DEXCOM INC
Form 10-K
February 27, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2006

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	**33-0857544**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
5555 Oberlin Drive	
San Diego, California	**92121**
(Address of Principal Executive offices)	(Zip Code)

Registrant s Telephone Number, including area code: **(858) 200-0200**

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 Par Value Per Share	The NASDAQ Stock Market LLC
Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Exchange Act: **None**

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

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 o No x

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 x No o

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-Ko

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filed and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated Filer o Accelerated Filer x Non-accelerated Filer o

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

As of February 16, 2007, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $219.7 million 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.

Class	**Outstanding at February 16, 2007**
Common stock, $0.001 par value per share	28,237,078 shares

DOCUMENTS INCORPORATED BY REFERENCE

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

Designated portions of the Proxy Statement relating to the 2007 Annual Meeting of the Stockholders (the Proxy Statement): Part III (Items 10, 11, 12, 13 and 14). Except with respect to information specifically incorporated by reference in the Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

DexCom, Inc.
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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 people with diabetes. We were incorporated in Delaware in May 1999. On March 24, 2006, we received approval from the U.S. Food and Drug Administration, or FDA, for our Short-Term Continuous Glucose Monitoring System, or STS®, and have launched this product throughout the United States. Our approval allows for the use of our STS 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. Hypoglycemia occurs when the body s blood glucose, or blood sugar, levels are lower than the normal range, and hyperglycemia occurs when the body s blood glucose levels are higher than the normal range. Our STS is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Our STS must be prescribed by a physician and includes a disposable sensor, a transmitter and a small cell phone-sized receiver. The sensor is inserted by a patient and intended to be used continuously for up to three days, after which it is removed and may be replaced by a new sensor. However, we are aware of reports from the field that patients have been able to defeat our three-day software shut-off, enabling them to use sensors for periods longer than three days. After insertion and initialization, our STS wirelessly transmits the patient s blood glucose levels to the receiver at specific intervals, which allows the patient to view real-time and trended blood glucose information with the touch of a button and alerts the patient when glucose levels are inappropriately high or low. Studies have demonstrated that patients who intensely managed glucose levels delayed the onset and slowed the progression of diabetes-related complications. Our glucose monitoring systems are also designed to offer convenience and comfort to diabetes patients, and to have an intuitive user interface.

We commenced initial commercial shipments of our STS in the United States on March 28, 2006. To support our national product launch, 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. To complement our direct sales efforts, we employ clinical specialists who help to educate patients on continuous glucose monitoring and provide clinical support to endocrinologists, physicians and diabetes educators who prescribe our products, and we currently offer 24-hour customer service and technical support. We have recently expanded our manufacturing capacity in our current facility and have relocated a portion of our manufacturing operations and research and development to our new 66,400 square foot facility in San Diego, California.

Since the launch of the STS, we have experienced field failures, including, but not limited to, periods of higher than expected out of box failure rates for the sensor to initialize and display data to the patient. We also experienced a component failure in our receiver which prevented data transmitted from the sensor being received by the handheld receiver. We do not believe these failures created any patient safety concerns and we are not aware of any reports of adverse events or incidents related to these failures. Although we believe we have taken appropriate actions aimed at reducing or eliminating field failures, there can be no assurances that we will not experience these or other failures going forward.

We are leveraging our technology platform to enhance the capabilities of our STS and develop additional continuous glucose monitoring products. We filed a PMA supplement in the second quarter of 2006 for approval of our next generation STS, which is expected to be used continuously for up to seven days. In October 2006, we received a written request from the FDA for additional information, and in November 2006 we responded to that request. We are currently awaiting additional questions or a decision from the FDA for this PMA supplement. We are continuing clinical development of a third generation STS which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, may be calibrated using any brand of home blood glucose meter, 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 STS product platform in the future. We are also developing a product platform specifically for the in-hospital glucose monitoring market, with an initial focus on a sensor specifically for the critical care market. We conducted initial human feasibility studies for this product in the first quarter of 2007. Finally, after review of several months of data from feasibility studies for our long term continuous glucose monitoring system, we determined that the product s performance does not warrant investing in a large pivotal trial to seek approval for the long term sensor at this time. However, we are utilizing technology from our long term sensor and members of that development team to enhance our STS product platform and our in-hospital technology platform.

Our STS does not have broad reimbursement and is generally not approved for insurance coverage. Until reimbursement or insurance coverage is established, patients will have to bear the financial cost of our STS. In order to establish reimbursement or insurance coverage for our STS, we believe that we need to develop an established base of STS users, gain the support of advocacy groups and show the benefits of our system through clinical data generated by clinical trials. We submitted an application to The Centers for Medicare and Medicaid, or CMS, to establish a Healthcare Common Procedures Coding System code, or HCPCS code, for continuous glucose monitoring in December 2006. We intend to vigorously pursue HCPCS coding and the coverage codes required for reimbursement. We have also begun to add in-house reimbursement expertise to assist physicians and patients in obtaining reimbursement from private third-party healthcare payors. We expect to begin having formal meetings and increase our efforts to create coverage policies with third-party payors during 2007. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them.

As of 2000, approximately 171 million people suffered from diabetes worldwide. In 2005, there were an estimated 20.8 million people in the United States with diabetes of which 14.6 million have been diagnosed. We estimate that approximately 4.1 million of these patients were insulin-dependent. In 2005, 1.5 million new cases of diabetes were diagnosed. The increased prevalence of diabetes is a result of an aging population, inappropriate diets and increasingly sedentary lifestyles. According to an article published in *Diabetes Care* in 2003, diabetes is the fifth leading cause of death by disease in the United States, and complications related to diabetes include heart disease, limb amputations, loss of kidney function and blindness.

According to the American Diabetes Association, or ADA, the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated $132 billion in 2002 and could reach $156 billion by 2010. Of the $132 billion in overall expenses, the ADA estimates that approximately $92 billion were direct medical costs. According to industry sources, the worldwide market for personal

glucose monitoring systems and related disposables, which include test strips and lancets, was approximately $6.2 billion in 2005, and is expected to grow to $8.9 billion in 2008.

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 lower 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 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 drive blood glucose levels down. 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 afraid of driving down blood glucose levels. Consequently, these patients often remain in a hyperglycemic state, exposing themselves to long-term chronic complications.

Diabetes is typically classified into two major groups: Type 1 and Type 2. We estimate that there are approximately 1.5 million diagnosed 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. Also, in 2005, there were approximately 13 million people in the United States who had been diagnosed with Type 2 diabetes, which results when the body is unable to produce sufficient levels of insulin or becomes insulin resistant. Depending on the severity of Type 2 diabetes, individuals may require diet and nutrition management, exercise, oral medications or insulin injections to regulate blood glucose levels. We estimate that approximately 2.6 million Type 2 patients use insulin injections.

There are various subgroups of diabetic patients, including in-hospital and pediatric patients, who present significant management challenges. According to the U.S. Center for Health Statistics, as of 1997, there were more than 4.2 million hospitalizations annually among people with diabetes. Diabetic patients stay in the hospital on average one to three days longer than patients without diabetes. Additionally, according to a *Diabetes Care* article, as of 1998, as many as 1.5 million hospitalized patients had significant hyperglycemia but no history of diabetes. A November 2001 article in the New England Journal of Medicine summarized results from a study of over 1,500 hospitalized patients, of which only 13% had a history of diabetes, that 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.

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. More recently, however, 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 1999, approximately 10 to 15% of children and teens were overweight, about double the number two decades before.

The ADA estimates that the direct medical costs and indirect expenditures attributable to diabetes in the United States were $132 billion in 2002, and could reach $156 billion by 2010. Of the $132 billion in overall expenses, the ADA estimates that approximately $92 billion were direct medical costs. A portion of

that amount is attributable to the costs associated with monitoring blood glucose levels. According to industry sources, the worldwide market for personal glucose monitoring systems and related disposables, which includes test strips and lancets, was approximately $6.2 billion in 2005, and is expected to grow to $8.9 billion in 2008. While we believe our systems will be adopted by patients and their physicians as a way to manage glucose levels more effectively, we do not expect that our systems will appeal to all types of diabetes patients, or that the worldwide market for personal glucose monitoring systems and related disposables is a direct indication of our market opportunity. In a study of Type 2 diabetes patients, fewer than 15% of all study patients and 39% of all insulin dependent study patients tested their glucose levels one or more times per day. If patients do not perceive our systems to be more convenient and effective for managing their glucose levels than other devices on the market, our market may be limited.

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 excursions above or below normal blood glucose levels that can be unpredictable. 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 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 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.

According to the ADA, 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%. Despite evidence that intensive glucose management reduces the long-term complications associated with diabetes, industry sources estimated in 2001 that people with diabetes test, on average, less than twice per day.

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:

- **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.

- **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 our long-term 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.

Single Day Continuous Data

- **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.

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 the DexCom STS, two other companies, Cygnus and Medtronic have received approval from the FDA for continuous glucose monitors and Abbott is seeking approval for another. We believe that one of the products, originally developed and marketed by Cygnus, is no longer actively marketed. In addition, Johnson & Johnson recently announced that it is developing and expects to commence clinical trials in support of a continuous glucose monitoring system in 2007. We believe that none of the products that have received FDA approval are labeled for more than three days of use or for use as a replacement for single-point finger stick devices.

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.

The DexCom Solution

Our STS offers the following advantages to diabetes patients:

- **Improved Outcomes**. Data published in a peer-reviewed article based on our approval support trial for our STS demonstrated that patients using the STS showed statistically significant improvements in their glucose levels when compared to patients relying solely on single-point finger stick measurements. Additional peer-reviewed data from our approval support trial for our seven-day STS demonstrated that patients with access to seven-day 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. Finally, data from our repeated use trial demonstrated a statistically significant reduction in hemoglobin A1c levels, a measure of the average amount of sugar in the blood over the last three months, in patients using our STS compared to patients relying solely on single-point finger stick measurements.

- **Convenience.** We believe that convenience is the paramount factor in achieving widespread adoption of a continuous glucose monitoring system. Our disposable sensors continuously measure and record the patient s glucose level and wirelessly transmit glucose values at specific intervals to a small cell phone-sized receiver throughout the day and night for up to three days. The patient can check his or her glucose level and trend information at any time with the touch of a button. Our STS is designed to measure patients glucose levels continuously for three days, and if approved by the FDA, our next generation STS is expected to be used continuously for up to seven days.

