a net decrease to deferred tax assets of approximately \$1.8 million and a corresponding reduction to valuation allowance. The following table summarizes the activity related to our gross unrecognized tax benefits (in thousands):

Balance at January 1, 2007	\$ 2,181
Increases related to current year tax positions	405
Balance at December 31, 2007	2,586
Increases related to current year tax positions	491
Balance at December 31, 2008	3,077
Adjustments related to prior year tax positions	51
Increases related to current year tax positions	604
Decreases due to IRC Section 382 limitation	(837)
Balance at December 31, 2009	\$ 2,895

Due to the valuation allowance, \$51,000 of the total unrecognized tax benefits as of December 31, 2009, would reduce our annual effective tax rate if recognized. Due to the valuation allowance, none of the total unrecognized tax benefits as of December 31, 2008 and 2007, would reduce our annual effective tax rate if recognized. We do not expect our unrecognized tax benefits to change significantly over the next 12 months.

We file income tax returns in the United States and in various state jurisdictions with varying statutes of limitations. Due to net operating losses incurred, our income tax returns from inception to date are subject to examination by taxing authorities. Our policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. As of December 31, 2009, we had no interest or penalties accrued for uncertain tax positions.

**Recent Accounting Pronouncements**

In September 2006, the FASB issued authoritative guidance which defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. The authoritative guidance for fair value measurements does not require any new fair value measurements, but



---

**Table of Contents**

provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. In February 2008, the FASB deferred the effective date of the authoritative guidance by one year for certain non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). On January 1, 2008, we adopted the provisions of the authoritative guidance for fair value measurements.

The fair value hierarchy described by the standard is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value and include the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The adoption of the authoritative guidance for fair value measurements did not have a material effect on our financial position or results of operations. The book values of cash and cash equivalents, short-term marketable securities, accounts receivable and accounts payable approximate their respective fair values due to the short-term nature of these instruments.

In December 2007, the FASB ratified the consensus reached for accounting for collaborative arrangements. The authoritative guidance requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, the guidance clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to the authoritative guidance for accounting for consideration given by a vendor to a customer. Effective January 1, 2009, we adopted the authoritative guidance for accounting for collaborative arrangement, which did not have a material effect on our consolidated financial statements.

In May 2008, the FASB issued authoritative guidance for accounting for convertible debt instruments that may be settled in cash upon conversion. The authoritative guidance requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability and equity components of the instrument. The debt would be recognized at the present value of its cash flows discounted using our nonconvertible debt borrowing rate. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The authoritative guidance also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The effective date of the authoritative guidance is for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. On January 1, 2009, we adopted the provisions of the authoritative guidance, which resulted in a reduction to the historical carrying value of the 4.75% convertible senior notes due in 2027 on our balance sheet of \$26.6 million, a reduction to the carrying value of the debt issuance costs of \$1.2 million, and a corresponding increase to paid in capital as of the date of issuance. Our estimated non-convertible borrowing rate of 19.5% was applied to the notes and coupon interest using a present value technique to arrive at the fair value of the liability component. The adoption of the authoritative guidance also resulted in an increase in accumulated deficit of \$6.2 million and a corresponding net decrease to the carrying value of the debt discount and issuance costs as of January 1, 2009. We recorded non-cash interest expense relating to the amortization of the debt discount in the amounts of \$4.9 million and \$4.1 million for the twelve months ended December 31, 2009 and 2008, respectively. We recorded interest expense

---

**Table of Contents**

relating to the contractual coupon payments in the amounts of \$2.9 million for the twelve months ended December 31, 2009 and 2008, respectively. The impact of adoption of the authoritative guidance was an increase to loss per share of \$0.09 and \$0.13 for the twelve months ended December 31, 2009 and 2008, respectively.

In June 2008, the FASB issued authoritative guidance which provides that we should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to our own stock, including evaluating the instrument's contingent exercise and settlement provisions. The effective date for the authoritative guidance for determining whether an instrument (or an embedded feature) is indexed to an entity's own stock is for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early application was not permitted. On January 1, 2009, we adopted the provisions of the authoritative guidance, which did not have a material impact on our consolidated financial statements.

In May 2009, the FASB issued authoritative guidance intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or are available to be issued. The effective date for the authoritative guidance for subsequent event disclosures is for interim or annual financial periods ending after June 15, 2009. We adopted the provisions of the authoritative guidance as of June 30, 2009. The adoption of authoritative guidance had no impact on our consolidated financial statements as we already followed a similar approach prior to the adoption of this standard.

In April 2009, the FASB issued authoritative guidance for the recognition and presentation of other-than-temporary impairments, which amends the other-than-temporary impairment guidance in U.S. GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This authoritative guidance does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. The effective date for the guidance is for financial statements issued for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. We adopted the provisions of the authoritative guidance as of June 30, 2009, which had no impact on our consolidated financial statements.

In June 2009, the FASB issued authoritative guidance on the FASB accounting standards codification and the hierarchy of generally accepted accounting principles, which replaces previously issued authoritative guidance for the hierarchy of generally accepted accounting principles and establishes the FASB Accounting Standards Codification™ ( Codification ) as the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The effective date for the guidance is for financial statements issued for interim and annual periods ending after September 15, 2009. We adopted the provisions of the authoritative guidance as of September 30, 2009, which only required a change in disclosure and did not impact our consolidated financial statements.

In October 2009, the FASB issued authoritative guidance for multiple-deliverable revenue arrangements that provides amendments to the criteria for separating consideration in multiple-deliverable arrangements. As a result of these amendments, multiple-deliverable revenue arrangements will be separated in more circumstances than under existing U.S. GAAP by establishing a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. A vendor will be required to determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. This guidance also eliminates the residual method of allocation and will require that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method, which allocates any discount in the overall arrangement proportionally to

**Table of Contents**

each deliverable based on its relative selling price. Expanded disclosures of qualitative and quantitative information regarding application of the multiple-deliverable revenue arrangement guidance are also required under the guidance. The guidance does not apply to arrangements for which industry specific allocation and measurement guidance exists, such as long-term construction contracts and software transactions. This guidance is effective for fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We may elect to adopt the provisions prospectively to new or materially modified arrangements beginning on the effective date or retrospectively to the beginning of the year of adoption if adopted early. We are currently evaluating the impact of this guidance on our consolidated results of operations and financial condition.

In October 2009, the FASB issued authoritative guidance for certain revenue arrangements that include software elements that reduces the types of transactions that fall within the current scope of software revenue recognition guidance. Existing software revenue recognition guidance requires that its provisions be applied to an entire arrangement when the sale of any products or services containing or utilizing software when the software is considered more than incidental to the product or service. As a result of the amendments included in the guidance, many tangible products and services that rely on software will be accounted for under the multiple-element arrangements revenue recognition guidance rather than under the software revenue recognition guidance. Under the guidance, the following components would be excluded from the scope of software revenue recognition guidance: the tangible element of the product, software products bundled with tangible products where the software components and non-software components function together to deliver the product's essential functionality, and undelivered components that relate to software that is essential to the tangible product's functionality. The guidance also provides direction on how to allocate transaction consideration when an arrangement contains both deliverables within the scope of software revenue guidance (software deliverables) and deliverables not within the scope of that guidance (non-software deliverables). The guidance is effective for fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We may elect to adopt the provisions prospectively to new or materially modified arrangements beginning on the effective date or retrospectively to the beginning of the year of adoption if adopted early. However, we must elect the same transition method for this guidance as that chosen for the guidance for multiple-deliverable revenue arrangements. We are currently evaluating the impact of this standard on the consolidated results of operations and financial condition.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.****Interest Rate Risk**

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including money market funds, U.S. Treasury debt and corporate debt securities. Due to the short-term nature of our investments, we believe that we have no material exposure to interest rate risk.

**Foreign Currency Risk**

To date we have recorded no product sales in other than U.S. dollars. We have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

**ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The information required is set forth under Report of Independent Registered Public Accounting Firm, Consolidated Balance Sheets, Consolidated Statements of Operations, Consolidated Statements of Stockholders' Equity (Deficit), Consolidated Statements of Cash Flows and Notes to Consolidated Financial Statements on pages F-2 to F-28 of this annual report.

**Table of Contents**

**DEXCOM, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Stockholders' Equity (Deficit)</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

F-1

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have audited the accompanying consolidated balance sheets of DexCom, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009. Our audits also included the financial statement schedule listed in the index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of DexCom, Inc. at December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 5 to the consolidated financial statements, the Company adopted FASB Accounting Standards Codification Topic 470-20, Debt with Conversion and Other Options, effective as of January 1, 2009 and retroactively adjusted all periods presented in the consolidated financial statements for this change.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), DexCom, Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 9, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 9, 2010

**Table of Contents****DEXCOM, INC.****CONSOLIDATED BALANCE SHEETS**

(In thousands except par value data)

	As of December 31,	
	2009	2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,577	\$ 12,700
Short-term marketable securities, available-for-sale	24,439	14,368
Accounts receivable, net	3,490	1,118
Inventory, net	2,641	2,446
Prepaid and other current assets	2,773	1,426
Total current assets	36,920	32,058
Property and equipment, net	6,422	6,105
Restricted cash	2,414	4,270
Other assets	1,192	1,449
Total assets	\$ 46,948	\$ 43,882
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 5,745	\$ 4,599
Accrued payroll and related expenses	4,406	2,115
Current portion of long-term debt	900	1,931
Current portion of deferred revenue	7,745	6,351
Total current liabilities	18,796	14,996
Long-term portion of deferred revenue		5,669
Other liabilities	840	889
Long-term debt, net of current portion	45,757	41,796
Total liabilities	65,393	63,350
Commitments and contingencies (Note 4)		
Stockholders deficit:		
Preferred stock, \$0.001 par value per share, 5,000 shares authorized; no shares issued and outstanding at December 31, 2009 and December 31, 2008, respectively.		
Common stock, \$0.001 par value per share, 100,000 authorized; 46,324 and 46,045 shares issued and outstanding, respectively, at December 31, 2009, and 30,103 and 29,824 shares issued and outstanding, respectively, at December 31, 2008		
	46	30
Additional paid-in capital	272,730	218,136
Accumulated other comprehensive income (loss)	(13)	50
Accumulated deficit	(291,208)	(237,684)
Total stockholders deficit	(18,445)	(19,468)
Total liabilities and stockholders deficit	\$ 46,948	\$ 43,882

See accompanying notes.





