DEXCOM INC
Form S-1
April 06, 2006

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As filed with the Securities and Exchange Commission on April 6, 2006

Registration Number 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DexCom, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**3841**	**33-0857544**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

DexCom, Inc.
5555 Oberlin Drive
San Diego, California 92121
(858) 200-0200
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Andrew P. Rasdal
President and Chief Executive Officer
DexCom, Inc.
5555 Oberlin Drive
San Diego, California 92121
(858) 200-0200
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Gordon K. Davidson, Esq.
Robert A. Freedman, Esq.
Scott J. Leichtner, Esq.
FENWICK & WEST LLP
801 California Street
Mountain View, California 94041
(650) 988-8500

Charles Ruck, Esq.
Shayne Kennedy, Esq.
LATHAM & WATKINS LLP
650 Town Center Drive, 20th Floor
Costa Mesa, California 92626
(714) 540-1235

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, par value $0.001 per share(2)	4,830,000(3)	$20.18	$97,469,400	$10,430

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low trading prices for the common stock on the NASDAQ National Market on March 30, 2006.

(2) This registration statement also covers rights to purchase shares of the Registrant's Series A junior participating preferred stock (the "Rights") that are attached to all shares of the Registrant's common stock. Until the occurrence of certain prescribed events, the Rights are not exercisable, are evidenced by the certificates for common stock and will be transferable along with and only with the common stock. The value attributable to the Rights, if any, is reflected in the value of the common stock.

(3) Includes 630,000 shares subject to the underwriters' over-allotment option.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. Neither we nor the selling stockholders may sell these securities until the the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated April 6, 2006

4,200,000 Shares

DEXCOM, INC.

Common Stock

$ per share

DexCom, Inc. is offering 1,200,000 shares and the selling stockholders are offering 3,000,000 shares. We will not receive any proceeds from the sale of our shares by the selling stockholders.

The last reported sale price of our common stock on April 5, 2006 was $20.60 per share.

Trading Symbol:
NASDAQ National Market DXCM.

This investment involves risk. See "Risk Factors" beginning on page 8.

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to DexCom, Inc.	$	$
Proceeds, before expenses, to the selling stockholders.	$	$

The underwriters have a 30-day option to purchase up to 630,000 additional shares of common stock from us to cover over-allotments, if any.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone's investment in these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Piper Jaffray **First Albany Capital**

Lazard Capital Markets **Montgomery & Co., LLC**

The date of this prospectus is , 2006.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover of this prospectus, but the information may have changed since that date.

SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should carefully read the more detailed information set out in this prospectus, especially the risks of investing in our common stock that we discuss under the "Risk Factors" section, as well as the financial statements and the related notes to those statements included elsewhere in this prospectus. References in this prospectus to "we," "us," "our" and "DexCom" refer to DexCom, Inc. unless the context requires otherwise.

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 , 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 used continuously for three days after which it is removed and may be replaced by a new sensor. Upon insertion, our STS wirelessly transmits the patient's blood glucose levels to the receiver, which allows the patient to view real-time and trended blood glucose information with the touch of a button and alerts the patient when blood glucose levels are inappropriately high or low. Studies have demonstrated that patients who intensely managed blood 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 intend to employ clinical specialists who will educate and provide clinical support, and we currently offer 24-hour customer service and technical support. We are expanding our manufacturing capacity in our current facility and have also signed a lease for an additional 66,400 square foot manufacturing facility in San Diego, California.

We are leveraging our technology platform to enhance the capabilities for our STS and develop additional continuous glucose monitoring products. We are continuing clinical development on our next generation STS, which is expected to be used continuously for seven days, and expect to file an application for pre market approval, or PMA, for this product by the middle of 2006. Our STS is not currently approved as a substitute for single-point finger stick devices. We have initiated feasibility studies to evaluate the trial design and sensor performance we believe may be appropriate for obtaining approval from the FDA for the use of our STS as the sole basis for making therapeutic adjustments, which we refer to as replacement claim labeling. By the end of 2006, we expect to complete a pivotal trial to seek replacement claim labeling from the FDA. In addition, we expect to complete a trial by the end of 2006 to support a PMA supplement to obtain a pediatric indication for

our STS. We are also developing a product for the in-hospital monitoring market, which we believe may be as large as the ambulatory monitoring market, and expect to complete feasibility studies by the end of 2006. Finally, we are continuing development of a long-term continuous blood glucose monitoring system with a sensor that can be implanted by a physician in a short outpatient procedure requiring only local anesthesia. We have recently implanted long-term sensors in seven patients in New Zealand.