- **Access to Real-Time Values and Trend Information.** By pushing a button, patients can view their current glucose value, along with a graphical display of one-, three- or nine-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 STS alerts patients when their glucose approaches 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.

- **Comfort.** Our STS provides 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. Finally, the wireless receiver is the size of a small cell phone and can be carried discreetly in a pocket or purse.

While we believe our STS 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 STS will appeal to all types of diabetes patients. Our STS requires a patient to insert a disposable sensor electrode under their skin at least every three days, and we are aware of reports from the field that patients have been able to defeat our three-day software shut-off, enabling them to use sensors for periods longer than three 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 sticks per day. Additionally, our STS is not approved as a replacement device for single-point finger stick devices, must be calibrated initially using two finger sticks and thereafter at least every 12 hours using single-point finger stick measurements and may be more costly to use. Also, our STS does not have broad reimbursement and is not approved for insurance coverage. Until reimbursement or insurance coverage is established, patients will have to bear the financial cost of our STS. Third-party coverage may be particularly difficult to obtain if our systems are not approved by the FDA as replacements for existing single-point finger stick devices. In order to establish reimbursement or insurance coverage for our STS, we believe that we need to develop an established base of STS users, gain the support of advocacy groups and show the benefits of our system through clinical data generated by clinical trials. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them.

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 conveniently and effectively manage their disease. To achieve this objective, we are pursuing the following business strategies:

- **Establish our technology platform as the leading approach to continuous glucose monitoring**. We have developed proprietary core technology and expertise that provide a broad platform for the development of innovative products for continuous glucose monitoring. On March 24, 2006, we received approval from the FDA for our STS and we are currently in national distribution with this product. 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.

- **Drive the adoption of our products through a direct sales and marketing effort.** We have a direct field sales force to call directly on endocrinologists, physicians and diabetes educators who can educate and influence patient adoption of continuous glucose monitoring. To complement our sales efforts, we employ clinical specialists who will educate and provide clinical support to patients. We have launched our STS initially in the United States only.

- **Seek broad reimbursement for our products by Medicare, Medicaid and third-party payors**. We submitted an application to CMS for a HCPCS code for continuous glucose monitoring in December 2006. We intend to vigorously pursue HCPCS coding and the coverage codes required for reimbursement. We have also begun to add in-house reimbursement expertise to assist physicians and patients in obtaining reimbursement from private third-party healthcare payors. We expect to begin having formal meetings and increase our efforts to create coverage policies with third-party payors during 2007.

- **Expand the use of our products to other patient care settings and patient demographics.** Our STS is approved for use at home and in health care facilities by adults (18 years and older) with diabetes. We believe there is an unmet medical need for continuous glucose monitoring in the hospital setting. As of 1997, there were more than 4.2 million hospitalizations annually among people with diabetes. In addition, as of 1998, as many as 1.5 million hospitalized patients in the United States had significant hyperglycemia but no 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 that end, we are developing a specific product platform for the in-hospital glucose monitoring market, with an initial focus on a sensor specifically for the critical care market. In addition, we believe our STS may be beneficial to pediatric diabetes patients and intend to seek approval for use in patients under 18 in the future.

- **Leverage our product development expertise to rapidly bring products to market**. We have demonstrated our ability to leverage our platform and apply our technical expertise to rapidly develop products. In less than two years, we brought our STS from concept to FDA approval. While our STS PMA was pending, we began developing a next generation STS intended to extend the useful life of the STS from three to seven days and completed an approval support trial. We have filed a PMA supplement for this next generation product which is currently under review by FDA. We are continuing clinical development of a third generation STS which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, may be calibrated using any brand of home blood glucose meter, and will be more comfortable for patients to wear. We plan 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.

- **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 and Internet access 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 these disciplines. We believe we have a broad technology platform that will support the development of multiple products for glucose monitoring.

Sensor Technology

The key enabling technologies for our sensors include biomaterials, membrane systems, electrochemistry and low power microelectronics. Our membrane technology consists of multiple polymer layers configured to selectively allow the appropriate mix of glucose and oxygen to travel through the membrane and react with a glucose specific enzyme to create an extremely low level electrical signal, measured in pico-amperes. This electrical signal is then translated into glucose values. We believe that the capability to measure very low levels of current 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 Technology

Our glucose monitoring systems use radiofrequency telemetry to wirelessly transmit information from the sensor to our platform receiver. We have developed the technology for reliable transmission and reception and have consistently demonstrated a high degree of capture of 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 January 2006, the Federal Communications Commission, or FCC, granted our request for a waiver from certain Medical Implant Communications Service, or MICS, rules concerning radio frequency transmissions of our continuous glucose monitoring systems. The waiver provides clearance for our continuous glucose monitoring systems to wirelessly transmit data to patients in the MICS band.

Medtronic has filed a petition with the FCC requesting the FCC establish a bifurcated MICS band which would require device manufacturers whose products will operate in the main MICS band to manufacture their devices using listen-before-transmit technology, or transmit on a side band outside the main MICS band at lower power. Medtronic and its supporters claim that unless the MICS band is bifurcated, there will not be sufficient spectrum for medical implant and body-worn devices to use without being subject to unacceptable levels of interference; and life critical devices, such as cardiac pacemakers, currently operating in the existing MICS spectrum, are likely to incur interference from other medical devices that are less time sensitive, such as glucose monitoring systems. Although our STS does not comply with existing MICS band listen-before-transmit requirements, the FCC determined that the likelihood of our device causing interference is low, which was the basis for the FCC granting us a waiver from these requirements. We have filed an opposition to Medtronic s petition asking that the FCC continue to allow certain non-listen-before-transmit devices to operate in the MICS band, not to impose more stringent power limits on these devices and not to bifurcate the spectrum based on unnecessary technology distinctions. If the FCC does create a separate spectrum and does not extend our waiver to allow us to continue to operate in the main MICS band, we may be required to re-engineer our product to transmit

over a different frequency which may require changes to our regulatory approvals and may have an adverse impact on the operation of our products.

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, sensor geometry and surgical techniques. We believe the expertise gained in overcoming these problems may support the development of additional products beyond glucose monitoring.

Our Products

On March 24, 2006, we received approval from the FDA for our STS, which includes a disposable sensor that can be inserted by a patient and used continuously for up to three days. Our approval allows for the use of our STS by adults (18 years and older) with diabetes to detect trends and track glucose patterns, to aid in the detection of hypoglycemia and hyperglycemia and to facilitate acute and long-term therapy adjustments. Our STS is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Our STS must be prescribed by a physician and is intended for use by patients at home and in healthcare facilities. Interpretation of the STS results should be based on trends and patterns seen with several sequential readings over time. We filed a PMA supplement in the second quarter of 2006 for approval of our next generation STS, which is expected to be used continuously for up to seven days. In October 2006, we received a written request from the FDA for additional information, and in November 2006 we responded to that request. We are currently awaiting additional questions or a decision on from the FDA on this PMA supplement. We are continuing clinical development of a third generation STS which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, may be calibrated using any brand of home blood glucose meter, and will be more comfortable for patients to wear. We also intend to seek a pediatric indication (patients under 18 years old) for our STS. We are also developing a specific product platform for the in-hospital glucose monitoring market, with an initial focus on a sensor specifically for the critical care market. We conducted initial human feasibility studies for this product in the first quarter of 2007. Finally, after review of several months of data from feasibility studies for our long term continuous glucose monitoring system, we determined that the product s performance does not warrant investing in a large pivotal trial to seek approval for the long term sensor at this time. However, we are utilizing technology from our long term sensor and members of that development team to enhance our STS product platform and our in-hospital technology platform.

Short-Term Continuous Glucose Monitoring Disposable Sensor

Our STS 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 electrode 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 extends a narrow gauge needle containing the electrode into the subcutaneous tissue and retracts the needle, leaving behind the electrode in the tissue and the pod adhered to the skin. The patient then disposes of the insertion device. 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 our STS twice per day with finger sticks throughout the three-day usage period to ensure reliable operation. At this time, our first generation STS will not eliminate the need

for finger sticks for therapy decisions, although in the future we may seek replacement claim labeling from the FDA for the use of a future generation STS as the sole basis for making therapeutic adjustments.

Our disposable sensor is intended to function for three days after which it may be replaced. After three days, the patient simply removes the pod and attached electrode from the skin and discards them. A new sensor and pod can then be inserted and used with the same receiver and transmitter. We are aware of reports from the field, however, that patients have been able to defeat our three-day software shut-off, enabling them to use sensors for periods longer than three days. We have developed and completed a trial showing a second generation STS can function reliably for up to seven days and we filed a PMA supplement in the second quarter of 2006 for approval of this next generation STS. In October 2006, we received a written request from the FDA for additional information, and in November 2006 we responded to that request. We are currently awaiting additional questions or a decision from the FDA on this PMA supplement.

Handheld Receiver

Our small cell phone-sized receiver is carried by the patient and wirelessly receives continuous glucose values data 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- and nine-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.

Clinical Development Program

Evaluating Continuous Glucose Monitoring Systems

Continuous glucose monitoring is an emerging technology. There are no clearly established guidelines or universally accepted measures for evaluating the performance of continuous glucose monitoring products, especially with respect to accuracy. As a result, analyses of continuous glucose monitoring products have generally utilized traditional single-point accuracy measures that were derived from the field of analytical chemistry to evaluate conventional single-point finger stick devices. However, we do not know whether the FDA, other regulatory bodies or physicians will consider these single-point measures to be the appropriate means to demonstrate the safety and efficacy of continuous glucose monitoring systems for real-time monitoring of glucose values and trends by patients or as a replacement for conventional blood glucose meters, nor do we know what threshold levels of these measures the FDA or others will determine to constitute acceptable performance. The FDA or others analyzing our clinical results may determine that different measures from those we have used are better indicators of accuracy, clinical utility and safety. In reporting data from our clinical trials, we report those measurements that we believe most appropriately characterize the performance of our continuous glucose monitoring systems in three primary areas: accuracy, clinical utility and safety.