**Table of Contents****DEXCOM, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands except per share data)

	Years Ended December 31,		
	2009	2008	2007
Product revenue	\$ 18,036	\$ 8,108	\$ 4,627
Development grant and other revenue	11,657	1,730	
<b>Total revenue</b>	<b>29,693</b>	<b>9,838</b>	<b>4,627</b>
Product cost of sales	18,216	13,383	12,736
Development and other cost of sales	7,816	1,984	
<b>Total cost of sales</b>	<b>26,032</b>	<b>15,367</b>	<b>12,736</b>
<b>Gross margin (deficit)</b>	<b>3,661</b>	<b>(5,529)</b>	<b>(8,109)</b>
Operating expenses			
Research and development	14,294	19,629	16,131
Selling, general and administrative	35,200	27,669	22,436
<b>Total operating expenses</b>	<b>49,494</b>	<b>47,298</b>	<b>38,567</b>
Operating loss	(45,833)	(52,827)	(46,676)
Other income		34	
Interest income	354	1,220	3,782
Interest expense	(8,045)	(7,283)	(5,560)
<b>Net loss</b>	<b>\$ (53,524)</b>	<b>\$ (58,856)</b>	<b>\$ (48,454)</b>
<b>Basic and diluted net loss per share attributable to common stockholders</b>	<b>\$ (1.21)</b>	<b>\$ (2.00)</b>	<b>\$ (1.71)</b>
Shares used to compute basic and diluted net loss per share attributable to common stockholders	44,347	29,487	28,313

See accompanying notes.

**Table of Contents****DEXCOM, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

(In thousands except per share data)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders equity (deficit)
	Shares	Amount				
Balance at December 31, 2006	28,164	\$ 28	\$ 187,162	\$ 12	\$ (130,374)	\$ 56,828
Purchase of call spread options in connection with the sale of convertible notes			(10,950)			(10,950)
Equity component of convertible debt			25,393			25,393
Settlement of the first tranche of the call spread option	(154)					
Exercise of stock options for cash	464	1	381			382
Issuance of stock for cash	40					
Issuance for Employee Stock Purchase Plan	72		515			515
Share-based compensation for employee stock options and award grants			5,929			5,929
Issuance of stock for services	38		288			288
Comprehensive loss:						
Unrealized gains on available-for-sale investment securities				1		1
Net loss					(48,454)	(48,454)
Comprehensive loss						(48,453)
Balance at December 31, 2007	28,624	\$ 29	\$ 208,718	\$ 13	\$ (178,828)	\$ 29,932
Settlement of the second tranche of the call spread option	(118)					
Exercise of stock options for cash	1,103	1	1,173			1,174
Issuance of stock for cash	92					
Issuance for Employee Stock Purchase Plan	98		588			588
Share-based compensation for employee stock options and award grants			7,477			7,477
Issuance of stock for services	25		180			180
Comprehensive loss:						
Unrealized gains on available-for-sale investment securities				37		37
Net loss					(58,856)	(58,856)
Comprehensive loss						(58,819)
Balance at December 31, 2008	29,824	\$ 30	\$ 218,136	\$ 50	\$ (237,684)	\$ (19,468)
Issuance of stock in follow-on offering in February 2009 at \$3.00 per share for cash, net of offering costs of \$2,409	15,994	16	45,633			45,649
Exercise of stock options for cash	34		120			120
Issuance for Employee Stock Purchase Plan	193		541			541
Share-based compensation for employee stock options and award grants			8,300			8,300
Comprehensive loss:						
Unrealized loss on available-for-sale investment securities				(54)		(54)
Foreign currency translation adjustments				(9)		(9)
Net loss					(53,524)	(53,524)
Comprehensive loss						(53,587)
Balance at December 31, 2009	46,045	\$ 46	\$ 272,730	\$ (13)	\$ (291,208)	\$ (18,445)

See accompanying notes.



**Table of Contents****DEXCOM, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Years Ended December 31,		
	2009	2008	2007
<b>Operating activities</b>			
Net loss	\$ (53,524)	\$ (58,856)	\$ (48,454)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	2,373	3,036	2,912
Share-based compensation	8,366	7,682	6,122
Non-cash restructuring charge	(362)	355	
Amortization of debt issuance costs	246	159	81
Accretion of non-cash interest expense related to convertible notes	4,861	4,059	2,915
Accretion and amortization related to investments, net	891	1	(492)
Compensation expense associated with stock options issued to consultants		1	
Changes in operating assets and liabilities:			
Accounts receivable	(2,372)	(903)	(95)
Inventory	(195)	(1,307)	274
Prepaid and other assets	(1,004)	148	326
Restricted cash	1,856	(3,356)	165
Accounts payable and accrued liabilities	1,508	(291)	1,771
Accrued payroll and related expenses	2,291	(422)	979
Deferred revenue	(4,275)	12,020	
Deferred rent and other liabilities	(49)	223	289
Net cash used in operating activities	(39,389)	(37,451)	(33,207)
<b>Investing activities</b>			
Purchase of available-for-sale marketable securities	(65,270)	(36,986)	(76,944)
Proceeds from the maturity of available-for-sale marketable securities	53,856	63,802	71,943
Purchase of property and equipment	(2,992)	(2,492)	(3,443)
Proceeds from the sale of equipment	302		
Net cash (used in) provided by investing activities	(14,104)	24,324	(8,444)
<b>Financing activities</b>			
Proceeds from issuance of senior convertible notes			60,000
Payment of senior convertible notes issuance costs			(2,728)
Purchase of senior convertible notes call spread options			(10,950)
Net proceeds from issuance of common stock	46,310	1,762	897
Proceeds from equipment loan		3,000	412
Repayment of equipment loan	(1,931)	(2,050)	(1,032)
Net cash provided by financing activities	44,379	2,712	46,599
Effect of exchange rate changes on cash and cash equivalents	(9)		
Increase (decrease) in cash and cash equivalents	(9,123)	(10,415)	4,948
Cash and cash equivalents, beginning of year	12,700	23,115	18,167
Cash and cash equivalents, ending of year	\$ 3,577	\$ 12,700	\$ 23,115

**Non-cash investing and financing transactions:**

Unrealized gain (loss) on marketable securities	\$ (54)	\$ 37	\$ 1
---	---------	-------	------

**Supplemental disclosure of cash flow information:**

Cash paid during the year for interest	\$ 2,932	\$ 3,074	\$ 1,721
--	----------	----------	----------

See accompanying notes.

---

**Table of Contents**

**DEXCOM, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2009**

**1. Organization and Summary of Significant Accounting Policies**

*Organization and Business*

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 by healthcare providers in the hospital for the treatment of both diabetic and non-diabetic patients. Unless the context requires otherwise, the terms we, us, our, the company, or DexCom refer to DexCom, Inc. and its subsidiary. 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, and on February 13, 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. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, and on September 30, 2009, we received CE Mark approval for the SEVEN PLUS. We initiated a limited commercial launch in the European Union in 2008 and 2009. On October 30, 2009, we received CE Mark approval for our blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, but have yet to seek approval for this system from the FDA.

*Basis of Presentation*

The consolidated financial statements include the accounts of DexCom and our wholly owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates*

The preparation of consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles ( GAAP ) requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates. Significant estimates include excess or obsolete inventories, warranty accruals, employee bonus, clinical study expenses, trade show expenses, allowances for returned product, allowance for bad debt, and share-based compensation expense. Excess and obsolete inventories are estimated by identifying the amount of on hand and on order materials compared to expected future sales, taking into account clinical trial and development usage along with new product introductions. Employee bonus estimates are based, in part, on the 2009 bonus plan's authorized target bonus amounts of up to 50%, 40%, 35% and 25% of base salary for our Chief Executive Officer, Chief Administrative Officer, Senior Vice Presidents, and the remainder of our non-sales management employees, respectively, to be awarded from the bonus pool based on the weighted average achievement of certain objectives. The amount of any bonus under the 2009 plan will be predicated on achieving targeted revenue goals and performance milestones. In general, 70% of any bonus paid under the 2009 plan is based on achieving certain annual product revenue goals and 30% is based on achieving certain performance milestones. Clinical trial expenses are accrued based on estimates of progress under related contracts and include initial set up costs as well as ongoing monitoring over multiple sites in the U.S. and abroad. An allowance for refunds for returned products is determined by analyzing the timing and amounts of past refund activity.

*Cash and Cash Equivalents*

We invest our excess cash in bank deposits, money market accounts, and highly liquid debt securities. We consider all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents.

**Table of Contents***Short-Term Marketable Securities*

We have classified our short-term investments as available-for-sale and carry them at fair value with unrealized gains and losses, if any, reported as a separate component of stockholders' equity and included in comprehensive loss. Realized gains and losses are calculated on the specific identification method and recorded as interest income.

*Fair Value of Financial Instruments*

Financial instruments, including cash and cash equivalents, prepaid expenses, accounts payable and accrued liabilities, are carried at cost, which we believe approximates fair value given their short-term nature.