Market Opportunity

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. As of 2000, approximately 171 million people suffered from diabetes worldwide. In 2005, there were an estimated 14.6 million diagnosed diabetes patients in the United States, with 1.5 milion new cases of diabetes 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.

Diabetes is typically classified into two major groups: Type 1 and Type 2. Type 1 diabetes patients suffer from an absence of insulin and require frequent insulin injections in order to regulate and maintain blood glucose levels. Type 2 diabetes patients are unable to produce sufficient levels of insulin or become insulin resistant and, depending on the severity, may require diet and nutrition management, exercise, oral medications or insulin injections to regulate blood glucose levels. We estimate that there are approximately 1.5 million diagnosed Type 1 diabetes patients and 2.6 million Type 2 patients who use insulin in the United States.

There are various subgroups of patients, including in-hospital and pediatric patients, who present significant diabetes 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. In addition, according to a *Diabetes Care* article, as of 1998, as many as 1.5 million hospitalized patients have significant hyperglycemia but no history of diabetes. Studies have shown that tighter glycemic control in hospitalized patients can reduce morbidity and mortality, shorten hospitalization times, reduce staff workloads, and significantly improve patient care and survival. About 75% of all newly diagnosed cases of Type 1 diabetes in the United States occur in people under 18 years old. In addition, Type 2 diabetes is occurring with increasing frequency in young people, largely as a result of the increase in obesity amongst children.

The American Diabetes Association, or 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.

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. As a result, blood glucose levels may fluctuate

throughout the day and patients are often unaware that their levels are too high or too low. 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. In addition, a peer-reviewed study that appeared in the December 2005 edition of the *New England Journal of Medicine* concluded that intensive diabetes therapy has long-term beneficial effects on the risk of cardiovascular disease in patients with Type 1 diabetes. 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. 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. 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. 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.

Difficulty of Use. To obtain a glucose level reading with a single-point finger stick device, patients conduct a multiple-step process to obtain a blood sample and measure their glucose level with a blood glucose meter. This task is more 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. As a result, lancing, subsequent manipulation of the finger to draw blood and multiple finger sticks can be painful.

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 our STS, three continuous glucose monitors have received FDA approval. We believe that one of the products is no longer actively marketed. Another continuous glucose monitor is approved for physician interpretation only and does not allow patients to see their blood glucose trends real-time. Finally, a third approved continuous monitoring device provides real-time glucose values without any trend information and alerts the patient at inappropriately high or low glucose levels. 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 blood glucose information, including trends, and that is convenient and easy to use.

The DexCom Solution

Our STS offers the following advantages to diabetes patients:

Convenience. We believe that convenience is the paramount factor in achieving widespread adoption of a continuous blood glucose monitoring system. Our sensors continuously measure and record the patient's blood glucose level and wirelessly transmit blood glucose values at specific intervals to a small cell phone-sized receiver throughout the day and night. The patient can check his or her blood glucose level and trend information at any time with the touch of a button.

Access to Real-Time Values and Trend Information. By pushing a button, patients can view their current blood glucose value, along with a graphical display of one-, three- or nine-hour trend information. Access to continuous real-time blood glucose measurements provides patients with information that may aid in attaining better glucose control. Additionally, our STS alerts patients when their blood glucose approaches inappropriately high or low levels so that they may intervene.

Intuitive Patient Interface. We have extensive experience in the clinical trial setting with real-time usage of our continuous glucose monitoring technology, and as a result, 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, and 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.

In a peer-reviewed article based on our approval support trial, patients demonstrated statistically significant improvements in blood glucose levels. When compared to patients relying solely on single-point finger stick measurements, patients with access to continuous data from our STS reduced time spent hyperglycemic by 23%, reduced time spent hypoglycemic by 21% and increased time spent in the target range by 26% in just nine consecutive days of use. This article was published by the clinical investigators of our approval support trial in the January 2006 edition of *Diabetes Care*.

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. Patients could find this process to be uncomfortable or inconvenient. 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. Additionally, our STS is not approved as a replacement device for single-point finger stick devices, must be calibrated twice per day using single-point finger stick measurements and may be more costly to use.