Accuracy Measures. Typically, to measure accuracy in our clinical trials, we compare the output from our continuous glucose monitoring systems at a specific point in time to a reference measurement at the same point in time. These two measurements are called paired points. The reference value is usually measured by a laboratory instrument, such as a Yellow Springs Instrument, or a conventional blood glucose meter using samples from finger sticks. These paired points are then compared to each other using statistical analyses intended to measure accuracy.

The primary statistical analyses we use include the following:

- **Bias.** Bias is the result of a mathematical calculation using a modified linear regression analysis that is designed to evaluate whether a device s measurement is systematically too high or too low, when compared to a reference measurement, usually determined by a single-point finger stick device. A device with a lower bias is generally considered to be more accurate.

- **Clarke Error Grid.** A Clarke Error Grid is a plot of all paired points categorized into five areas denoted A, B, C, D and E, with A and B being the most clinically desirable and D and E being the least clinically desirable. Devices with higher combined A and B percentages closer to 100% and lower combined D and E percentages closer to 0% are considered to have better performance.

- **Mean Absolute Relative Difference, or MARD.** MARD is the result of a mathematical calculation that measures the average disparity between the sensor and the reference measurement. The lower the MARD, the more accurate the device is considered relative to the reference measurement.

- **R-Value.** An R-value is the result of a mathematical calculation using linear regression techniques to measure the relationship between the paired points. The maximum R-value is 1.0. A higher R-value means a more linear relationship with the reference measurement and is assumed to be more accurate.

Clinical Utility Measures. We have designed our clinical trials to measure whether the use of real-time continuous glucose data reduces the time a patient spends in abnormally high and low glucose ranges, and increases the time spent in the target range. In our studies, we measure a patient s glucose level continuously for a defined period of time, using our continuous glucose monitoring systems, but do not permit the patient to view the data. These measurements are used to establish a baseline. Subsequently, we measure the same patient s glucose level continuously for a similar or longer period of time, but the patient is allowed to view and utilize the data. These unblinded glucose levels are then compared to the baseline glucose levels to determine whether the use of the data from our continuous glucose monitoring system affected the amount of time the patient s glucose level was high, low and within the target range.

Safety Measures. The safety profile of any new product must be clearly established before it can be approved for commercial use. Data must be collected to demonstrate that patients can use the device safely, the device operates safely and any procedure associated with the device is also safe. We typically record adverse events related to the implant or insertion and removal of our sensors, related to the operation of the systems or related to the patient s use of the data from the systems. Of most concern is the occurrence of serious or unexpected adverse events. The desired result is that adverse events are not more serious and do not occur more frequently than similar products currently commercially available and utilized by patients for the same purpose.

Clinical Trials

We began our first human clinical trial in 2001 and to date have over 10,000 patient days of unblinded clinical use of our devices. Throughout these studies and trials we have experienced successes and failures, which we have relied upon in the continual design and development of our products. As a result, we have developed our STS, which has been approved by the FDA, we have a PMA supplement for a second generation short-term sensor pending approval by the FDA and we have a third generation short-term sensor currently being evaluated in human clinical trials. Throughout these trials, there have been no serious or unexpected adverse events reported related to the insertion or removal of the devices or the use of our systems. Given the ongoing process of design and development, we believe that our more recent clinical trials are most relevant to an understanding of our current clinical performance. The table below and the following discussion summarize our primary STS clinical trials that were completed, and our ongoing clinical trials:

Product	Clinical Trial	Year Completed	Clinical Trial Sites	Patients
STS	STS Approval Support Trial	2005	4 Sites; United States	91
STS-7	7-Day Approval Support Trial	2005	5 Sites; United States	86
STS	Replacement Feasibility Trials	2005	3 Sites; United States	36
STS	Repeated Use Trial	2006	7 Sites; United States	136
STS-7	7-Day Accuracy vs YSI	2006	5 Sites, United States	72
STS-7	JDRF-Sponsored Reimbursement Trial	Ongoing	10 Sites; United States	*

* expected to enroll approximately 500 patients

Short Term Disposable Sensor Trials

STS Approval Support Trial. In 2005, we enrolled ninety-one patients at four sites in the United States in a two-arm, prospective, randomized trial designed to measure the accuracy, safety and clinical benefits of the STS sensor in improving glycemic control. Patients were randomized to either a blinded group (control) that wore three successive sensors for 72 hours each (for a total of nine days), but was blinded to the continuous data and relied solely on finger stick measurement data to manage their diabetes, or an unblinded group that wore three successive sensors for 72 hours each (also for a total of nine days) but was allowed to view and utilize the real-time continuous data to manage their diabetes for the last two periods, or six days. Patients in both groups inserted the sensors themselves and wore them at home and at work in their daily activities. To measure the potential clinical benefit to patients of access to real-time continuous glucose data, we compared glucose data obtained from patients in the blinded group to glucose data obtained from patients in the unblinded group. The results of the comparison demonstrated a statistically significant improvement in glucose control with a 21% reduction in time spent in a hypoglycemic state (low glucose), a 23% reduction in time spent in a hyperglycemic state (high glucose), and a 26% increase in time spent in the target (normal) glucose range. As an additional measure of the potential clinical benefit to patients of access to real-time continuous glucose data, we also analyzed glucose data obtained only from the unblinded group. The unblinded group had both a blinded and unblinded period. Glucose data for the first three-day period, during which patients were blinded to the continuous glucose data and relied solely on finger stick measurements to manage their diabetes, was compared to the last two three-day periods, during which patients were unblinded to the continuous glucose data and allowed to use it to manage their diabetes. The results of the comparison showed statistically significant improvement in glucose control with a 9% reduction in time spent in a hypoglycemic state, a 15% reduction in time spent in a hyperglycemic state, and a 16% increase in time spent in the target glucose range. These data, which were published in a peer-reviewed article in the January 2006 edition of *Diabetes Care*, served as the basis for our original PMA for the STS. We sponsored the trial that is the subject of this article and each of the authors received research grant funds from us for conducting the trial. None of the authors received consulting or other fees for conducting the trial or authoring the article.

Seven-Day STS Approval Support Trial. In July 2005, we enrolled eighty-six insulin-dependent diabetes patients in a study designed to measure the accuracy, safety and clinical benefits of our second generation seven day STS sensor. Patients inserted the sensors themselves and wore them at home and at work in their daily activities for a total of 21 days in three consecutive seven-day periods. Patients were blinded to continuous data during the first seven-day period and relied solely on finger stick measurements to manage their diabetes. During the second and third seven-day periods, patients were unblinded to the continuous data and were allowed to use continuous glucose values, trend graphs, and high/low alerts and alarms to manage their disease. These data were published in a peer-reviewed article in the December 2006 edition of *Diabetes Care* and served as the basis for our PMA supplement for the seven-day STS. Again in this clinical trial, patients with access to continuous glucose data statistically improved glucose control by further increasing the time spent with glucose levels in the target range, thereby reducing time spent in both hyperglycemic and hypoglycemic ranges. We sponsored the trial that is the subject of this article and each of the authors received research grant funds from us for conducting the trial. None of the authors received consulting or other fees for conducting the trial or authoring the article.

Replacement Feasibility Trials. In 2005, we conducted two initial feasibility trials to evaluate patients using the STS as the sole means of decision making to manage their diabetes. Data from this study were peer-reviewed and presented in an abstract at the Scientific Sessions of the June 2006 Annual Meeting of the ADA. The data from these trials showed that individuals with Type 1 diabetes more frequently made appropriate self-management decisions using data from the STS than they did using traditional finger stick measurement data to manage their diabetes. Study participants maintained better glycemic control when decision-making was guided by continuous glucose monitoring. In the first study, 71% of self-management decisions made using data from the STS were deemed appropriate as compared to 53% using traditional finger stick monitoring. In the second study, these percentages were 65% of self-management decisions made using data from the STS were deemed appropriate as compared to 46% using traditional finger stick monitoring. Currently, no company has been successful in obtaining approval from the FDA for replacement claim labeling, nor has the FDA provided any clear guidance on what might be required for such labeling. We have had productive dialogue with clinicians and the FDA about appropriate study design and measures for replacement claim labeling and we would expect to work cooperatively with both groups toward replacement claim labeling in the future.

Repeated Use Trial. In 2006, we enrolled a repeated use trial that allowed patients to use our STS for 90 consecutive days, with patients replacing the disposable sensor every three days. We enrolled approximately 136 patients in seven sites in the United States. Analysis of the preliminary results in the first 60 of 136 patients, consisting of both Type 1 and Type 2 patients, to complete the full 90 days in our Repeated Use Trial demonstrated a statistically significant reduction in their hemoglobin A1c levels, or A1c levels. A1c levels are a measure of the average amount of sugar in the blood over the last three months. Preliminary results of the first 60 patients showed an average 0.49% decrease in A1c levels. The 20 patients that started the study with an A1c greater than 8% showed an average 1.03% decrease in A1c levels over the study period. Both reductions were statistically significant. Results from the UK Prospective Diabetes Study as published in the January 2002 edition of *Diabetes Care* showed that for every percentage point decrease in A1c levels, there was a 35% reduction in the risk for diabetes-related complications. Additionally, each percentage point reduction also lowered the risk of heart attack by 18%. Preliminary results from the first 60 of 140 patients in our Repeated Use Trial were published in abstract in the Late Breaking Clinical Trials section of the Scientific Sessions of the 2006 Annual Meeting of the ADA in June 2006 and these data have been submitted for peer-reviewed publication.

Seven-Day STS Accuracy Compared to YSI Blood Glucose Values. In 2006, we enrolled a clinical trial to evaluate the accuracy of our seven day STS compared to a laboratory method of obtaining blood glucose values using a Yellow Springs Instrument, or YSI. We enrolled 72 Type 1 and insulin-requiring Type 2 subjects in a non-randomized study at 5 sites in the United States. Patients inserted the sensors themselves

and wore them at home and at work in their daily activities for a total seven days. During the study, patients participated in one 10-hour in-clinic session with blood draws every 20 minutes on day 1, 4, or 7 of the study to obtain YSI reference information in a controlled setting. Results of the study showed an overall mean ARD of 16.6% and a median ARD of 13.3%, and also showed that accuracy improved across seven days of patient usage. These data have been submitted in abstract for publication at the Scientific Sessions of the 2007 Annual Meeting of the ADA in June 2007 and were submitted as part of our PMA supplement for the seven-day STS.