The estimated fair value of our convertible notes is determined by using observable market information and valuation methodologies that correlate fair value with the market price of our common stock. The estimated fair value and carrying amounts of our convertible notes at December 31, 2009 and 2008 were as follows (in thousands):

	December 31, 2009		December 31, 2008	
	Fair Value	Carrying Value	Fair Value	Carrying Value
Convertible notes	\$ 69,661	\$ 45,232	\$ 35,104	\$ 40,371
Letters of Credit				

At December 31, 2009 and 2008, we had irrevocable letters of credit outstanding with a commercial bank for approximately \$914,000 securing our facility leases. The letters of credit are secured by cash and an equal amount of restricted cash has been separately disclosed in the accompanying consolidated balance sheets.

*Concentration of Credit Risk*

Financial instruments which potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investment securities, and accounts receivable. We limit our exposure to credit loss by placing our cash with high credit quality financial institutions. We have established guidelines relative to diversification of our cash and investment securities and their maturities that are intended to secure safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates and changes in our operations and financial position. The following table summarizes customers who accounted for 10% or more of net accounts receivable:

	Years Ended December 31,		
	2009	2008	2007
Customer A	19%		
Customer B	18%	27%	
Customer C	17%		

*Property and Equipment*

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, generally three years for computer equipment, four years for machinery and equipment, and five years for furniture and fixtures, using the straight-line method. Leasehold improvements are stated at cost and amortized over the shorter of the estimated useful lives of the assets or the lease term.

During the fourth quarter of 2009, we sold Edwards Lifesciences certain equipment totaling \$302,000, which were sold at their net book value. We also sold Edwards supplies totaling \$241,000, which were offset against cost of sales and research and development expense.



---

## **Table of Contents**

### *Impairment of Long-Lived Assets*

We will record impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. We have not experienced any material impairment losses on assets used in operations.

### *Share-Based Compensation*

Our share-based employee compensation plans are described in Note 9. We measure and recognize compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants including grants of employee stock options and stock purchases by employees under the Employee Stock Purchase Plan ( ESPP ) based on estimated fair values. Share-based compensation expense recognized for the years ended December 31, 2009, 2008 and 2007 was \$8.4 million, \$7.7 million and \$6.1 million, respectively.

We estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods as share-based compensation expense in our consolidated statement of operations. For the years ended December 31, 2009, 2008, and 2007, our consolidated statement of operations included compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions the previous guidance and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the estimated grant date fair value. We changed our method of attributing the value of share-based compensation to expense from the accelerated multiple-option approach to the straight-line single option method. Compensation expense for all share-based payment awards granted on or prior to December 31, 2005 will continue to be recognized using the accelerated multiple-option approach while compensation expense for all share-based payment awards granted subsequent to December 31, 2005 is recognized using the straight-line single-option method. As share-based compensation expense recognized in the consolidated statement of operations during fiscal 2009, 2008, and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We utilize the Black-Scholes option-pricing model ( Black-Scholes model ) as our method of valuation for share-based awards granted. The Black-Scholes model was previously utilized for our pro forma disclosure. Our determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors.

### *Revenue Recognition*

We sell our durable systems and disposable units through a direct sales force in the United States and through distribution arrangements in the United States and in portions of Europe. Components are individually priced and can be purchased separately or together. We receive payment directly from patients who use our products, as well as from distributors and third party payors. The SEVEN PLUS durable system includes a reusable transmitter, a receiver, a power cord, data management software and a USB cable. Disposable sensors for use with the durable system are sold separately in packages of four. The initial SEVEN PLUS durable system price is not dependent upon the purchase of any amount of disposable sensors. We discontinued sales of our SEVEN durable system in the United States in the first quarter of 2009, although we continues to sell disposable sensors for use with both the SEVEN and SEVEN PLUS durable systems.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Revenue on

---

**Table of Contents**

product sales is recognized upon shipment, which is when title and the risk of loss have been transferred to the customer and there are no other post shipment obligations. With respect to customers who directly pay for products, the products are generally paid for at the time of shipment using a customer's credit card and do not include customer acceptance provisions. We recognize revenue from contracted insurance payors based on the contracted rate. For non-contracted insurance payors, we obtain prior authorization from the payor and recognize revenue based on the estimated collectible amount and historical experience. We also receive a prescription or statement of medical necessity and, for insurance reimbursement customers, an assignment of benefits prior to shipment.

We provide a 30-day money back guarantee program whereby customers who purchase a durable system and a package of four disposable sensors may return the durable system for any reason within thirty days of purchase and receive a full refund of their purchase price. We accrue for estimated returns and/or refunds by reducing revenues and establishing a liability account at the time of shipment based on historical experience.

During 2008 and 2009, we entered into distribution agreements with RGH Enterprises, Inc., or Edgepark, and other distributors that allow the distributors to sell our durable systems and disposable units. Revenue on product sales to distributors is recognized at the time of shipment, which is when title and risk of loss have been transferred to the distributor and there are no other post-shipment obligations. Revenue is recognized based on contracted prices and invoices are either paid by check following the issuance of a purchase order or letter of credit, or they are paid by wire at the time of placing the order. Terms of distributor orders are FOB shipping point (FCA shipping point for international orders). Distributors do not have rights of return per their distribution agreement outside of our standard warranty. We accrue for estimated returns, refunds and rebates by reducing revenues and establishing a liability account at the time of shipment based on historical experience. The distributors typically have a limited timeframe to notify us of any missing, damaged, defective or non-conforming products. For any such products, we shall either, at our option, replace the portion of defective or non-conforming product at no additional cost to the distributor or cancel the order and refund any portion of the price paid to us at that time for the sale in question.

We shipped product directly to Edgepark's customers and recognized \$4.5 million and \$1.2 million in revenue, which represents 15% and 12% of our revenues, respectively, for the twelve months ended December 31, 2009 and 2008. With respect to other distributors which stock inventory of our product and fulfill orders from their inventory, we shipped product to these distributors and recognized \$1.4 million in revenue from these arrangements for the twelve months ended December 31, 2009. We monitor shipments to, and on-hand inventory levels of, these distributors, and at December 31, 2009 these distributors had limited amounts of our product in their year-ending inventory.

We have collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing our technologies. The terms of these agreements typically include multiple deliverables by us (for example, license rights, provision of research and development services and manufacture of clinical materials) in exchange for consideration to us of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development milestones and royalties in the form of a designated percentage of product sales or profits. With the exception of royalties, these types of considerations are classified as development grant and other revenue in our consolidated statements of operations when revenue recognition is appropriate.

Non-refundable license fees are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Multiple element arrangements, such as license, development or other multiple element service arrangements, are analyzed to determine how the arrangement consideration should be allocated among the separate units of accounting, or whether they must be accounted for as a single unit of accounting. We recognize deliverables as revenue upon delivery only if the deliverable has stand-alone value and the fair value of the undelivered performance

## **Table of Contents**

obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting. We use judgment in estimating the value allocable to product revenues or development grant and other revenue based on our estimate of the fair value attributable to the related deliverables.

For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement are recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. The cumulative amount of revenue earned is limited to the cumulative amount of payments received as of the period ending date.

If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance. Deferred revenue amounts are classified as current liabilities to the extent that revenue is expected to be recognized within one year.

Significant management judgment is necessary in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

Under the collaboration agreement with Edwards Lifesciences LLC ( Edwards ) which provided us with a development grant, we recognized \$11.1 million in development revenue, which represents 37% of our total revenues for the twelve months ended December 31, 2009.

### *Warranty Accrual*

Estimated warranty costs are recorded at the time of shipment. We estimate future warranty costs by analyzing the timing, cost and amount of returned product. Assumptions and historical warranty experience are evaluated on at least a quarterly basis to determine the continued appropriateness of such assumptions.

### *Research and Development*

All costs of research and development are expensed as incurred. Research and development expenses primarily include salaries and related costs, overhead, part components, and fees paid to consultants.

### *Foreign Currency*

The consolidated financial statements of our non-U.S. subsidiary, whose functional currency is the Swedish Krona, is translated into U.S. dollars for financial reporting purposes. Assets and liabilities are translated at period-end exchange rates, and revenue and expense transactions are translated at average exchange rates for the period. Cumulative translation adjustments are recognized as part of comprehensive income and are included in accumulated other comprehensive income in the consolidated balance sheet. Gains and losses on transactions denominated in other than the functional currency are reflected in operations.

### *Comprehensive Loss*

We report all components of comprehensive income (loss), including net income (loss), in the consolidated financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments

**Table of Contents**

and foreign currency translation adjustments, shall be reported, net of their related tax effect, to arrive at comprehensive income (loss). Our comprehensive loss is as follows (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Net loss	\$ (53,524)	\$ (58,856)	\$ (48,454)
Unrealized gain (loss) on available-for-sale marketable securities	(54)	37	1
Foreign currency translation adjustments	(9)		
Comprehensive loss	\$ (53,587)	\$ (58,819)	\$ (48,453)

*Inventory*

Inventory is valued at the lower of cost or market value. We make adjustments to reduce the cost of inventory to its net realizable value, if required, for estimated excess, obsolete and potential scrapped inventories. Factors influencing these adjustments include inventories on hand and on order compared to estimated future usage and sales for existing and new products, as well as judgments regarding quality control testing data, and assumptions about the likelihood of scrap and obsolescence. Once written down the adjustments are considered permanent and are not reversed until the related inventory is sold or disposed. We utilize a standard cost system to track inventories on a part-by-part basis that approximates first in, first out. If necessary, adjustments are made to the standard materials, standard labor and standard overhead costs to approximate actual labor and actual overhead costs. The labor and overhead elements of inventory are based on full utilization of our manufacturing capacity.

*Deferred Rent*

Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense accrued and amounts paid under the lease agreement is recorded as deferred rent in the accompanying consolidated balance sheets.

