DEXCOM INC
Form S-3ASR
May 04, 2011
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As filed with the Securities and Exchange Commission on May 4, 2011

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

DEXCOM, INC.

(Exact name of registrant as specified in its charter)

Delaware		**33-0857544**
(State or other jurisdiction of incorporation or organization)		**(IRS Employer Identification No.)**

6340 Sequence Drive

San Diego, California 92121

(858) 200-0200

(Address, including zip code and telephone number, including area code, of the registrant s principal executive offices)

Jess Roper

Chief Financial Officer

6340 Sequence Drive

San Diego, California 92121

(858) 200-0200

(Name, address, including zip code and telephone number, including area code, of the agent for service)

Copies to:

Robert A. Freedman, Esq.

Michael A. Brown, Esq.

Fenwick & West LLP

Silicon Valley Center

801 California Street

Mountain View, California 94041

(650) 988-8500

John Lister, Esq.

Vice President of Legal Affairs

6340 Sequence Drive

San Diego, California 92121

(858) 200-0200

Approximate date of commencement of proposed sale to the public:

From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

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

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. ¨

If this form is a registration statement filed pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. x

If this form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (Check one):

Large Accelerated Filer ¨	Accelerated Filer x
Non-Accelerated Filer ¨	Smaller Reporting Company ¨

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share (1)	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee (2)
Common stock, $0.001 par value per share (3)				

(1) An indeterminate number of shares of common stock are being registered for possible issuance from time to time with proposed maximum offering price per share and proposed maximum aggregate offering price to be determined from time to time by the Registrant in connection with the issuance by the Registrant of the common stock registered hereunder.

(2) In accordance with Rules 456(b) and 457(r), the Registrant is deferring payment of all of the registration fee.

(3) Each share of common stock being registered hereunder also includes one preferred stock purchase right pursuant to the Registrant s rights agreement.

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PROSPECTUS

Common Stock

From time to time, we may offer shares of our common stock, par value $0.001, in one or more offerings, in amounts, at prices and on the terms that we will determine at the time of the offering and which will be set forth in a prospectus supplement, which may also add, update or change information contained in this prospectus.

You should read this prospectus, the information incorporated, or deemed to be incorporated, by reference in this prospectus and any prospectus supplement carefully before you invest.

Our common stock is traded on The NASDAQ Global Market under the symbol DXCM.

INVESTING IN OUR COMMON STOCK INVOLVES RISKS. SEE RISK FACTORS BEGINNING ON PAGE 2.

The common stock may be sold by us to or through underwriters or dealers, directly to purchasers or through agents designated from time to time. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution in this prospectus. If any underwriters, dealers or agents are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters or agents and any applicable fees, discounts or commissions, details regarding over-allotment options, if any, and the net proceeds to us will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is May 4, 2011.

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You should rely only on the information contained in or incorporated by reference into this prospectus or any applicable prospectus supplement. No dealer, salesperson or any other person is authorized to give any information or to make any representation other than the information and representations contained in or incorporated by reference into this prospectus or any applicable prospectus supplement. If different information is given or different representations are made, you may not rely on that information or those representations as having been authorized by us. You may not imply from the delivery of this prospectus and any applicable prospectus supplement, nor from a sale made under this prospectus and any applicable prospectus supplement, that our affairs are unchanged since the date of this prospectus and any applicable prospectus supplement or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus and any applicable prospectus supplement or any sale of a security. This prospectus and any applicable prospectus supplement may only be used where it is legal to sell the securities.

ABOUT THIS PROSPECTUS

This prospectus is part of an automatic shelf registration statement that we filed with the Securities and Exchange Commission, or SEC, as a well-known seasoned issuer as defined in Rule 405 under the Securities Act of 1933, as amended, or the Securities Act, using a shelf registration process. Under this shelf registration process, we may sell common stock. Each time we offer common stock under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of the offering. We may also add, update or change in a prospectus supplement any of the information contained in this prospectus or in documents we have incorporated by reference into this prospectus. Any statement that we make in this prospectus will be modified or superseded by any inconsistent statement made by us in a prospectus supplement. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to this offering. You should carefully read both this prospectus and the applicable prospectus supplement, together with the additional information described under the headings Incorporation of Documents by Reference and Where You Can Find More Information before buying securities in this offering.

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus to the terms DexCom, we, our, and us or similar references refer to DexCom, Inc. and our consolidated subsidiaries.

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SUMMARY

This summary may not contain all the information that you should consider before investing in securities. You should read the entire prospectus and the information incorporated by reference in this prospectus carefully, including Risk Factors and the financial data and related notes and other information incorporated by reference, before making an investment decision.

DexCom, Inc.

We are a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems for ambulatory use by people with diabetes and for use by healthcare providers in the hospital for the treatment of both diabetic and non-diabetic patients.