JDRF-Sponsored Reimbursement Trial. We have agreed to provide product, along with at least two other companies, to support an independent, randomized clinical trial sponsored by the Juvenile Diabetes Research Foundation, or JDRF, which is expected to provide data comparing both health-related and economic outcomes from patients using continuous glucose monitoring versus patients using only single-point finger stick monitoring. This clinical trial is expected to enroll several hundred patients and follow these patients for 12-months. If this independently-conducted study is successfully enrolled and completed, and demonstrates improved health-related and economic outcomes for continuous glucose monitoring versus finger stick monitoring, it could serve as a potential catalyst for wider and more accelerated reimbursement for continuous glucose monitoring in the future.

Long-Term Sensor Trials

After review of several months of data from feasibility studies for our long term continuous glucose monitoring system, we determined that the product s performance does not warrant investing in a large pivotal trial to seek approval for the long term sensor at this time. However, we are utilizing technology from our long term sensor and members of that development team to enhance our STS product platform and our in-hospital technology platform.

Clinical Trial Process

We enter into contracts with clinical investigators, surgeons and clinical trial sites to conduct our clinical trials. These contracts include terms requiring the parties to comply with regulations and guidelines issued for the type of study being performed. Generally, we contract with clinical trial sites to screen and enroll patients, schedule visits for implants or insertions, conduct in-clinic studies, prepare patient report forms and collect and aggregate trial data. Clinical trial site fees generally include a set-up fee, a per-patient trial management fee and an overhead charge. We contract with clinical investigators to implement our trial protocol, acquire institutional review board approval, and generally ensure that the study is conducted in a safe and ethical manner while complying with all regulations and guidelines related to the clinical trial.

Our research and development expenses were $12.4 million, $26.8 million and $19.4 million for 2004, 2005 and 2006, respectively.

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. 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, 2006, we employed over 40 direct sales personnel and clinical education specialists. In addition, we hired our Vice President of Marketing in April 2006, and we have built a small marketing team. We continue to evolve our sales and marketing organization as necessary to support the national commercial launch of our STS. We believe that referrals by physicians and diabetes educators, together with self-referrals by patients, have driven and will continue

to drive initial adoption of our STS. 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 2001, there were an estimated 3,700 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 intend to use a variety of marketing tools to drive initial adoption, ensure continued usage and establish brand loyalty for our continuous glucose monitoring systems by:

- creating awareness of the benefits of continuous 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

- establishing a readily-accessible telephone and web-based technical and customer support infrastructure, which we expect to include 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 and 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 Disetronic, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; the MediSense and TheraSense divisions of Abbott Laboratories; and Bayer Corporation, currently account for substantially all of the worldwide sales of self-monitored glucose testing systems. These competitors products use a meter and disposable test strips to test blood obtained by pricking the finger or, in some cases, the forearm. In addition, other companies are developing or marketing minimally invasive or noninvasive glucose testing devices and technologies that could compete with our devices. There are also a number of academic and other institutions involved in various phases of our industry s technology development.

Several companies have attempted to address the limitations of single-point finger stick devices by developing continuous glucose monitoring systems. To date, in addition to the DexCom STS, two other companies, Cygnus and Medtronic, have received approval from the FDA for continuous glucose monitors and Abbott is currently seeking approval for another. We believe that one of the products, originally developed and marketed by Cygnus, is no longer actively marketed. In addition, Johnson & Johnson recently announced that it is developing and expects to commence clinical trials in support of a continuous glucose monitoring system in 2007. We believe that none of the products that have received FDA approval are labeled for more than three days of use or 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:

- comfort and ease of use;
- safe, reliable and high quality performance of products;
- cost of products and eligibility for reimbursement;
- effective sales, marketing and distribution;
- 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

Prior to FDA approval of our STS, we manufactured our glucose monitoring systems, including our STS, in limited quantities sufficient to meet the needs for our clinical trials. We currently have limited resources, facilities and experience in commercially manufacturing sufficient quantities to meet expected demand for our STS. Since the commercial launch of our STS in March 2006, we have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support our commercialization efforts. As a result of these product shortages, we have experienced periods of backorder and, at times, have also had to limit the efforts of our sales force to introduce the STS 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.

We currently manufacture our devices at our headquarters in San Diego, California, and a new facility located nearby. In these facilities we have more than 5,000 square feet of laboratory space and approximately 5,000 square feet of controlled environment rooms. In January 2007, both facilities were subject to a post-approval PMA and QSR audit by the FDA. Based on the results of this inspection, we believe we are in substantial compliance with the regulatory requirements for a commercial medical device manufacturer and there were no major observations from the FDA resulting from this audit. At the close of the inspection, the FDA issued a Form 483 identifying several inspectional observations and, although we have no formal requirements or obligations to provide anything further to the FDA regarding these observations, we intend to voluntarily provide formal written evidence to the FDA of our actions taken to address these minor observations no later than May 1, 2007. 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 believe we have addressed the manufacturing challenges we have faced in a timely and effective manner. Additionally, the production of our continuous glucose monitoring systems, including our STS, must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Moreover, before we can produce product at this new facility for commercial use, the facility will have to undergo a pre-approval inspection by the FDA and corresponding state agencies. Developing commercial-scale manufacturing facilities will 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 continuous glucose monitoring systems with components supplied by outside vendors and with parts manufactured by us internally. Key components that we manufacture internally include our wire-based sensors for our STS and software in our receivers and transmitters. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished continuous monitoring systems, which consist of a sensor, a transmitter and a receiver.

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 AMI Semiconductor, Inc., which produces the application specific integrated circuits used in our transmitters; CardioTech, which manufactures the polymers used to synthesize our polymeric membranes for our STS; Flextronics International Ltd., which assembles the printed circuit boards for our transmitters and receivers; The Tech Group, which produces injection molded components; and Vita Needle, which manufactures the insertion needle for our STS. 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

Our STS does not have broad reimbursement and is not approved for insurance coverage. The availability of insurance coverage and reimbursement for newly approved medical devices is uncertain. Until reimbursement or insurance coverage is established, patients will have to bear the financial cost of our STS. 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 coverage and reimbursement is available for patients that use our products. Third-party coverage may be particularly difficult to obtain if our systems are not approved by the FDA as replacements for existing single-point finger stick devices. In order to establish reimbursement or insurance coverage for our STS, we believe that we need to develop an established base of STS users, gain the support of advocacy groups and show the benefits of our system through clinical data generated by clinical trials. The lack of reimbursement or insurance coverage may prevent us from establishing a base of STS users. Even if we are able to establish a base of users, advocacy groups may not be supportive of our efforts to obtain reimbursement, or Medicare, Medicaid, health maintenance organizations and other third-party payors may not agree with the conclusions of clinical data showing the benefits of our system.

In November 2006, The Centers for Medicare & Medicaid Services, or CMS, denied an application made by Medtronic to establish a Healthcare Common Procedures Coding System code, or HCPCS code, for continuous glucose monitoring. The HCPCS panel within CMS cited that the applicant had not demonstrated superior patient outcomes as a result of the use of the device and that no insurer had identified a national program operating need to establish the codes. Given our national launch of our STS, peer-reviewed clinical outcomes data demonstrating the benefits of our STS, individual patient reports of favorable coverage decisions from third-party payers, and strong support from Congress, specifically the House and Senate Diabetes Caucuses, and patient advocacy groups such as the Juvenile Diabetes Research Foundation, we submitted an application to CMS for a HCPCS code for continuous glucose monitoring in December 2006. We intend to vigorously pursue HCPCS coding and the coverage codes required for reimbursement. We have also begun to add in-house reimbursement expertise to assist physicians and patients in obtaining reimbursement from private third-party healthcare payors. We expect to begin having formal meetings and increase our efforts to create coverage policies with third-party payors during 2007.

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 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 STS 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, patients may not use them.

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 15, 2007, we had obtained 13 issued U.S. patents, and had 108 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 15, 2007, we had 14 open international applications filed under the Patent Cooperation Treaty, one granted European patent, 18 European patent applications pending, 13 Japanese

patent applications pending, one registered U.S. trademark, 14 pending U.S. trademark applications, four registered European trademarks, four pending European trademark applications, two registered Japanese trademarks and four pending Japanese trademark applications.

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, 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 short-term glucose monitor infringes certain patents held by Abbott. We moved to dismiss these claims on August 31, 2005 on the grounds that Abbott s complaint was premature. In addition to our motion to dismiss, we also filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office on January 25, 2006 and February 1, 2006. On February 22, 2006, we filed a motion to stay the entirety of the Delaware case pending decision from the Patent Office on those requests for reexamination, and in March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against us in the litigation. On February 23, 2006, the Court held a scheduling conference, during which it set a trial date of October 9, 2007. On June 27, 2006, Abbott amended its complaint to include three additional patents owned or licensed by Abbott which are allegedly infringed by our short term 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 a declatory judgment 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. On November 11, 2006, the Patent Office issued a non-final rejection of all claims we submitted for re-examination in one of the Abbott patents cited in the original lawsuit, and on December 27, 2006, the Patent Office issued a non-final rejection of all claims we submitted for re-examination in a second of the Abbott patents cited in the original lawsuit. No decision has yet been published by the Patent Office on the other two patents cited in the first complaint and currently under reexamination. Subject to the stay, we intend to continue to vigorously contest the action.

Subsequent to the court s ruling, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of those same three additional patents. We believe this complaint, like the first, is without merit and we intend to vigorously contest the action. To that end, we

filed requests with the Patent Office to reexamine each of the three additional patents cited by Abbott and 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 October 2006 and December 2006, the Patent Office ordered reexamination of two of the three patents cited in this new lawsuit. The third reexamination request is still under review by the Patent Office. Although it is our position that Abbott s assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees 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.

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.

The federal trademark application for the DEXCOM mark has been opposed, and we intend to vigorously defend against the opposition. The opposition proceeding only determines the right to federally register a trademark and cannot result in the award of any damages. We maintain that we are entitled to a registration for the DEXCOM mark; however, we cannot assure you that we will be successful in defending against this opposition. If we are unsuccessful, we could be forced to change our company name or market our products under a different name, which could result in a loss of brand recognition, could require us to retrieve product and interrupt supply and could require us to devote substantial resources to advertising and marketing our products under the new brand.