*Income Taxes*

In July 2006, the Financial Accounting Standards Board ( FASB ) issued authoritative guidance for accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement process for recording in the consolidated financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, the accounting standard provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions.

We adopted the guidance as of January 1, 2007. Due to the valuation allowance, the adoption of the guidance did not impact our financial condition, results of operations or cash flows. As a result of the adoption, we recorded a net decrease to deferred tax assets of approximately \$1.8 million and a corresponding reduction to valuation allowance. The following table summarizes the activity related to our gross unrecognized tax benefits (in thousands):

Balance at January 1, 2007	\$ 2,181
Increases related to current year tax positions	405
Balance at December 31, 2007	2,586
Increases related to current year tax positions	491
Balance at December 31, 2008	3,077
Adjustments related to prior year tax positions	51
Increases related to current year tax positions	604

Edgar Filing: DEXCOM INC - Form 10-K

Decreases due to IRC Section 382 limitation

(837)

Balance at December 31, 2009

\$ 2,895

F-12

**Table of Contents**

Due to the valuation allowance, \$51,000 of the total unrecognized tax benefits as of December 31, 2009 would reduce our annual effective tax rate if recognized. Due to the valuation allowance, none of the total unrecognized tax benefits as of December 31, 2008 and 2007 would reduce our annual effective tax rate if recognized.

We file income tax returns in the United States and in various state jurisdictions with varying statutes of limitations. Due to net operating losses incurred, our tax returns from inception to date are subject to examination by taxing authorities. Our policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. As of December 31, 2009, we had no interest or penalties accrued for uncertain tax positions.

*Recent Accounting Pronouncements*

In September 2006, the FASB issued authoritative guidance, which defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. The authoritative guidance for fair value measurements does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. In February 2008, the FASB deferred the effective date of the authoritative guidance for fair value measurements by one year for certain non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). On January 1, 2008, we adopted the provisions of the authoritative guidance for fair value measurements.

The fair value hierarchy described by the authoritative guidance is based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value and include the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table represents our fair value hierarchy for our financial assets (cash equivalents and investments) measured at fair value on a recurring basis as of December 31, 2009 (in thousands):

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Cash equivalents	\$ 1,000			\$ 1,000
Marketable securities, available for sale	\$ 24,439			\$ 24,439
Restricted cash	\$ 2,414			\$ 2,414

We have maintained only Level 1 financial assets during the twelve months ended December 31, 2009.

The book values of cash and cash equivalents, short-term marketable securities, accounts receivable and accounts payable approximate their respective fair values due to the short-term nature of these instruments.

In December 2007, the FASB authoritative guidance which requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy

**Table of Contents**

election. Further, the authoritative guidance for accounting for collaborative arrangements clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to the authoritative guidance for accounting for consideration given by a vendor to a customer. Effective January 1, 2009, we adopted the authoritative guidance for accounting for consideration given by a vendor to a customer, which did not have a material effect on our consolidated financial statements.

In May 2008, the FASB issued authoritative guidance for accounting for convertible debt instruments that may be settled in cash upon conversion. The authoritative guidance requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability and equity components of the instrument. The debt would be recognized at the present value of its cash flows discounted using our nonconvertible debt borrowing rate. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The authoritative guidance also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The effective date of the authoritative guidance is for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. On January 1, 2009, we adopted the provisions of the authoritative guidance which resulted in a reduction to the historical carrying value of the 4.75% convertible senior notes due in 2027 on our balance sheet of \$26.6 million, a reduction to the carrying value of the debt issuance costs of \$1.2 million, and a corresponding increase to paid in capital as of the date of issuance. Our estimated non-convertible borrowing rate of 19.5% was applied to the notes and coupon interest using a present value technique to arrive at the fair value of the liability component. The adoption of the authoritative guidance also resulted in an increase in accumulated deficit of \$6.2 million and a corresponding net decrease to the carrying value of the debt discount and issuance costs as of January 1, 2009. We recorded non-cash interest expense relating to the amortization of the debt discount in the amounts of \$4.9 million and \$4.1 million for the twelve months ended December 31, 2009 and 2008, respectively. We recorded interest expense relating to the contractual coupon payments in the amounts of \$2.9 million for each of the twelve months ended December 31, 2009 and 2008, respectively. The impact of adoption of the authoritative guidance was an increase to loss per share of \$0.09 and \$0.13 for the twelve months ended December 31, 2009 and 2008, respectively.

The following table sets forth our net carrying amount of the 4.75% convertible senior notes, which is included in long-term debt in the consolidated balance sheets (in thousands):

	December 31, 2009	December 31, 2008
Principal of convertible notes	\$ 60,000	\$ 60,000
Unamortized debt discount	(14,768)	(19,629)
<b>Net carrying amount of convertible notes</b>	<b>\$ 45,232</b>	<b>\$ 40,371</b>

The remaining unamortized debt discount will be amortized over the expected life of the convertible notes, which was determined to be the date of the first put option on March 15, 2012.

In June 2008, the FASB issued authoritative guidance which provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. The effective date for the authoritative guidance for determining whether an instrument (or an embedded feature) is indexed to an entity's own stock is for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early application was not permitted. On January 1, 2009, we adopted the provisions of the authoritative guidance, which did not have a material impact on our consolidated financial statements.

In May 2009, the FASB issued authoritative guidance intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued

---

**Table of Contents**

or are available to be issued. The effective date for the authoritative guidance for subsequent event disclosures is for interim or annual financial periods ending after June 15, 2009. We adopted the provisions of the authoritative guidance as of June 30, 2009. The adoption of the authoritative guidance had no impact on our consolidated financial statements as management already followed a similar approach prior to the adoption of this standard.

In April 2009, the FASB issued authoritative guidance for the recognition and presentation of other-than-temporary impairments, which amends the other-than-temporary impairment guidance in U.S. GAAP for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. This authoritative guidance does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. The effective date for the guidance is for financial statements issued for interim and annual reporting periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. We adopted the provisions of the authoritative guidance as of June 30, 2009, which had no impact on our consolidated financial statements.

In June 2009, the FASB issued authoritative guidance on the FASB accounting standards codification and the hierarchy of generally accepted accounting principles, which replaces previously issued authoritative guidance for the hierarchy of generally accepted accounting principles, and establishes the FASB Accounting Standards Codification ( Codification ) as the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The effective date for the guidance is for financial statements issued for interim and annual periods ending after September 15, 2009. We adopted the provisions of the authoritative guidance as of September 30, 2009, which only required a change in disclosure and did not impact our consolidated financial statements.

In October 2009, the FASB issued authoritative guidance for multiple-deliverable revenue arrangements that provides amendments to the criteria for separating consideration in multiple-deliverable arrangements. As a result of these amendments, multiple-deliverable revenue arrangements will be separated in more circumstances than under existing U.S. GAAP by establishing a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. A vendor will be required to determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. This guidance also eliminates the residual method of allocation and will require that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method, which allocates any discount in the overall arrangement proportionally to each deliverable based on its relative selling price. Expanded disclosures of qualitative and quantitative information regarding application of the multiple-deliverable revenue arrangement guidance are also required under the guidance. The guidance does not apply to arrangements for which industry specific allocation and measurement guidance exists, such as long-term construction contracts and software transactions. This guidance is effective for fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We may elect to adopt the provisions prospectively to new or materially modified arrangements beginning on the effective date or retrospectively to the beginning of the year of adoption if adopted early. We are currently evaluating the impact of this guidance on our consolidated results of operations and financial condition.

In October 2009, the FASB issued authoritative guidance for certain revenue arrangements that include software elements that reduces the types of transactions that fall within the current scope of software revenue recognition guidance. Existing software revenue recognition guidance requires that its provisions be applied to an entire arrangement when the sale of any products or services containing or utilizing software when the software is considered more than incidental to the product or service. As a result of the amendments included in the guidance, many tangible products and services that rely on software will be accounted for under the multiple- element arrangements revenue recognition guidance rather than under the software revenue recognition guidance. Under the guidance, the following components would be excluded from the scope of software revenue



**Table of Contents**

recognition guidance: the tangible element of the product, software products bundled with tangible products where the software components and non-software components function together to deliver the product's essential functionality, and undelivered components that relate to software that is essential to the tangible product's functionality. The guidance also provides direction on how to allocate transaction consideration when an arrangement contains both deliverables within the scope of software revenue guidance (software deliverables) and deliverables not within the scope of that guidance (non-software deliverables). The guidance is effective for fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We may elect to adopt the provisions prospectively to new or materially modified arrangements beginning on the effective date or retrospectively to the beginning of the year of adoption if adopted early. However, we must elect the same transition method for this guidance as that chosen for the guidance for multiple-deliverable revenue arrangements. We are currently evaluating the impact of this standard on the consolidated results of operations and financial condition.