Our Strategy

Our objective is to become the leading provider of continuous glucose monitoring systems and related products to enable people with diabetes to more 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;
- Drive the adoption of our products through a direct sales and marketing effort;
- Expand the use of our products to other patient care settings and patient demographics;
- Leverage our product development expertise to rapidly bring products to market;
- Provide a high level of customer support, service and education; and
- Pursue the highest safety and quality levels for our products.

Risk Factors

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary on page 8.

Corporate Information

We were incorporated in Delaware in May 1999. Our principal offices are located at 5555 Oberlin Drive, San Diego, California 92121, and our telephone number is (858) 200-0200. Our World Wide Web address is http://www.dexcom.com. The information found on, or accessible through, our website is not a part of this prospectus.

We are seeking to register our trademark DEXCOM with the U.S. Patent and Trademark Office. However, our application has been opposed. We intend to vigorously defend against the opposition, but cannot assure you that we will succeed in these efforts. We also have a trademark application pending in the United States for STS. All other trademarks, tradenames and service marks appearing in this prospectus are the property of their respective owners.

The Offering

Common stock offered:	
By DexCom, Inc.	1,200,000 shares
By the selling stockholders	3,000,000 shares
Total	4,200,000 shares
Common stock to be outstanding after this offering	26,616,559 shares
Use of proceeds	We intend to use the net proceeds of this offering for expanding our commercialization infrastructure, conducting clinical trials and other research and development, working capital and general corporate purposes. We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders. See "Use of Proceeds."
NASDAQ National Market symbol	DXCM

The number of shares of common stock to be outstanding after this offering is based on 25,416,559 shares outstanding as of December 31, 2005, and excludes:

- 43,729 shares of common stock issuable upon exercise of an outstanding warrant with an exercise price of $5.38 per share;
- 3,557,395 shares of common stock subject to outstanding options as of December 31, 2005 at a weighted average exercise price of $4.33 per share;
- 2,419,753 shares of common stock reserved for future grant or issuance as of December 31, 2005 under our 2005 equity incentive plan and 2005 employee stock purchase plan; and
- automatic annual increases in the number of shares of common stock reserved for issuance under our 2005 equity incentive plan and 2005 employee stock purchase plan. On January 1, 2006, the authorized number of shares under the 2005 equity incentive plan and 2005 employee stock purchase plan were increased by 762,496 and 254,165, respectively.

Except as otherwise noted, all information in the prospectus assumes no exercise of the underwriters' over-allotment option.

Summary Financial Data

The following table summarizes our financial data. The statements of operations data for the years ended December 31, 2003, 2004 and 2005 and for the period from May 13, 1999 (inception) through December 31, 2005 and the balance sheet data as of December 31, 2005 have been derived from our audited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes to those statements included elsewhere in this prospectus and the information under "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Years Ended December 31,			Period from May 13, 1999 (inception) through December 31, 2005
	2003	2004	2005	
	(in thousands, except share and per share data)			
Statements of Operations Data:				
Costs and expenses:				
Research and development	$ 8,935	$ 12,179	$ 25,497	$ 61,609
Selling, general and administrative	1,250	1,440	5,147	12,737
Stock-based compensation:				
Research and development		291	1,273	1,564
Selling, general and administrative		157	513	671
Total costs and expenses	10,185	14,067	32,430	76,581
Interest and other income, net	270	121	1,662	3,067
Net loss	(9,915)	(13,946)	(30,768)	(73,514)
Accretion to redemption value of Series B, Series C and Series D redeemable convertible preferred stock	(3,234)	(3,235)	(122)	(10,261)
Net loss attributable to common stockholders	$ (13,149)	$ (17,181)	$ (30,890)	$ (83,775)
Basic and diluted net loss per share attributable to common stockholders[1]	$ (6.06)	$ (7.51)	$ (1.63)	
Shares used to compute basic and diluted net loss per share attributable to common stockholders[1]	2,169,922	2,286,320	18,994,208	

	As of December 31, 2005	
	Actual	As Adjusted[2]
	(in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and short-term marketable securities	$ 50,525	
Working capital	43,939	
Total assets	56,726	
Total stockholders' equity	49,412	

[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)On an as adjusted basis to reflect the sale of 1,200,000 shares of our common stock by us in this offering at the assumed public offering price of $ per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase or decrease in the assumed public offering price of $ would increase or decrease, respectively, each of these line items by $, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this prospectus, before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition and results of operations would suffer. In that case, the trading price of our common stock would likely decline and you might lose all or part of your investment in our common stock. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our operations and business results.