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, product manufacturing, product labeling, product storage, advertising and promotion, product sales, distribution, 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 PMA process. 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, as well as general controls. Some Class I and Class II devices are exempted by regulation from the pre market notification, or 510(k) clearance requirement or the requirement of compliance with substantially all of the QSR. 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 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.

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 as to the approvability of the device. 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 January 2007, both our facilities were subject to a post-approval PMA and QSR audit by the FDA. Based on the results of this inspection, we believe we are in substantial compliance with the regulatory requirements for a commercial medical device manufacturer and there were no major observations from the FDA resulting from this audit. At the close of the inspection, the FDA issued a Form 483 identifying several inspectional observations and, although we have no formal requirements or obligations to provide anything further to the FDA regarding these observations, we intend to voluntarily provide formal written evidence to the FDA of our actions taken to address these minor observations no later than May 1, 2007.

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 for certain indications. 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 then the data 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 for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling and 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 not require as extensive clinical data or the convening of an advisory panel.

Clinical trials are almost always required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an 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 more 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. 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;

- 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;

- 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.

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, documentation and other quality assurance procedures;

- labeling regulations, which prohibit the promotion of products for unapproved or off-label uses or indication 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;

- fines and civil penalties;

- unanticipated expenditures;

- delays in approving or refusal to approve our short-term continuous glucose monitoring system or other products;
- 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, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business. We 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 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 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.

Advisory Boards

We have relied upon the advice of experts in the development and commercialization of our products. Though 2004, we had formal clinical and scientific advisory boards assisting us in various capacities. 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.

Employees

As of December 31, 2006, we had 224 full-time employees and 36 temporary employees. Approximately 82 employees are engaged in research and development, clinical, regulatory and quality assurance, 99 in manufacturing and 79 in selling, general and administrative functions. None of our employees is represented by a labor union or is covered by a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our employee relations to be good.

Available Information

Our Internet website address is www.dexcom.com. We provide free access to various reports that we file with or furnish to the 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. 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 into any other report we file or furnish with the SEC. Stockholders may request copies of these documents from:

DexCom, Inc.
5555 Oberlin Drive
San Diego, CA 92121
(858) 200-0200

ITEM 1A. RISK FACTORS

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

We are a medical device company with a limited operating history. We received approval from the FDA for our STS on March 24, 2006 and have recently commercialized this product throughout the United States. We expect that sales of our STS, which consists of a cell phone-sized receiver, transmitter and disposable sensor, will account for substantially all of our revenue for the foreseeable future. Through December 31, 2006, revenues from sales of our STS total approximately $2.2 million. However, we have limited experience in selling our products and we might be unable to successfully commercialize our STS for a number of reasons, including:

- market acceptance of our STS by physicians and patients will largely depend on our ability to demonstrate its relative safety, efficacy, reliability, cost-effectiveness and ease of use;
- we may not be able to manufacture our STS in commercial quantities or at an acceptable cost;
- patients do not generally receive reimbursement from third-party payors for their purchase of our STS, which may reduce widespread use of our STS;
- our inexperience in marketing, selling and distributing our products;
- we may not have adequate financial or other resources to successfully commercialize our STS;
- the uncertainties associated with establishing and qualifying our new manufacturing facility;
- our STS 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 the STS 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 from our sole source and other key suppliers; and
- rapid technological change may make our technology and our STS obsolete.

Our STS 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 STS until there is long-term clinical evidence to convince them to alter their existing treatment methods, there are recommendations from prominent physicians that our STS is effective in monitoring glucose levels and reimbursement or insurance coverage is available. We cannot predict when, if ever, physicians and patients may adopt the use of our STS. If our STS 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.

Additionally, since the launch of the STS, we have experienced field failures, including, but not limited to, periods of higher than expected out of box failure rates for the sensor to initialize and display data to the patient. We also experienced a component failure in our receiver which prevented data transmitted from the sensor being received by the handheld receiver. We do not believe these failures created any patient safety concerns and we are not aware of any reports of adverse events or incidents related to these

failures. Although we believe we have taken appropriate actions aimed at reducing or eliminating field failures, there can be no assurances that we will not experience these or other failures going forward.

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 $46.6 million for the twelve months ended December 31, 2006. As of December 31, 2006, we had an accumulated deficit of $130.4 million. We have financed our operations primarily through private placements of our equity securities and our public offerings, and have devoted a substantial portion of our resources to research and development relating to our continuous glucose monitoring systems, and more recently, we have incurred significant sales and marketing and manufacturing expenses associated with the commercialization of our STS. 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.

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 STS, our business may be harmed.

To achieve commercial success for our STS, we must either continue to develop and grow our sales and marketing organization or enter into arrangements with others to market and sell our products. We currently employ a small direct sales force to market our STS in the United States. 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 marketing and distributing our products, and we may be unsuccessful in our attempt to do so. 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 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.

We may contract with third parties to market and sell our STS in the United States if we are unable to develop an adequate direct sales organization. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States, our product margins could be lower than if we directly marketed and sold our STS. 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 do not know whether these efforts will be successful. 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 products 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 for our STS. Since the commercial launch of our STS in March 2006, we have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support our commercialization efforts. As a result of these product shortages, we have experienced periods of backorder and, at times, have also had to limit the efforts of our sales force to introduce the STS to new customers. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. Although we believe we have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts, there an be no assurances that supply will not be constrained going forward. In order to produce our STS 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, such as construction timelines, design, installation and maintenance of manufacturing equipment, among others, which can lead to unexpected delays. 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 STS 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 STS 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 in a lot. 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.

Our STS does not have reimbursement and is not approved for insurance coverage. If we are unable to obtain adequate reimbursement at acceptable prices for our products from third-party payors, we will be unable to generate significant revenue.

Our STS does not have reimbursement and is not approved for insurance coverage. The availability of insurance coverage and reimbursement for newly approved medical devices is uncertain. 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 STS in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our STS. In November 2006, CMS denied an application made by Medtronic to establish a HCPCS code for continuous glucose monitoring. The HCPCS panel within CMS cited that the applicant had not demonstrated superior patient outcomes as a result of the use of the device and that no insurer had identified a national program operating need to establish the codes. Third-party coverage may also be difficult to obtain if our STS is not approved by the FDA as a replacement for existing single-point finger stick devices. 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 STS. 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 STS 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 STS, patients may not use it.

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 STS 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 the receiver included as part of our continuous glucose monitoring systems and the circuit boards for our short-term sensors; we rely on AMI Semiconductor, Inc. to manufacture and supply the application specific integrated circuit, or ASIC, that is incorporated into the transmitter for our continuous glucose monitoring systems; we rely on CardioTech, which manufactures the polymers used to synthesize our polymeric biointerface membranes for our STS; we rely on Vita Needle to manufacture and supply the insertion needle in our STS applicator; and we rely on The Tech Group to supply our injection molded components. Each of these suppliers is a sole-source supplier. In some cases, our agreements with these and our other suppliers can be terminated by either party upon short notice. In other cases we operate without a written agreement with the supplier. Our contract manufacturers also rely on sole-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 are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

- 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 sole-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, which could inhibit their ability to fulfill our orders and meet our requirements.

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

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 short-term glucose monitor infringes certain patents held by Abbott. We moved to dismiss these claims on August 31, 2005 on the grounds that Abbott s complaint was premature. In addition to our motion to dismiss, we also filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office on January 25, 2006 and February 1, 2006. On February 22, 2006, we filed a motion to stay the entirety of the Delaware case pending decision from the Patent Office on those requests for reexamination, and in March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against us in the litigation. On February 23, 2006, the Court held a scheduling conference, during which it set a trial date of October 9, 2007. On June 27, 2006, Abbott amended its complaint to include three additional patents owned or licensed by Abbott which are allegedly infringed by our short term 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 a declatory judgment 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. On November 11, 2006, the Patent Office issued a non-final rejection of all claims we submitted for re-examination in one of the Abbott patents cited in the original lawsuit, and on December 27, 2006, the Patent Office issued a non-final rejection of all claims we submitted for re-examination in a second of the Abbott patents cited in the original lawsuit. No decision has yet been published by the Patent Office on the other two patients cited in the complaint and currently under examination. Subject to the stay, we intend to continue to vigorously contest the action.

Subsequent to the court s ruling, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of those same three additional patents. We believe this complaint, like the first, is without merit and we intend to vigorously contest the action. To that end, we filed requests with the Patent Office to reexamine each of the three additional patents cited by Abbott and 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 October 2006 and December 2006, the Patent Office ordered reexamination of two of the three patents cited in this new lawsuit. The third reexamination request is still under review by the Patent Office.

Although it is our position that Abbott s assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees 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 STS. Our STS is our only product that is approved for commercial sale, and if we were forced to stop selling it, 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.

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 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, 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 is 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.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties to protect our intellectual property. 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. 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.

The federal trademark application for the DEXCOM mark has been opposed, and we continue to vigorously defend against the opposition. The opposition proceeding only determines the right to federally register a trademark and cannot result in the award of any damages. We believe that we are entitled to a registration for our DEXCOM mark, but cannot assure you that we will succeed in these efforts. If we are unsuccessful, we could be forced to change our company name or market our products under a different name, which could result in a loss of brand recognition, could require us to retrieve product and interrupt supply and could require us to devote substantial resources to advertising and marketing our products under the new brand.

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 our STS, we compete directly with Roche Disetronic, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; the MediSense and TheraSense divisions of Abbott Laboratories; and Bayer Corporation, 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 STS. To date, in addition to our STS, two other companies, Cygnus and Medtronic have received approval from the FDA for continuous glucose monitors and Abbott is seeking approval for another. We believe that one of the products, originally developed and marketed by Cygnus, is no longer actively marketed. In addition, Johnson & Johnson recently announced that it is developing and expects to commence clinical trials in support of a continuous glucose monitoring system in 2007. 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.

No continuous glucose monitoring system, including our STS, has yet received FDA clearance as a replacement for single-point finger stick devices, and our products may never be approved for that indication.