**2. Net Loss Per Common Share**

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, options, and the conversion of convertible senior notes are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Historical outstanding anti-dilutive securities not included in diluted net loss per share attributable to common stockholders calculation (in thousands):

	December 31,		
	2009	2008	2007
Options outstanding to purchase common stock	7,972	7,112	5,900
Restricted stock	31	75	43
Convertible senior notes	7,692	7,692	7,692
Total	15,695	14,879	13,635

**3. Financial Statement Details***Short Term Marketable Securities, Available for Sale*

As described in Note 1, short-term investment securities, consisting solely of debt securities with contractual maturities of less than one year, were as follows (in thousands):

	December 31, 2009			Estimated Market Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government agencies	\$ 16,198	\$ 7	\$ (10)	\$ 16,195
Commercial paper	8,244	1	(1)	8,244
Total	\$ 24,442	\$ 8	\$ (11)	\$ 24,439

**Table of Contents**

	Amortized Cost	December 31, 2008		Estimated Market Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government agencies	\$ 12,288	\$ 49	\$	\$ 12,337
Corporate debt	2,030	2	(1)	2,031
<b>Total</b>	<b>\$ 14,318</b>	<b>\$ 51</b>	<b>\$ (1)</b>	<b>\$ 14,368</b>

*Accounts Receivable*

	December 31,	
	2009	2008
Accounts receivable	\$ 3,811	\$ 1,247
Less allowance for doubtful accounts and sales returns	(321)	(129)
<b>Total</b>	<b>\$ 3,490</b>	<b>\$ 1,118</b>

*Inventory*

	December 31,	
	2009	2008
Raw materials	\$ 1,613	\$ 1,426
Work in process	398	198
Finished goods	630	822
<b>Total</b>	<b>\$ 2,641</b>	<b>\$ 2,446</b>

*Property and Equipment*

	December 31,	
	2009	2008
Furniture and fixtures	\$ 1,408	\$ 1,182
Computer equipment	4,258	3,227
Machinery and equipment	8,712	7,477
Leasehold improvements	4,843	4,764
<b>Total</b>	<b>19,221</b>	<b>16,650</b>
Accumulated depreciation and amortization	(12,799)	(10,545)
<b>Property and equipment, net</b>	<b>\$ 6,422</b>	<b>\$ 6,105</b>

Depreciation and amortization expense for the years ended December 31, 2009, 2008, and 2007 was \$2.4 million, \$3.0 million, and \$2.9 million, respectively.

*Accounts Payable and Accrued Liabilities*

Edgar Filing: DEXCOM INC - Form 10-K

	December 31,	
	2009	2008
Accounts payable trade	\$ 2,600	\$ 1,123
Accrued tax, audit, and legal fees	761	426
Clinical trials	238	132
Accrued interest on convertible debt	831	831
Accrued other including warranty	1,315	2,087
 Total	 \$ 5,745	 \$ 4,599

F-17

**Table of Contents***Accrued Payroll and Related Expenses*

	December 31,	
	2009	2008
Accrued paid time off	\$ 1,254	\$ 893
Accrued wages, bonus and taxes	2,779	928
Other accrued employee benefits	373	294
Total	\$ 4,406	\$ 2,115

*Accrued Warranty*

	Year Ended December 31,	
	2009	2008
Beginning balance	\$ 71	\$ 52
Charges to costs and expenses	1,223	615
Costs incurred	(1,165)	(596)
Ending balance	\$ 129	\$ 71

**4. Commitments and contingencies***Equipment Line*

In March 2006, we entered into a loan and security agreement (the *Loan Agreement*) that provided for up to \$5.0 million to finance various equipment purchases through March 2007. In January 2008, we entered into an amendment to the *Loan Agreement* to finance additional equipment purchases. The amendment allows us to draw an additional amount of up to \$3.0 million under a new and additional Facility B Equipment Line.

At December 31, 2009, we had total borrowings of \$1.4 million under the *Loan Agreement* pursuant to the Facility A Equipment Line and Facility B Equipment Line and none was available for future borrowings. The loan bears an interest rate equal to the lender's prime rate plus 0.25% and at December 31, 2009, the interest rate was 3.5%. Beginning April 2008, terms of the Facility B Equipment Line began to require monthly amortized payments through the maturity date of July 2011. Under the amended *Loan Agreement*, we continue to grant a security interest in substantially all of our personal property as collateral for the loan and are required to maintain cash balances equal to total outstanding loan balances with the lender.

*Convertible Senior Notes*

In March 2007, we issued \$60 million aggregate principal amount of Convertible Senior Notes due 2027 in a private offering. The notes are convertible into shares of common stock based on an initial conversion rate of 128.2051 shares of common stock per \$1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately \$7.80 per share.

Interest on the notes is due semiannually on March 15 and September 15 of each year at a rate of 4.75% per year. The notes are redeemable by us beginning March 20, 2010 at a price equal to 100% of the principal amount to be redeemed plus accrued and unpaid interest. Holders of the notes may require us to repurchase the notes for cash equal to 100% of the principal amount to be repurchased plus accrued and unpaid interest upon the occurrence of certain designated events, including a change of control. In addition, we will have the right to automatically convert the notes if the closing price of our common stock exceeds 150% of the conversion price, or \$11.70 per share, for at least 20 trading days during any 30-day period. If such an automatic conversion occurs



**Table of Contents**

before March 15, 2010, we are required to pay additional interest in cash or, at our option, in shares of our common stock, equal to three full years of interest on the converted notes, less any interest actually paid or provided for on the notes prior to automatic conversion. The holders of the notes may require us to repurchase the notes for cash on March 15, 2012, March 15, 2017 and March 15, 2022 at a repurchase price equal to 100% of the principal amount, plus accrued and unpaid interest. The notes contain no financial covenants, and therefore, the note holders do not have protection against adverse changes in our business, and have limited protections in the event of a fundamental change to the Company.

The aggregate underwriting commissions and other debt issuance costs incurred with respect to the issuance of the notes was \$2.7 million. These costs have been allocated to the debt and equity components of the convertible debt per the guidance for accounting for convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement), and capitalized as debt issuance costs on our consolidated balance sheet and are being amortized through March 15, 2012 which is the first date holders may require us to repurchase the notes. As of December 31, 2009, the remaining unamortized costs totaled \$1.0 million.

Repayment obligations for the convertible senior notes and equipment lines as of December 31, 2009 were as follows (in thousands):

<b>Fiscal Year Ending</b>	
2010	900
2011	525
2012	60,000
2013	
Thereafter	
<b>Total</b>	<b>\$ 61,425</b>

*Call Spread Option*

In March 2007, we entered into hedge transactions to minimize the potential dilution of our common stock upon conversion of the Convertible Senior Notes if our stock price exceeds \$7.80 per share through March 2009. We had the right to purchase a number of shares of common stock equal to the number of shares underlying the \$60 million principal amount of the notes, at a strike price equal to the conversion price of the notes, or \$7.80 per share. The call spread options were structured in four tranches with one tranche expiring in each six-month interval for two years from the date of March 6, 2007. Each of the four options capped the potential benefit to us at market prices ranging from \$9.00 for the option which expired in September 2007 to \$18.50 for the option which expired in March 2009. The call spread options were separate transactions entered into by us and were not part of the terms of the Convertible Senior Notes.

In accordance with authoritative guidance for accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, we recorded the \$11.0 million cost of the call spread transactions as a net reduction in paid in capital in the Balance Sheet for the quarter ended March 31, 2007, and will not recognize subsequent changes in fair value. During September 2007, we received approximately 154,000 shares of our common stock with a value of \$1.4 million on the date the shares were returned to us as settlement of the first tranche. During March 2008, we received approximately 118,000 shares of our common stock with a value of \$869,000 on the date the shares were returned to us as settlement for the second tranche.

*Leases*

In January 2007, we entered into a sublease agreement to sublet an existing facility near our corporate headquarters to a third party. Under the terms of the agreement, we sublet approximately 7,000 square feet of facilities space at terms and conditions, including real estate taxes and operating costs, which mirror the original lease agreement. We retain obligations per the original lease. Rental obligations, excluding real estate taxes and

**Table of Contents**

operating costs, owed by us, but subject to reimbursement by the subtenant in accordance with the terms of the sublease agreement, as of December 31, 2009, were as follows (in thousands):

<b>Fiscal Year Ending</b>	
2010	114
2011	48
Total	\$ 162

We maintain our headquarters in San Diego, California in one leased facility of approximately 66,400 square feet which expires in 2014. We have the right to extend the term of this lease for one period of five years. We also currently maintain a second lease for approximately 23,000 square feet which expires in 2011. These facility leases have annual rental increases ranging from approximately 2.5% to 4.0%. The difference between the straight-line expense over the term of the lease and actual amounts paid are recorded as deferred rent. In November 2007, we entered into a one year lease for approximately 1,200 square feet of storage. In November 2008, we renewed the lease of the storage facility for an additional year. In September 2008, our subsidiary in Sweden entered into a three year lease for a small shared office space, which has a quarterly adjustment clause for rent to increase or decrease in proportion to changes in consumer prices. Rental obligations, excluding real estate taxes, operating costs, and tenant improvement allowances, under all lease agreements as of December 31, 2009 were as follows (in thousands):

<b>Fiscal Year Ending</b>	
2010	1,731
2011	1,457
2012	1,326
2013	1,379
Thereafter	472
Total	\$ 6,365

Rent expense for the years ended December 31, 2009, 2008, and 2007 was \$1.5 million, \$2.2 million, and \$1.5 million, respectively.

*Litigation*

On August 11, 2005, Abbott Diabetes Care, Inc., or 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, or 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

## **Table of Contents**

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.

Each of the seven patents described above have one or more associated reexamination requests in various stages at the Patent Office. 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, and/or seeking to add new claims. With regard to the four patents originally asserted, two of the patents are in the Appeal process and two of the patents have been issued a Certificate of Reexamination. With regard to the two patents in the Appeal process, all of the claims for which reexamination was requested currently stand rejected and Abbott has filed an Appeal Brief in each of the cases. Each of the two Examiner's Answers maintained all rejections. We also filed a second and a third reexamination request against each of the two patents in the Appeal process. The Patent Office denied the second requests and ordered reexamination of certain claims raised in the third requests for each of the two patents. With regard to the two patents for which a Certificate of Reexamination has been issued, subsequent reexamination requests have been filed and the determination has been issued ordering reexamination for each of the two patents. With regard to the three patents subsequently asserted, the first patent has recently been issued a Certificate of Reexamination, the second patent has been issued a Notice of Intent to Issue a Reexamination Certificate and the third one is under non-final rejection. A subsequent reexamination request has been granted for the first patent and a subsequent reexamination request has been filed for the second patent. In the non-finally rejected case, 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, and/or seeking to add new claims.