Risks Related to Our Business

We are a development stage company and our STS may never achieve market acceptance.

We are a development stage medical device company with a limited operating history. We received approval from the FDA for our STS on March 24, 2006 and have recently launched this product throughout the United States. We expect that sales of our STS, which consists of a cell phone-sized receiver, transmitter and diposable sensor, will account for substantially all of our revenue for the foreseeable future. However, we do not have any 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 will largely depend on our ability to demonstrate its relative safety, efficacy, cost-effectiveness and ease of use;
- our inexperience in marketing, selling and distributing our products;
- we may not have adequate financial or other resources to successfully commercialize our STS;
- we may not be able to manufacture our STS in commercial quantities or at an acceptable cost;
- 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;
- patients will not receive reimbursement from third-party payors for their purchase of our STS, which may reduce widespread use of our STS;
- our STS may not be accepted in the marketplace by physicians and patients;
- the introduction and acceptance of competing products and technologies;
- our inability to obtain sufficient quantities of supplies from our sole source 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 blood 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.

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 attributable to common stockholders of $30.9 million for the twelve months ended December 31, 2005. As of December 31, 2005, we had a deficit accumulated during the development stage of $83.8 million. We have financed our operations primarily through private placements of our equity securities and our initial public offering, and have devoted substantially all of our resources to research and development relating to our continuous glucose monitoring systems. We expect to incur significant sales and marketing and manufacturing expenses associated with the commercialization of our STS product. 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 and increasing 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 develop a sales and marketing organization or enter into arrangements with others to market and sell our products. We have recently established 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 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.

If we are unable to develop 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 to meet expected demand for our STS. 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, material 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 retaining 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 the availability and suitability of facility space, construction timelines, design, installation and maintenance of manufacturing equipment, among others, which can lead to unexpected delays. In addition, before we can produce our STS for commercial use at the new facility we have recently leased, the facility will have to undergo a pre-approval inspection 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 new facility in a timely manner or at all. If we are unable to manufacture a sufficient supply of our STS and 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 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 and long-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 Vita Needle to manufacture and supply the insertion needle in our STS; and we rely on The Tech Group, which supplies 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. 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. 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 material and adverse effects on our business, including those discussed in the following risk factor.

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 and 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 and implantable sensors 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 self-monitored glucose testing 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 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 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 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.

Our STS does not have reimbursement and is not approved for insurance coverage. If we are unable to obtain acceptable prices or adequate reimbursement 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. Third-party coverage will 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.

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, the FDA has approved three continuous monitors or sensors, including the CGMS System Gold and Guardian RT by Medtronic, and the GlucoWatch, currently owned by Johnson & Johnson. Medtronic's CGMS System Gold and Guardian RT are currently in commercial use. Progress of others developing continuous glucose monitors is difficult to assess, but we are aware that Abbott has submitted applications for real-time continuous monitors or sensors to the FDA but is not yet approved. 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 believe that Abbott is attempting to obtain approval from the FDA for the replacement of single-point finger stick devices with its

continuous glucose monitoring system, but has experienced substantial delays. We have not yet filed for FDA approval for replacement claim labeling and we cannot assure you that we will not experience similar or greater delays if we do file. If Abbott or any other competitor 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 IRB, 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. We believe the data and performance from each of our clinical trials relating to our long-term system were likely insufficient to support a PMA application. While these previous trials were not designed or intended to be used to support a PMA application, our ongoing and future clinical trials that are designed to support a PMA application may not be sufficient to do so. 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. If we are unsuccessful in either filing or receiving FDA approval for additional PMA applications related to our glucose monitoring systems, our business strategy may have to be altered to rely solely on our STS.

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 and long-term continuous blood glucose monitoring systems. 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 of our systems. 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 complete 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 STS and other continuous glucose monitoring systems. For the twelve months ended December 31, 2005, our net cash used in operating activities was $22.6 million, compared to $12.4 million for the same period in 2004, and as of December 31, 2005, we had working capital of $43.9 million, including $50.5 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 complete 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 a