Our STS 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 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 STS 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 three 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 applications, we may be unable to commercialize our continuous glucose monitoring systems under development, which could impair our financial position.

Before submitting any additional PMA applications, we must successfully complete pre-clinical studies 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 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 application, even if the trial s intended safety and efficacy endpoints are achieved.

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, 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;
- 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;
- 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 predecessor clinical trial results may 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. 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.

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

We rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trial and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If

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

We have not received, and may never receive, FDA approval to market our continuous glucose monitoring systems that are under development.

We are continuing to invest in the development of our technology platform and will seek to obtain additional FDA approvals for continuous glucose monitoring systems in addition to our STS, including our seven-day STS, for which we have filed a PMA supplement during the second quarter of 2006, and our continuous glucose monitoring system for the in-hospital market. The regulatory approval process for these continuous glucose monitoring systems that are under development involves, among other things, successfully completing clinical trials and obtaining a PMA from the FDA. The PMA process requires us to prove the safety and efficacy of our continuous glucose monitoring systems 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 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.

Even if approved, our continuous glucose monitoring systems under development may not be approved for the indications that are necessary or desirable for successful commercialization. We may not obtain the necessary regulatory approvals to market these continuous glucose monitoring systems in the United States or anywhere else. Any delay in, or failure to receive or maintain, approval 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 STS or the development and commercialization of our other continuous glucose monitoring systems without additional funding.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our STS, including further development of a direct sales force and expansion of our manufacturing capacity, and on research and development, including conducting clinical trials for our next generation continuous glucose monitoring systems. For the twelve months ended December 31, 2006, our net cash used in operating activities was $43.7 million, compared to $22.6 million for the same period in 2005, and as of December 31, 2006, we had working capital of $52.1 million, including $54.5 million in cash, cash equivalents and short-term marketable securities. We expect that our cash used by operations will increase significantly in each of the next several years, and we may

need additional funds to continue the commercialization of our STS 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 STS 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 STS 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 STS or other continuous glucose monitoring systems under development may not be revealed by our clinical experience to date.

If unanticipated long-term side-effects result from the use of our STS or other glucose monitoring systems under development, we could be subject to liability and our systems would not be widely adopted. Our clinical trials have been limited to seven days of continuous use with our STS. Additionally, we have limited clinical experience with repeated use of our STS 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 STS will result in unanticipated adverse effects, potentially even after the device is removed.

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. 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, quality assurance, labeling, packaging, storage, shipping and servicing of our products. The FDA enforces the QSR through unannounced inspections. We currently manufacture our devices at our headquarters in San Diego, California, and a new facility located nearby. In these facilities we have more than 5,000 square feet of laboratory space and approximately 5,000 square feet of controlled environment rooms. In January 2007, both facilities were subject to a post-approval PMA and QSR audit by the FDA. Based on the results of this inspection, we believe we are in substantial compliance with the regulatory requirements for a commercial medical device manufacturer and there were no major observations from the FDA resulting from this audit. At the close of the inspection, the FDA issued a form 483 identifying several inspectional observations and, although we have no formal requirements or obligations to provide anything further to the FDA regarding these observations, we intend to voluntarily provide formal written evidence to the FDA of our actions taken to address these minor observations no later than May 1, 2007.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;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve our continuous glucose monitoring systems;
- 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.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and 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, 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. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedure and related processes to implant our long-term sensor into patients. If these medical personnel are not properly trained or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, 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 STS is designed to be used by a patient continuously for three days, but the patient might be able to circumvent the safeguards designed into the STS and use the product for longer than three days. Off-label use of products by patients is common, and any such off-label use of our STS 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.

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 two facilities in San Diego, California. Any disruption at these facilities could increase our expenses.

Historically, the majority of our operations have been conducted at a single location in San Diego, California. We recently entered into a lease for additional manufacturing facilities also located in San Diego, California and have relocated a portion of our manufacturing operations and research and development to this new facility. 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.

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 may seek to market our products internationally. 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 have not taken any actions to obtain foreign regulatory approvals. 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 Andrew P. Rasdal, our President and Chief Executive Officer, Andrew K. Balo, our Vice President of Clinical and Regulatory Affairs, and Mark Brister, our Vice President of Advanced Development Teams. 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 STS and the development and introduction of our other 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.

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

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 FAS 123(R), involves significant assumptions that are subject to change and difficult to predict.

On January 1, 2006, we adopted SFAS 123(R), which requires that we record compensation expense in the statement of income for share-based payments, such as employee stock options, using the fair value method. The requirements of SFAS 123(R) 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 that 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.

SFAS 123(R) 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, SFAS 123(R) 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.

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

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions

completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. 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.

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

On March 20, 2006, we entered into a loan and security agreement that provides for a loan of up to $5.0 million to finance various equipment and leasehold improvement expenses. The agreement 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;
- 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 23,000 square feet, which includes our laboratory, research and development, manufacturing and general administration functions. The lease for this facility expires in 2011. We have the right to extend the term of this lease for one period of five years, and a right of first offer for an adjacent facility as space becomes available in that facility. We have recently expanded our manufacturing capacity in our current facility and relocated a portion of our manufacturing operations and research and development to our new 66,400 square foot facility which is also in San Diego, California. The lease for this new facility expires in 2014. In January 2007, both our facilities were subject to a post-approval PMA and QSR audit by the FDA. Based on the results of this inspection, we believe we are in substantial compliance with the regulatory requirements for a commercial medical device manufacturer and there were no major observations from the FDA resulting from this audit. At the close of the inspection, the FDA issued a Form 483 identifying several inspectional observations and, although we have no formal requirements or obligations to provide anything further to the FDA regarding these observations, we intend to voluntarily provide formal written evidence to the FDA of our actions taken to address these minor observations no later than May 1, 2007. We previously leased two smaller facilities of approximately 7,000 square feet each near our headquarters. One of these leases expired by its terms in November 2006 and we entered into a sublease agreement with an unaffiliated third-party to lease the other 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 reasonably 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 short-term glucose monitor infringes certain patents held by Abbott. We moved to dismiss these claims on August 31, 2005 on the grounds that Abbott s complaint was premature. In addition to the our motion to dismiss, we also filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office on January 25, 2006 and February 1, 2006. On February 22, 2006, we filed a motion to stay the entirety of the Delaware case pending decision from the Patent Office on those requests for reexamination, and in March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against us in the litigation. On February 23, 2006, the Court held a scheduling conference, during which it set a trial date of October 9, 2007. On June 27, 2006, Abbott amended its complaint to include three additional patents owned or licensed by Abbott which are allegedly infringed by the Company s short term 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 a declaratory judgment 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. On November 11, 2006, the Patent Office issued a non-final rejection of all claims we submitted for re-examination in one of the Abbott patents cited in the original lawsuit and on December 27, 2006, the Patent Office issued a non-final rejection of all claims we submitted for re-examination in a second of the Abbott patents cited in the original lawsuit. No decision has yet been

published by the Patent Office on the other two patents cited in the first complaint and currently under reexamination. Subject to the stay, we intend to continue to vigorously contest the action.

Subsequent to the court s ruling, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of those same three additional patents. We believe this complaint, like the first, is without merit and we intend to vigorously contest the action. To that end, we filed requests with the Patent Office to reexamine each of the three additional patents cited by Abbott and 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 October 2006 and December 2006, the Patent Office ordered reexamination of two of the three patents cited in this new lawsuit. The third reexamination request is still under review by the Patent Office. Although it is our position that Abbott s assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees 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.

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

Not applicable.

PART II

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

DexCom s common stock is traded on the NASDAQ Global Market under the symbol DXCM. As of February 16, 2007, there were approximately 263 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 sales price per share for DexCom s common stock for the periods indicated:

Year Ended December 31, 2006	**High**	**Low**
First Quarter	$ 23.70	$ 14.31
Second Quarter	$ 26.70	$ 11.70
Third Quarter	$ 14.40	$ 10.05
Fourth Quarter	$ 12.17	$ 8.35

Year Ended December 31, 2005	**High**	**Low**
Second Quarter (from April 14, 2005)	$ 15.99	$ 9.61
Third Quarter	$ 13.40	$ 9.85
Fourth Quarter	$ 16.17	$ 10.00

Neither we nor any affiliated purchaser repurchased any of our equity securities in the fourth quarter of fiscal year 2006.

Recent Sales of Unregistered Securities

On December 1, 2006, pursuant to Section 4(2) of the Act, we issued 22,524 shares of our common stock upon exercise of an outstanding warrant. The exercise price per share was $5.38, and the holder elected, in lieu of payment of the exercise price in cash, to surrender the warrant and receive a net amount of shares based on the fair market value of our common stock determined as an average of the closing price for our common stock for the five trading days prior to the date of exercise, after deduction of the aggregate exercise price.

ITEM 6. SELECTED FINANCIAL DATA

The statements of operations data for the years ended December 31, 2006, 2005 and 2004 and the balance sheet data as of December 31, 2006 and 2005 have been derived from our audited financial statements included elsewhere in this annual report. The statements of operation data for the years ended December 31, 2003 and 2002 and the balance sheet data as of December 31, 2004, 2003 and 2002 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 financial statements and related notes to those statements included elsewhere in this annual report.

	Years Ended December 31,				
	2006	2005	2004	2003	2002
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenues	$ 2,170	$	$	$	$
Cost of sales	10,959				
Gross margin	(8,789)				
Operating expenses:					
Research and development(2)	19,420	26,770	12,470	8,934	6,311
General and administrative(2)	21,111	5,660	1,597	1,250	1,860
Total costs and expenses	40,531	32,430	14,067	10,184	8,171
Interest and other income, net	2,721	1,662	121	270	463
Net loss	(46,599)	(30,768)	(13,946)	(9,914)	(7,708)
Accretion to redemption value of Series B and Series C redeemable convertible preferred stock		(122)	(3,235)	(3,235)	(2,451)
Net loss attributable to common stockholders	$ (46,599)	$ (30,890)	$ (17,181)	$ (13,149)	$ (10,159)
Basic and diluted net loss per share attributable to common stockholders(1)	$ (1.71)	$ (1.63)	$ (7.51)	$ (6.06)	$ (4.96)
Shares used to compute basic and diluted net loss per share attributable to common stockholders(1)	27,235,704	18,944,208	2,286,320	2,169,922	2,046,208

	As of December 31,				
	2006	2005	2004	2003	2002
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$18,167	$ 37,247	$ 27,229	$ 20,016	$ 29,844
Working capital	52,127	43,939	25,705	19,152	29,079
Total assets	64,553	56,726	29,358	20,767	30,611
Long term obligations	2,118				
Redeemable convertible preferred stock			76,974	52,384	49,356
Total stockholders equity (deficit)	56,828	49,412	(49,310)	(32,601)	(19,485)

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

(2) For the years ended December 31, 2004 and 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.