In 2008 and 2009, Abbott 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 an interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also in 2008, Abbott filed reexamination requests seeking to invalidate two of our patents in the Patent Office. In both reexamination requests, the Patent Office ordered the reexamination and issued non-final office actions and we responded to those non-final office actions by seeking claim construction to differentiate certain claims from the prior art, seeking to amend certain claims to overcome the prior art, and canceling certain claims. In one of the proceedings, Abbott recently appealed the Examiner's decision to confirm the patentability of our original and amended claims. In the other proceeding, we have filed an Amendment to allow the claims the Examiner has indicated are patentable to stand on their own, to address the Examiner's rejections of other claims based on form, to seek clarification of the basis for the Examiner's rejections of certain claims based on the prior art and to ask reconsideration of the rejections, to which the Examiner has recently issued an action maintaining his positions with a Right of Appeal Notice.

Although it is our position that Abbott's assertions of infringement have no merit, and that the potential interference and reexamination requests 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.

### *Purchase Commitments*

We are party to various purchase arrangements related to our development activities including materials used in our glucose monitoring systems. As of December 31, 2009, we had purchase commitments with vendors totaling \$3.8 million due within one year. There are no purchase commitments due beyond one year.



---

## **Table of Contents**

### **5. Development Agreements**

#### *Insulet Corporation*

On January 7, 2008, we entered into a development agreement with Insulet Corporation ( *Insulet* ) to integrate our continuous glucose monitoring technology into Insulet's wireless, handheld OmniPod System Personal Diabetes Manager. The agreement is non-exclusive and does not impact either party's existing third party development agreements.

#### *Animas Corporation*

On January 10, 2008, as amended on January 12, 2009 and July 30, 2009 ( *the Animas Amendments* ), we entered into a joint development agreement with Animas Corporation ( *Animas* ) to integrate our continuous glucose monitoring technology into Animas insulin pumps. Under the terms of the amended agreement, Animas will contribute up to \$1.1 million to DexCom to offset certain development, clinical and regulatory expenses. The agreement is non-exclusive in the United States, but exclusive outside the United States and does not impact either party's existing third party development agreements. In January of 2008 we received \$500,000. In January of 2009 we received \$250,000. We recorded \$279,000 in revenue for the twelve months ended December 31, 2009, compared to \$183,000 for the same period in 2008. Pursuant to the Animas Amendments, we will collaborate with Animas to develop a modified version of our transmitter to support a single, global CGM-enabled insulin pump launch by Animas. We are entitled to receive a one-time \$1.0 million milestone payment upon the achievement of performance qualification of a manufacturing line for the modified transmitter and are also entitled to receive an additional one-time \$4.0 million payment upon the first regulatory body approval outside the United States for the new system. The Animas Amendments modify the original \$5.0 million milestone payment that we were entitled to receive upon receipt of a CE Mark for the first commercializable OUS product.

#### *Edwards Lifesciences LLC*

On November 10, 2008, and as amended on May 5, 2009, we entered into a Collaboration Agreement (the *Agreement* ) with Edwards. Pursuant to the Agreement, we and Edwards agreed to develop jointly and to market an in-hospital continuous blood glucose monitoring system. Under the terms of the Agreement, Edwards was obligated to pay us an upfront fee of \$13.0 million. In addition, we are entitled to receive up to \$22.0 million, as revised, over the next three years for product development costs and milestones related to regulatory approvals and manufacturing readiness. We will also receive either a profit-sharing payment of up to 10% of commercial sales of the product, or a royalty of up to 6% of commercial sales of the product. The Agreement provides Edwards with an exclusive license under our intellectual property in the hospital market. Edwards will be responsible for global sales and marketing, and we will initially be responsible for manufacturing. In November 2008 we received \$13.0 million. We received \$7.0 million during the twelve months ended December 31, 2009. We recorded \$11.1 million in revenue for the twelve months ended December 31, 2009, compared to \$1.5 million for the same period in 2008.

### **6. Stockholders' Equity**

#### *Follow-on Stock Offering*

In February 2009, we completed a public follow-on stock offering of 15,994,000 shares of our common stock for net proceeds of approximately \$45.6 million.

### **7. Income Taxes**

We have recorded a net tax benefit of \$15,000 and \$34,000 for the years ended December 31, 2009 and 2008, respectively, related to refundable income tax credits and foreign income tax expense. The amounts have been included in other income in the consolidated financial statements.

At December 31, 2009, we had federal and state tax net operating loss carryforwards of approximately \$203.2 million and \$138.3 million, respectively. The federal and state tax loss carryforwards will begin to expire

**Table of Contents**

in 2019 and 2011, respectively, unless previously utilized. We also had federal and state research and development tax credit carryforwards of approximately \$2.3 million and \$4.7 million, respectively. The federal research and development tax credit will begin to expire in 2019, unless previously utilized.

Utilization of net operating losses and credit carryforwards are subject to an annual limitation due to ownership change limitations provided by Section 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions. An ownership change limitation occurred as a result of the stock offering completed in February 2009. The limitation will likely result in approximately \$2.1 million of U.S. income tax credits and approximately \$9.2 million of state net operating loss carryforwards that will expire unused. The related deferred tax assets have been removed from the components of our deferred tax assets as summarized below. The tax benefits related to the remaining federal and state net operating losses and tax credit carryforwards may be further limited or lost if future cumulative changes in ownership exceed 50% within any three-year period.

Significant components of our deferred tax assets as of December 31, 2009 and 2008 are shown below (in thousands). A valuation allowance of approximately \$97.4 million has been established as of December 31, 2009 to offset the deferred tax assets, as realization of such assets is uncertain.

	December 31,	
	2009	2008
Deferred tax assets:		
Net operating loss carryforwards	\$ 75,325	\$ 64,165
Capitalized research and development expenses	16,578	12,780
Tax credits	3,165	3,748
Share-based compensation	5,627	3,831
Fixed and intangible assets	1,358	1,149
Other, net	815	648
Total gross deferred tax assets	102,868	86,321
Less: valuation allowance	(97,353)	(78,922)
Net deferred tax assets	5,515	7,399
Deferred tax liabilities		
Convertible debt	(5,515)	(7,399)
Net deferred tax assets	\$	\$

As a result of the adoption of authoritative guidance for share-based payment we recognized windfall tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss carryforwards resulting from windfall tax benefits occurring from January 1, 2006 onward. At December 31, 2009, deferred tax assets do not include \$3.6 million of excess tax benefits from share-based compensation.

The reconciliation between our effective tax rate on income (loss) from continuing operations and the statutory rate is as follows:

	2009	December 31,	
		2008	2007
Income taxes (benefit) at statutory rates	35.00%	35.00%	35.00%
State income tax, net of federal benefit	3.16%	3.06%	1.54%
Permanent items	(2.20)%	(1.58)%	(2.11)%
Research and development credits	2.32%	1.77%	1.72%
Tax attribute carryover limitation	(4.89)%		
Other	1.09%	(1.23)%	(1.39)%
Change in valuation allowance	(34.45)%	(36.96)%	(34.76)%

0.03%

0.06%

0.00%

F-23

---

**Table of Contents****8. Related Party Transactions**

Our Chairman is a director of Oracle Corporation. Costs incurred relating to an Oracle ERP system for the years ended December 31, 2009, 2008 and 2007 totaled \$94,000, \$105,000, and \$96,000, respectively.

**9. Employee Benefit Plans***401(k) Plan*

We have a defined contribution 401(k) retirement plan, or the 401(k) Plan, covering substantially all employees that meet certain age requirements. Employees may contribute up to 90% of their compensation per year (subject to a maximum limit by federal tax law). Under the 401(k) Plan, we may elect to match a discretionary percentage of contributions. No such matching contributions have been made to the 401(k) Plan since its inception.

*Employee Stock Purchase Plan*

The Employee Stock Purchase Plan permits eligible employees of the Company to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 10% of the participant's cash compensation subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair market value of the stock at either the beginning of the applicable Offering Period or the Purchase Date. Except for the First Offering Period, each Offering Period is 12 months, with new Offering Periods commencing every six months on the dates of February 1 and August 1 of each year. Each Offering Period consists of two (2) six month purchase periods (each a Purchase Period) during which payroll deductions of the participants are accumulated under the ESPP. The last business day of each Purchase Period is referred to as the Purchase Date. The First Offering Period ran from April 13, 2005 to July 31, 2006 and included the Purchase Dates of January 31 and July 31 of 2006. Thereafter, Purchase Dates are every six months on the dates of January 31 and July 31. Annually in January of each year, subject to Board discretion and certain limitations, shares reserved for the ESPP will automatically be increased by a number of shares equal to 1% of the total number of issued and outstanding shares of our common stock at the preceding year end. On January 31, 2007, July 31, 2007, January 31, 2008, July 31, 2008, January 30, 2009 and July 31, 2009, we issued 33,621, 38,154, 48,584, 49,238, 84,062, and 108,629 respectively, shares of common stock under the ESPP.

*Equity Incentive Plans*

In 2005, we adopted the 2005 Equity Incentive Plan (2005 Plan) which replaced the 1999 Incentive Stock Plan and provides for the grant of incentive and nonstatutory stock options, restricted stock, stock bonuses, stock appreciation rights, and restricted stock units to employees, directors or consultants of the Company. Shares reserved include all shares that were available under the 1999 Incentive Stock Plan on the day it was terminated. Options generally vest over four years and expire ten years from the date of grant. In addition, incentive stock options may not be granted at a price less than the 100% of the fair market value on the date of grant. The term of the 2005 Plan is scheduled to end in March 2015. Annually in January of each year, subject to Board discretion and certain limitations, shares reserved for the 2005 Plan will automatically be increased by a number of shares equal to 3% of the total number of issued and outstanding shares of our common stock during the preceding year end.