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 the company s research and development programs, the inability of patients to receive reimbursements from third-party payors, inadequate financial and other resources 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 people with diabetes. On March 24, 2006, we received approval from the U.S. Food and Drug Administration, or FDA, for our Short-Term Continuous Glucose Monitoring System, or STS. We commenced initial commercial shipments of our STS throughout the United States on March 28, 2006. Our approval allows for the use of our STS 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 STS is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Our STS must be prescribed by a physician and includes a disposable sensor, a transmitter and a small cell phone-sized receiver. The sensor is inserted by the patient and is intended to be used continuously up to three days after which it is removed and may be replaced by a new sensor. Our STS transmitter and receiver are reusable. Since inception, we have devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. More recently, we have devoted considerable resources for the commercialization of our STS, as well as the continued development of our technology platform and future generations of products.

To support our national product launch, 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. To complement our direct sales efforts, we also employ clinical specialists who educate and provide clinical support in the field.

We are leveraging our technology platform to enhance the capabilities of our STS and develop additional continuous glucose monitoring products. We filed a PMA supplement in the second quarter of 2006 for approval of our next generation STS, which is expected to used continuously for up to seven days. In October 2006, we received a written request from the FDA for additional information, and in November 2006 we responded to that request. We are currently awaiting additional questions or a decision from the FDA for this PMA supplement. We are continuing clinical development of a third generation STS which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, may be calibrated using any brand of home blood glucose meter, 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 STS product platform in the future. We are also developing a product platform specifically for the

in-hospital glucose monitoring market, with an initial focus on a sensor specifically for the critical care market. We conducted initial human feasibility studies for this product in the first quarter of 2007. Our clinical trials may be delayed due to scheduling issues with patients and investigators, institutional review boards, sensor performance and manufacturing supply constraints, among other factors. Support of these clinical trials requires significant resources in 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.

We currently manufacture our devices at our headquarters in San Diego, California, and a new facility located nearby. In these facilities we have approximately 5,000 square feet of laboratory space and 5,000 square feet of controlled environment rooms. In January 2007, both our facilities were subject to a post-approval PMA and QSR audit by the FDA. Based on the results of this inspection, we believe we are in substantial compliance with the regulatory requirements for a commercial medical device manufacturer and there were no major observations from the FDA resulting from this audit. At the close of the inspection, the FDA issued a Form 483 identifying several inspectional observations and, although we have no formal requirements or obligations to provide anything further to the FDA regarding these observations, we intend to voluntarily provide formal written evidence to the FDA of our actions taken to address these minor observations as soon as practical. We manufacture our STS with components supplied by outside vendors and with parts manufactured by us internally. Key components that we manufacture internally include our wire-based sensor for our STS. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished product, which includes a transmitter, a receiver and a disposable sensor. We are expanding our manufacturing capacity in our two facilities in San Diego, California. Our capacity expansion could be constrained by the lack of material availability, equipment design, production and validation, regulatory approval of our new facility, personnel staffing and other factors.

Revenues are generated from sales of our STS transmitter and receiver and from the recurring sales of disposable sensors. The disposable sensor is inserted by the patient and intended to be used continuously for up to three days, after which it may be replaced with a new disposable sensor. Our STS transmitter and receiver are reusable. In the event we establish an installed base of patients using our STS, we expect to generate an increasing portion of our revenues through recurring sales of our disposable sensors. We recognize revenue on our products upon shipment and our sales terms provide for customer payment at the time of order.

Through December 31, 2006, we had generated $2.2 million of revenue, and we have incurred net losses in each year since our inception in May 1999. Through December 31, 2006, we had an accumulated deficit of $130.4 million. We expect our losses to continue and increase as we expand our clinical trial activities and continue commercialization activities. We have financed our operations primarily through offerings of equity securities. 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. As of December 31, 2006, we had $3.0 million in borrowings under our loan and security agreement. In May 2006 we completed a follow-on offering of 2,117,375 shares of our common stock for net proceeds of $47.0 million.

Financial Operations

Revenue

Through December 31, 2006, we generated $2.2 million in revenue from the sale of our continuous glucose monitoring systems after launching our system on March 28, 2006. We expect that revenues we generate from the sales of our STS will fluctuate from quarter to quarter.

Cost of Sales

Cost of sales includes direct labor and material costs related to each product sold or produced including assembly and test labor and scrap, as well as factory overhead supporting our manufacturing operations. Factory overhead includes facilities, material procurement and control, manufacturing engineering, quality control, supervision and management. These costs are primarily salary, fringe benefits, stock based compensation, facility expense, supplies and purchased services. The majority of our costs are currently fixed due to the relatively low production volumes compared to our potential capacity. From our inception until December 31, 2005, all of our manufacturing costs were included in research and development expense due to our development stage. From January 1, 2006 these costs are included in cost of sales.

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, recruitment, stock based compensation, relocation and temporary employee expenses. We also incur significant expenses to operate our clinical trials including trial design, clinical site reimbursement, data management, clinical trial product and associated travel expenses. Our research and development expenses also include fees for design services, contractors and development materials. We expect our research and development expenses to increase as we continue to support the development and clinical trials of additional products.

Selling, General and Administrative

Our selling, general and administrative expenses primarily consist of salary, fringe benefits and stock 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 expenses for board meetings. We expect our selling, general and administrative expenses to increase as we continue to support the commercialization of our STS platform.

Results of Operations

Fiscal year ending December 31, 2006 compared to December 31, 2005

Revenue, Cost of Sales and Gross Margin. We recorded revenues of $2.2 million for the twelve months ending December 31, 2006 after launching our first product on March 28, 2006. No revenues were recorded in 2005. Cost of sales increased $11.0 million to $11.0 million for the twelve months ending December 31, 2006 compared to zero for the twelve months ending December 31, 2005. The $11.0 million of cost of sales for the twelve months ending December 31, 2006 reflects a $0.7 million increase compared to the $10.3 million of these expenses that were included in research and development expense during 2005. Included in the 2005 costs were a charge of $2.0 million to write down component inventory to the lower of cost or market value. The increase in fiscal year cost of sales in 2006 was primarily related to variable costs to produce our revenues including a $1.4 million increase in compensation expense, $1.4 million in increased scrap and $1.0 million in increased depreciation, offset by $6.9 million in lower expensed materials and a benefit of $1.3 million for materials purchased in 2005 and utilized in 2006.

Research and Development. Research and development expense, including stock-based compensation, decreased $7.3 million to $19.4 million for the twelve months ending December 31, 2006, compared to $26.8 million for the same period in 2005. Development expenses increased $1.9 million and clinical and

regulatory costs increased $1.0 million and these increases were more than offset by a $10.3 million decrease in manufacturing expenses that are now classified in cost of sales for 2006. Changes in research and development and clinical expenses were driven by $2.1 million in increased compensation expenses, and $847,000 in increased facility and depreciation costs, partially offset by $1.2 million in lower outside design costs.

Selling, General and Administrative. Selling, general and administrative expense, including stock-based compensation, increased $15.5 million to $21.1 million for the twelve months ending December 31, 2006, compared to $5.7 million for the same period in 2005. The increase was primarily due to $10.7 million in higher sales and marketing costs and $4.8 million in higher administrative costs. Changes in selling, general and administrative expense were driven by $9.0 million in increased compensation costs, primarily in sales and marketing where we have hired a direct sales force in 2006, $2.8 million in increased advertising and promotions and $1.0 million in increased legal expenses.

Interest Income and Expense, Net. Interest income and expense, net, increased $1.1 million to $2.7 million for the twelve months ending December 31, 2006, compared to $1.7 million for the same period in 2005. The increase was due to higher combined average cash, cash equivalents, and short-term marketable securities balances due to our April 2006 follow-on public offering partially offset by $95,000 in interest expense on our bank equipment line.

Fiscal year ending December 31, 2005 compared to December 31, 2004

Revenue. We generated no revenue during 2004 or 2005.

Research and Development. Research and development expense, including stock-based compensation, increased $14.3 million to $26.8 million for the twelve months ended December 31, 2005, compared to $12.5 million for the twelve months ended December 31, 2004. The increase was primarily related to $7.7 million in increased manufacturing expenses, $3.7 million in higher development costs and $1.9 million in increased clinical and regulatory expense as we scaled our operations after completing our approval support trial and submitting our PMA to the FDA. Included in the higher R&D spending were $6.4 million in higher material procurements which includes a $2.0 million loss on firm purchase commitments, $4.4 million in increased salary, fringe and temporary employee expenses, $1.2 million in greater product and tooling design costs, $1.0 million in higher clinical trial expense and $0.5 million in increased depreciation. To date, we have expensed purchases of materials, some of which may be used to generate product sales, if and when we receive FDA approval.

Selling, General and Administrative. Selling, general and administrative expense, including stock based compensation, increased $4.1 million to $5.7 million for the twelve months ended December 31, 2005, compared to $1.6 million for the twelve months ended December 31, 2004. The increase was primarily due to $1.4 million in initial marketing costs, $1.2 million related to expenses associated with operating as a public company, and increased litigation expenses.

Interest and Other Income, Net. Interest and other income increased $1.5 million to $1.7 million for the twelve months ended December 31, 2005, compared to $121,000 for the twelve months ended December 31, 2004. The increase was due to higher combined average cash, cash equivalents, and short-term marketable securities balances due to our April 2005 IPO along with higher interest rates.