**Table of Contents**

A summary of our stock option activity, and related information for the three years ended December 31, 2009, 2008 and 2007 is as follows (in thousands except per share data):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2006	3,991	\$ 8.13		
Granted	3,016	\$ 7.63		
Exercised	(464)	\$ 0.82		
Cancelled	(643)	\$ 12.17		
Outstanding at December 31, 2007	5,900	\$ 6.46		
Granted	3,676	\$ 5.75		
Exercised	(1,110)	\$ 1.07		
Cancelled	(1,354)	\$ 10.48		
Outstanding at December 31, 2008	7,112	\$ 9.18		
Granted	1,189	\$ 5.56		
Exercised	(35)	\$ 3.43		
Cancelled	(294)	\$ 9.47		
Outstanding at December 31, 2009	7,972	\$ 7.12	8.0	14,966
Exercisable at December 31, 2009	4,292	\$ 8.17	7.4	6,248

The weighted average fair values of options granted was \$3.42, \$3.00, and \$4.09 for the three years ended December 31, 2009, 2008, and 2007, respectively. The total intrinsic value of options exercised was \$110,000, \$7.8 million, and \$3.8 million determined as of the date of exercise during the years ended December 31, 2009, 2008, and 2007, respectively.

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected life of our employee stock options and stock purchase plan. The dividend yield assumption is based on our history and expectation of dividend payouts.

Due to our limited history as a publicly traded company that began in April 2005, our expected volatility is based on both our historical stock prices and the historical prices of similar companies, as determined by us. Accordingly, we used the simplified method to determine the expected life.

As share-based compensation expense recognized in the consolidated statement of operations for fiscal 2009, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Authoritative guidance for share-based payment requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. In our pro forma information required under the guidance for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

**Table of Contents**

The following table summarizes information about stock options outstanding at December 31, 2009 (in thousands except for exercise price and contractual life):

Range of Exercise Price	Options Outstanding			Options Exercisable			
	Number of Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$0.30 \$2.40	328	4.9	\$ 1.61	\$ 2,121	303	\$ 1.58	\$ 1,970
\$3.19 \$4.71	2,008	9.0	\$ 3.58	9,023	570	\$ 3.75	2,459
\$5.05 \$8.06	3,762	8.2	\$ 7.05	3,822	1,950	\$ 7.14	1,819
\$8.26 \$9.56	932	7.8	\$ 8.93		602	\$ 8.93	
\$10.00 \$19.75	663	6.0	\$ 12.44		604	\$ 12.53	
\$20.05 \$25.80	279	6.3	\$ 21.23		263	\$ 21.21	
\$0.30 \$25.80	7,972	8.0	\$ 7.12	\$ 14,966	4,292	\$ 8.17	\$ 6,248

We define in-the-money options at December 31, 2009 as options that had exercise prices that were lower than the \$8.07 closing market price of our common stock at that date. The aggregate intrinsic value of options outstanding at December 31, 2009 is calculated as the difference between the exercise price of the underlying options and the market price of our common stock for the 6.1 million options that were in-the-money at that date. There were 2.8 million in-the-money options exercisable at December 31, 2009.

The following table sets forth a summary of our nonvested stock options and activity as of and for the year ended December 31, 2009:

	Shares (in thousands)	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2008	4,655	\$ 3.43
Granted	1,189	3.42
Vested	(1,871)	4.11
Forfeited	(294)	4.93
Nonvested at December 31, 2009	3,679	\$ 3.23

*Valuation and expense information*

The following table summarizes share-based compensation expense related to employee stock options and employee stock purchases for the years ended December 31, 2009, 2008 and 2007 were allocated as follows (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Cost of sales	\$ 580	\$ 561	\$ 385
Research and development	1,850	1,740	1,797
Selling, general and administrative	5,936	5,382	3,940
Share-based compensation expense included in operating expenses	\$ 8,366	\$ 7,683	\$ 6,122



**Table of Contents**

We estimated the fair value of each option grant and ESPP purchase rights on the date of grant using the Black-Scholes option pricing model with the below assumptions.

Options:

	Years Ended December 31,			
	2009	2008	2007	2007
Risk free interest rate	2.0	2.8%	4.5%	4.6%
Dividend yield		0%	0%	0%
Expected volatility of the Company's stock	0.63	0.67	0.48	0.50
Expected life (in years)		6.1	6.1	6.1

ESPP:

	Years Ended December 31,				
	2009	2008	2008	2007	2007
Risk free interest rate	0.5	1.0%	4.6%	5.0	5.16%
Dividend yield		0%	0%		0%
Expected volatility of the Company's stock	0.69	0.91	0.48		0.50
Expected life (in years)		1	1		1

*Restricted Stock Awards*

We have periodically granted unvested restricted common stock awards to certain employees. As of December 31, 2009, a total of 151,963 such shares had been granted. The grant awards typically vest 25% annually and are fully vested following the fourth anniversary of the vesting start date. In 2008, we granted 92,213 shares of restricted stock to our President and CEO pursuant to an amended offer letter. These shares vest monthly and are fully vested following the thirtieth month after the vesting start date. Vesting of all restricted common stock awards is subject to continued employment and we have the right to repurchase unvested shares at the original issuance price of \$0.001 per share subject to certain terms and conditions. The shares had a weighted-average fair value of \$8.64 per share at date of grant. As of December 31, 2009, there were 31,333 shares subject to repurchase with an intrinsic value of \$253,000.

*Reserved Shares*

We have reserved shares of common stock for future issuance as follows (in thousands):

	December 31,	
	2009	2008
Stock options and awards under our plans:		
Granted and outstanding	7,972	7,112
Reserved for future grant	136	135
Employee Stock Purchase Plan	849	743
Convertible senior notes	7,692	7,692
Total	16,649	15,682



**Table of Contents****10. Quarterly Financial Information (Unaudited)**

The following is a summary of the quarterly results of operations for the years ended December 31, 2009 and 2008 (in thousands except per share data):

	December 31	For the Three Months Ended		
		September 30	June 30	March 31
<b>Year ended December 31, 2009</b>				
Revenues	\$ 10,471	\$ 7,259	\$ 6,751	\$ 5,212
Gross margin (deficit)	4,107	865	(1,048)	(263)
Total operating costs	13,569	12,444	12,407	11,074
Net loss attributable to common stockholders	(11,529)	(13,523)	(15,330)	(13,142)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.25)	\$ (0.29)	\$ (0.33)	\$ (0.33)
<b>Year ended December 31, 2008</b>				
Revenues	\$ 4,074	\$ 1,920	\$ 1,982	\$ 1,862
Gross margin (deficit)	(818)	(1,920)	(1,411)	(1,380)
Total operating costs	11,920	12,070	12,044	11,264
Net loss attributable to common stockholders	(14,445)	(15,631)	(14,966)	(13,814)
Basic and diluted net loss per share attributable to common stockholders	\$ (0.49)	\$ (0.53)	\$ (0.51)	\$ (0.47)

**11. Subsequent Events***Follow-on Stock Offering*

In January 2010, we completed a public follow-on stock offering, selling an aggregate of 4,025,000 shares of our common stock for net proceeds of approximately \$33.1 million, after deducting underwriting discounts, commissions and estimated offering expenses.

From January 1, 2010 to March 9, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of 2.7 million shares of our common stock, par value \$0.001 per share, in exchange for \$20.3 million in aggregate principal amount of the Notes previously held by the exchanging holders.

**Table of Contents****SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS****For the Years Ended December 31, 2009, 2008 and 2007****(in thousands)**

<b>Allowance for doubtful accounts</b>	
Balance December 31, 2006	\$ 5
Provision for doubtful accounts	74
Write-off and adjustments	(54)
Recoveries	
Balance December 31, 2007	\$ 25
<b>Allowance for doubtful accounts</b>	
Balance December 31, 2007	\$ 25
Provision for doubtful accounts	61
Write-off and adjustments	(19)
Recoveries	
Balance December 31, 2008	\$ 67
<b>Allowance for doubtful accounts</b>	
Balance December 31, 2008	\$ 67
Provision for doubtful accounts	356
Write-off and adjustments	(137)
Recoveries	
Balance December 31, 2009	\$ 286

---

**Table of Contents**

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES.**

*Disclosure Controls and Procedures*

Regulations under the Securities Exchange Act of 1934 require public companies to maintain disclosure controls and procedures, which are defined to mean a company's controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and timely communicated to management, including our Chief Executive Officer and Chief Financial Officer, recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures. Based on their evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective for this purpose.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during our last fiscal year that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

*Management's Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements.

Our management, with the participation of the Chief Executive and Chief Financial Officers, assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. Based on this assessment, our management, with the participation of the Chief Executive and Chief Financial Officers, believes that, as of December 31, 2009, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by Ernst & Young LLP an independent Public Registered Accounting firm, as stated in their report which is included herein.

The certifications of our Chief Executive Officer and Chief Financial Officer required under Section 302 of the Sarbanes-Oxley Act have been filed as Exhibits 31.01 and 31.02 to this report.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

**Limitation on Effectiveness of Controls**

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of DexCom, Inc.

We have audited DexCom, Inc.'s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). DexCom, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, DexCom, Inc. maintained in all material respects effective internal control over financial reporting as of December 31, 2009 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of DexCom, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009 of DexCom, Inc. and our report dated March 9, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California

March 9, 2010

**ITEM 9B. OTHER INFORMATION.**

None.

**Table of Contents**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information concerning our directors required by this Item is incorporated by reference to the section in our Proxy Statement entitled Proposal No. 1 Election of Directors.

The information concerning our executive officers required by this Item is incorporated by reference to the section in our Proxy Statement entitled Executive Officers.

The information concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 required by this Item is incorporated by reference to the section in our Proxy Statement entitled Section 16(a) Beneficial Ownership Reporting Compliance.