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, 2006, we had an accumulated deficit of $130.4 million and had working capital of $52.1 million, which included $54.5 million in cash, cash equivalents and short-term marketable securities. We have funded our operations primarily from the sale of equity securities and our bank line, raising aggregate net proceeds of $171.8 million from equity sales through December 31, 2006. 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. On March 20, 2006, we entered into a loan and security agreement that provides for a loan of up to $5.0 million to finance various equipment purchases. As of December 31, 2006 we had drawn $3.0 million under our bank equipment loan. On May 2, 2006 we completed the sale of 2,117,375 shares of common stock for net proceeds of $47.0 million.

Net Cash Used in Operating Activities. Net cash used in operating activities increased $21.2 million to $43.7 million for the twelve months ending December 31, 2006, compared to $22.6 million for the same period in 2005. The increase in cash used in operations was primarily due to a $15.8 million increase in our net loss and $8.4 million in lower accounts payable and accrued liabilities, as well as $1.4 million in higher inventories, partially offset by a $4.2 million increase in stock based compensation and a $1.6 million increase in depreciation, which are non-cash expenses.

Net Cash Used in Investing Activities. Net cash used in investing activities increased $8.4 million to $26.6 million for the twelve months ending December 31, 2006, compared to $18.2 million for the same period of 2005. The increase was primarily due to $9.7 million in net purchases and sales of short-term marketable securities as we invested the proceeds from our follow-on offering. For the twelve months ending December 31, 2006, we invested $3.4 million in equipment and facilities to support manufacturing capacity increases and sales and marketing expansion, a decrease of $1.3 million compared to the $4.7 million invested in 2005.

Net Cash Provided by Financing Activities. Net cash provided by financing activities increased $473,000 to $51.2 million for the twelve months ending December 31, 2006, compared to $50.7 million for the same period of 2005. The increase was primarily due to an increase of $0.9 million in proceeds from stock option exercises and employee stock purchases. The proceeds from our 2006 follow on offering and our bank line draws in 2006 were approximately equal to our 2005 IPO proceeds.

Operating Capital and Capital Expenditure Requirements

We recently commercialized our first product, the STS Continuous Glucose Monitoring System. However, we anticipate that we will continue to incur net losses for the next several years as we incur expenses to commercialize our STS, develop new continuous glucose monitoring products, and expand our sales, marketing, manufacturing and corporate infrastructure.

We believe that our cash, cash equivalents and short-term marketable securities balances, and the interest we earn on these balances, will be sufficient to meet our anticipated cash requirements with respect to the commercial launch of our STS, clinical trials, PMA applications and to meet our other anticipated cash needs for 2007. If our available cash, cash equivalents and short-term marketable securities and the funds available under our loan and security agreement 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. 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 and commercialization of continuous glucose monitoring technologies, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current research and

development and commercialization efforts. Our future funding requirements will depend on many factors, including, but not limited to:

- the revenue generated by sales of our STS and other future products;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- the quality levels of our products and services;
- potential reimbursement to purchasers of our products by third-party payors;
- our ability to efficiently scale our manufacturing operations to meet demand for our current and any future products;
- the costs to produce our 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, 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.

Contractual Obligations

In March 2006, the Company entered into a loan and security agreement that provides for a loan of up to $5.0 million to finance various equipment and leasehold improvement purchases through March 2007. As of December 31, 2006, there was an outstanding balance of $3.0 million on our loan and $2.0 million available for future borrowings that must be accessed by March 31, 2007. We are required to repay the outstanding balance in monthly installments beginning April 2007 until September 2009.

In April 2006, we entered into an office lease agreement for approximately 66,400 square feet of additional facilities located near our headquarters in San Diego, CA. We also 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. Excluding real estate taxes and operating costs, we are required to make future monthly payments as of December 2006 through April 2014 totaling $8.7 million. Our facility leases have annual rental escalation clauses and are expensed on a straight-line basis.

We are party to various purchase arrangements related to components used in production and research and development activities. As of December 31, 2006, the Company had purchase commitments with certain vendors totaling approximately $1.4 million due within one year. There are no purchase commitments due beyond one year.

The following table summarizes our outstanding contractual obligations as of December 31, 2006 and the effect those obligations are expected to have on our liquidity and cash flows in future periods:

Contractual Obligations	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Notes payable	$ 3,026,000	$ 907,800	$ 2,118,200	$	$
Operating leases	10,797,112	1,166,931	3,271,765	3,181,168	3,177,248
Royalty obligations	1,160,000	116,000	232,000	232,000	580,000
Purchase commitments	1,366,000	1,366,000			
Total	$ 16,349,112	$ 3,556,731	$ 5,621,965	$ 3,413,168	$ 3,757,248

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 $38,168, $6,483, and $10,046 relating to an Oracle ERP system for the years ended December 31, 2006, 2005 and 2004, respectively. The Chairman was not involved in the selection of the Company s 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 financial statements, which we have prepared in accordance with generally accepted accounting principles. The preparation of these 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 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 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.

Share-Based Compensation

Our share-based employee compensation plans are described in Note 4 to our financial statements. On January 1, 2006, we adopted SFAS 123(R) which requires the measurement and recognition of 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. SFAS 123(R) supersedes our previous accounting under APB 25 and SFAS 123, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued SAB 107 relating to SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R).

We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our

Statement of Operations as of and for the year ended December 31, 2006 reflects the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company s Statements of Operations for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Share-based compensation expense recognized under SFAS 123(R) for the years ended December 31, 2006 was $5,852,901. Share-based compensation expense of $1,785,729 and $448,689 for the years ended December 31, 2005 and 2004, respectively, was related to the grant of certain options to employees during 2004 which represented the difference between the fair value of the common stock and the option exercise price at the date of grant accounted for in accordance with APB 25. As of December 31, 2006, there was $11.9 million of unrecognized compensation cost related to outstanding options that is expected to be recognized as a component of our operating expenses through 2010. Compensation costs will be adjusted for future changes in estimated forfeitures.

Prior to January 1, 2006, we had adopted the disclosure-only provision of SFAS 123. Accordingly, we had not previously recognized compensation expense, except for share-based compensation expense accounted for in accordance with APB 25.

SFAS 123(R) requires companies to 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 the Company s Statement of Operations. For the year ended December 31, 2006, the 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 of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). In conjunction with the adoption of SFAS 123(R), 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 Statement of Operations in fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be 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 required under SFAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

As permitted by SFAS 123(R), 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 required under SFAS 123. 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 in accordance with SFAS 123(R) using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

Prior to the adoption of SFAS 123(R), we presented deferred compensation as a separate component of stockholders equity. In accordance with the provisions of SFAS 123(R), on January 1, 2006 we reclassified the balance in deferred compensation to additional paid-in capital on our balance sheet.

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. 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 standard costs are based on full utilization of our manufacturing capacity.

Bonus Accrual

For the 2006 bonus pool, the Compensation Committee authorized an amount of up to 25% of salary and wages for non sales employees to be awarded from the pool based on the weighted average achievement measured against certain objectives. No company wide bonus was paid for 2006 and the $773,000 that had been accrued in prior quarters was reversed to the Statement of Operations in the fourth quarter of 2006.

Revenue Recognition

We sell products through a direct sales force in the United States. We recognize revenue on product sales upon shipment. We accrue for estimated returns at the time of shipment.

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.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes*, or FIN 48, 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, FIN 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The accounting provisions of FIN 48 will be effective for us beginning October 1, 2007. Only tax positions that meet the more likely than not recognition threshold at

the effective date may be recognized upon adoption of FIN 48. We are in the process of determining the effect, if any, the adoption of FIN 48 will have on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET 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.

To date we have recorded no product sales and have not entered into any agreements denominated in other than U.S. dollars. Accordingly we believe we have no material exposure to risk from changes in foreign currency exchange rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The information required is set forth under Report of Independent Registered Public Accounting Firm, Balance Sheets, Statements of Operations, Statement of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit), Statements of Cash Flows and Notes to Financial Statements on pages F-2 to F-13 of this annual report.

DEXCOM, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have audited the accompanying balance sheets of DexCom, Inc. as of December 31, 2006 and 2005, and the related statements of operations, redeemable convertible preferred stock and stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006. 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 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 our 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 financial position of DexCom, Inc. at December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 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 1 to the financial statements, effective January 1, 2006, DexCom, Inc. changed its method of accounting for share-based payments in accordance with Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of DexCom, Inc. s internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 23, 2007 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California
February 23, 2007

DEXCOM, INC.
BALANCE SHEETS

	Years Ended December 31, 2006	2005
Assets		
Current assets:		
Cash and cash equivalents	$ 18,167,066	$ 37,247,064
Short-term marketable securities, available-for-sale	36,341,449	13,277,688
Accounts receivable, net	120,477	
Inventory	1,413,024	
Prepaid and other current assets	1,313,907	488,015
Total current assets	57,355,923	51,012,767
Property and equipment, net	6,117,685	5,463,491
Restricted cash	1,079,000	250,000
Total assets	$ 64,552,608	$ 56,726,258
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,763,300	$ 6,184,734
Accrued payroll and related expenses	1,557,578	889,362
Current portion of long-term debt	907,800	
Total current liabilities	5,228,678	7,074,096
Deferred rent	377,463	240,099
Long-term debt, net of current portion	2,118,200	
Commitments and contingencies (Note 4)		
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2006 and December 31, 2005, respectively.		
Common stock, $0.001 par value, 100,000,000 authorized; 28,163,690 and 25,416,559 shares issued and outstanding at December 31, 2006 and December 31, 2005, respectively.	28,164	25,417
Additional paid-in capital	187,162,062	134,257,379
Deferred stock-based compensation		(1,084,214)
Accumulated other comprehensive income (loss)	11,923	(11,928)
Accumulated deficit	(130,373,882)	(83,774,591)
Total stockholders equity	56,828,267	49,412,063
Total liabilities and stockholders equity	$ 64,552,608	$ 56,726,258

See accompanying notes.

DEXCOM, INC.
STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2006	**2005**	**2004**
Revenues	$ 2,169,790	$	$
Cost of sales	10,958,953		
Gross margin	(8,789,163)		
Operating expenses			
Research and development	19,419,550	26,769,514	12,469,842
Selling, general and administrative	21,111,325	5,659,960	1,597,275
Total operating expenses	40,530,875	32,429,474	14,067,117
Operating loss	(49,320,038)	(32,429,474)	(14,067,117)
Interest and other income, net	2,720,747	1,662,044	120,653
Net loss			