We have adopted a written code of ethics for financial employees that applies to our principal executive officer, principal financial officer, principal accounting officer, controller and other employees of the finance department designated by our Chief Financial Officer. This code of ethics, titled the Code of Conduct and Ethics for Chief Executive Officer and Senior Finance Personnel, is publicly available on our Internet website at <http://investor.shareholder.com/dexcom/governance.cfm>. The information contained on our Internet website is not incorporated by reference into this Report on Form 10-K.

The information concerning the audit committee of the Board of Directors required by this Item is incorporated by reference to information set forth in the Proxy Statement.

The information concerning material changes to the procedures by which stockholders may recommend nominees to the Board of Directors required by this Item is incorporated by reference to information set forth in the Proxy Statement.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item concerning executive compensation and our Compensation Committee is incorporated by reference to information set forth in the Proxy Statement.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this Item is incorporated by reference to information set forth in the Proxy Statement under the headings Principal Stockholders and Stock Ownership by Management and Equity Compensation Plan Information.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item with respect to director independence is incorporated by reference to information set forth in the Proxy Statement.

The information concerning certain relationships and related transactions required by the Item is incorporated by reference to the section in our Proxy Statement entitled Certain Transactions.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information concerning principal accountant fees and services required by this Item is incorporated by reference to the section in our Proxy Statement entitled Ratification of Selection of Independent Registered Public Accounting Firm.



**Table of Contents****PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this annual report:

1. *Financial Statements.* The financial statements in Part II, Item 8 of this annual report are incorporated by reference.

2. *Financial Statement Schedules.*

For the three fiscal years ended December 31, 2009 Schedule II Valuation and Qualifying Accounts, the financial statements in Part II, Item 8 of this annual report are incorporated by reference.

Schedules not listed above have been omitted because information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

3. *Exhibits.*

Exhibit Number	Exhibit Description	Incorporated by Reference			Exhibit Number	Provided Herewith
		Form	File No.	Date of First Filing		
3.01	Registrant's Restated Certificate of Incorporation.	S-1	000-51222	February 1, 2005	3.01	
3.02	Registrant's Restated Bylaws.	8-K	000-51222	May 22, 2009	99.01	
4.01	Form of Specimen Certificate for Registrant's common stock.	S-1/A	000-51222	March 24, 2005	4.01	
4.02	Second Amended and Restated Investors' Rights Agreement, dated December 30, 2004.	S-1	000-51222	February 1, 2005	4.02	
4.03	Form of Rights Agreement, between DexCom, Inc. and American Stock Transfer & Trust Company, including the Certificate of Designations of Series A Junior Participating Preferred Stock, Summary of Stock Purchase Rights and Forms of Right Certificate attached thereto as Exhibit A, B and C, respectively.	S-1/A	000-51222	March 24, 2005	4.03	
4.04	Indenture, dated as of March 9, 2007, between DexCom, Inc. and Wells Fargo Bank, National Association as trustee (including form of 4.75% Convertible Senior Note due 2027).	8-K	000-51222	March 12, 2007	4.01	
4.05	Registration Rights Agreement, dated as of March 9, 2007, between DexCom, Inc. and Piper Jaffray & Co.	8-K	000-51222	March 12, 2007	4.02	
10.01	Form of Indemnity Agreement between Registrant and each of its directors and executive officers.	S-1	000-51222	February 1, 2005	10.01	

**Table of Contents**

Exhibit Number	Exhibit Description	Incorporated by Reference			Exhibit Number	Provided Herewith
		Form	File No.	Date of First Filing		
10.02	1999 Stock Option Plan and related agreements.*	S-1	000-51222	February 1, 2005	10.02	
10.03	2005 Equity Incentive Plan and forms of stock option agreement and stock option exercise agreements.*	S-1/A	000-51222	March 24, 2005	10.03	
10.04	2005 Employee Stock Purchase Plan and form of subscription agreement.*	S-1/A	000-51222	March 24, 2005	10.04	
10.05	Sorrento Valley Business Park Lease dated December 3, 2003 between Hub Properties Trust and DexCom, Inc.	S-1/A	000-51222	March 25, 2005	10.08	
10.06	Exclusive Patent License Agreement dated August 17, 2001 between SM Technologies, LLC and DexCom, Inc.**	S-1/A	000-51222	April 5, 2005	10.09	
10.07	Agreement Regarding Terms of Sale dated May 23, 2003 between AMI Semiconductor, Inc. and DexCom, Inc.**	S-1/A	000-51222	April 5, 2005	10.10	
10.08	Lease from Hub Properties Trust to DexCom, Inc. dated May 13, 2005.	8-K	000-51222	May 18, 2005	99.1	
10.09	Board Member Agreement between DexCom, Inc. and Terrance H. Gregg dated May 19, 2005.	8-K	000-51222	May 24, 2005	99.01	
10.10	Offer letter between DexCom, Inc. and Jorge Valdes dated October 17, 2005.*	10-K	000-51222	February 27, 2006	10.14	
10.11	Loan and Security Agreement between Square I Bank and DexCom, Inc., dated March 20, 2006.	8-K	000-51222	March 24, 2006	99.01	
10.12	Office Lease Agreement, dated April 4, 2006, between DexCom, Inc. and Kilroy Realty, L.P.	8-K	000-51222	April 7, 2006	99.01	
10.13	Offer letter between DexCom, Inc. and Steven R. Pacelli dated April 10, 2006*	8-K	000-51222	April 13, 2006	99.01	
10.14	Issuer Call Option Confirmation Letters, dated as of March 9, 2007, between DexCom, Inc. and Capital Ventures International.	8-K	000-51222	March 12, 2007	10.01	



**Table of Contents**

Exhibit Number	Exhibit Description	Incorporated by Reference			Exhibit Number	Provided Herewith
		Form	File No.	Date of First Filing		
10.15	First Amendment to Loan and Security Agreement, dated January 31, 2008, between DexCom, Inc. and Square 1 Bank.	8-K	000-51222	February 5, 2008	99.01	
10.16	Collaboration Agreement, dated November 10, 2008 between the Company and Edwards Lifesciences LLC**	8-K/A	000-51222	January 28, 2009	10.1	
10.17	Amended and Restated Joint Development Agreement, dated January 12, 2009, between the Company and Animas Corporation **	8-K/A	000-51222	January 28, 2009	10.1	
10.18	OUS Commercialization Agreement, dated January 12, 2009, between the Company and Animas Corporation**	8-K/A	000-51222	January 28, 2009	10.2	
10.19	Form of Amended and Restated Executive Change of Control & Severance Agreement.*	10-K	000-51222	March 9, 2009	10.20	
10.20	Amended and Restated Offer Letter Agreement dated December 19, 2008 between the Company and Terrance H. Gregg.*	10-K	000-51222	March 9, 2009	10.21	
10.21	Letter Agreement, between Edwards Lifesciences LLC and DexCom, Inc., dated May 5, 2009.	10-Q	000-51222	August 3, 2009	10.22	
10.22	Distribution Agreement, between RGH Enterprises, Inc. and DexCom, Inc., dated April 30, 2008.**	10-Q	000-51222	August 3, 2009	10.23	
10.23	Letter of Amendment of the Amended and Restated Joint Development Agreement, between Animas Corporation and DexCom, Inc., dated July 30, 2009.**	10-Q	000-51222	November 4, 2009	10.24	
10.24	Amendment No. 1 to the Commercialization Agreements, between Animas Corporation and DexCom, Inc., dated July 30, 2009.**	10-Q	000-51222	November 4, 2009	10.25	

**Table of Contents**

Exhibit Number	Exhibit Description	Incorporated by Reference			Exhibit Number	Provided Herewith
		Form	File No.	Date of First Filing		
10.25	Amended and Restated Development, Manufacturing, Licensing and Supply Agreement, between DSM PTG, Inc. and DexCom, Inc., dated February 19, 2010**					X
14.01	Code of Ethics for Financial Employees	10-K	000-51222	February 27, 2006	14.1	
21.01	List of Subsidiaries					X
23.01	Consent of Independent Registered Public Accounting Firm.					X
24.01	Power of Attorney. (See page 71 of this Form 10-K).					X
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).***					X
32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).***					X

\* Represents a management contract or compensatory plan.

\*\* Confidential treatment has been requested for certain portions of this document pursuant to an application for confidential treatment sent to the Securities and Exchange Commission. Such portions are omitted from this filing and were filed separately with the Securities and Exchange Commission.

\*\*\* This certification is not deemed filed for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that DexCom specifically incorporates it by reference.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DEXCOM, INC.  
(Registrant)

Dated: March 9, 2010

By:

/s/ JESS ROPER  
**Jess Roper, Chief Financial Officer**

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Terrance Gregg and Jess Roper, jointly and severally, his attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Report on Form 10-K and to file same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ TERRANCE GREGG  <b>Terrance Gregg</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2010
/s/ JESS ROPER  <b>Jess Roper</b>	Chief Financial Officer (Principal Financial Officer)	March 9, 2010
/s/ DONALD L. LUCAS  <b>Donald L. Lucas</b>	Chairman of the Board of Directors	March 9, 2010
/s/ NICHOLAS AUGUSTINOS  <b>Nicholas Augustinos</b>	Director	March 9, 2010
/s/ JONATHAN LORD  <b>Jonathan Lord</b>	Director	March 9, 2010
/s/ DONALD A. LUCAS  <b>Donald A. Lucas</b>	Director	March 9, 2010
/s/ KEVIN SAYER  <b>Kevin Sayer</b>	Director	March 9, 2010
/s/ JAY SKYLER  <b>Jay Skyler, M.D.</b>	Director	March 9, 2010

Edgar Filing: DEXCOM INC - Form 10-K

/s/ ERIC TOPOI

Director

March 9, 2010

**Eric Topol, M.D.**

72