We received approval from the Food and Drug Administration, or FDA, and commercialized our first product in 2006. In 2007, we received approval and began commercializing our second generation system, the SEVEN, and on February 13, 2009, we received approval for our third generation system, the SEVEN PLUS, which is designed for up to seven days of continuous use, and we began commercializing this product in the first quarter of 2009. We no longer market or provide support for the SEVEN system. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. The approval of the SEVEN PLUS by the FDA allows for the use of the SEVEN PLUS 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.

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

We were incorporated in Delaware in May 1999. Our principal offices are located at 6340 Sequence Drive, San Diego, California 92121, and our telephone number is (858) 200-0200. Our website address is *http://www.dexcom.com*. The information found on, or accessible through, our website is not a part of this prospectus.

The Securities We May Offer

We may offer shares of our common stock from time to time under this prospectus, at prices and on terms to be determined by market conditions at the time of offering. Each time we offer shares of common stock under this prospectus, we will provide a prospectus supplement that will describe the specific amount, price and other important terms of the offering. The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus.

This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

We may sell our securities directly or through underwriters, dealers or agents. We, and our underwriters, dealers or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer our securities through underwriters or agents, we will include in the applicable prospectus supplement:

- the names of the underwriters or agents;
- applicable fees, discounts and commissions to be paid to them;
- details regarding over-allotment options, if any; and

the net proceeds to us.

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RISK FACTORS

Risks Related to Our Business

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

We expect that sales of our SEVEN PLUS, which consists of a handheld receiver, reusable transmitter and disposable sensor, will account for substantially all of our product revenue for the foreseeable future. From inception through March 31, 2011, product revenues total approximately $86.3 million. We have relatively limited experience in selling our products and we might be unable to successfully expand the commercialization of our products on a wide scale for a number of reasons, including:

- widespread market acceptance of our products by physicians and patients will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use;
- the limited size of our sales force and our relative inexperience in marketing, selling and distributing our products;
- we may not have sufficient financial or other resources to adequately expand the commercialization efforts for our products;
- our FDA and other regulatory submissions may be delayed, or approved with limited product labeling;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost;
- patients with diabetes do not generally receive broad reimbursement from third-party payors for their purchase of our products since many payors require that a patient meet specific medical criteria to qualify for reimbursement, which may reduce widespread use of our products;
- the uncertainties associated with establishing and qualifying new manufacturing facilities;
- our SEVEN PLUS is not labeled as a replacement for the information that is obtained from single-point finger stick devices;
- patients will need to incur the costs of our SEVEN PLUS in addition to single-point finger stick devices;
- the relative immaturity of the continuous glucose monitoring market internationally, and the general absence of international reimbursement of continuous glucose monitoring devices by third party payors and government healthcare providers outside the United States;
- the introduction and market acceptance of competing products and technologies;
- our inability to obtain sufficient quantities of supplies at appropriate quality levels from our sole source and other key suppliers;

our inability to manufacture products that perform in accordance with expectations of consumers; and

rapid technological change may make our technology and our products obsolete.

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

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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 $11.9 million for the three months ended March 31, 2011. As of March 31, 2011, we had an accumulated deficit of $358.2 million. We have financed our operations primarily through private placements of our equity and debt securities and our public offerings, and have devoted a substantial portion of our resources to research and development relating to our continuous glucose monitoring systems, including our in-hospital product development, and more recently, we have incurred significant sales and marketing and manufacturing expenses associated with the commercialization of the SEVEN PLUS. In addition, we expect our research and development expenses to increase in connection with our clinical trials and other development activities related to our products, including our next generation sensor and the GlucoClear. We also expect that our general and administrative expenses will continue to increase due to the additional operational and regulatory burdens applicable to public healthcare and medical device companies. As a result, we expect to continue to incur 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.

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

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

We may require additional funding to continue the commercialization of our SEVEN PLUS or the development and commercialization of our next generation and other continuous glucose monitoring systems, including the GlucoClear and our systems to be integrated with Animas and Insulet s insulin pump delivery systems.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our products, including growth of our manufacturing capacity, and on research and development, including conducting clinical trials for our GlucoClear in-hospital system as well as our next generation ambulatory continuous glucose monitoring sensors and systems. For the three months ended March 31, 2011, our net cash used in operating activities was $9.3 million, compared to $10.4 million for the same period in 2010, and as of March 31, 2011, we had working capital of $42.8 million, and we had $38.8 million in cash, cash equivalents and short-term marketable securities, and includes $1.5 million in restricted cash. We expect that our cash used by operations will increase significantly in each of the next several years, and, although we recently completed a follow-on public offering of 3,277,500 shares of our common stock for net proceeds to DexCom of approximately $33.0 million, we may need additional funds to continue the commercialization of our products and for the development and commercialization of our next generation sensors and systems. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

- the revenue generated by sales of our products and other future products;
- the costs, timing and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- our ability to scale our manufacturing operations to meet demand for our current and any future products;

the costs to produce our continuous glucose monitoring systems;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

the rate of progress and cost of our clinical trials and other development activities;

the success of our research and development efforts;

the emergence of competing or complementary technological developments;

the terms and timing of any collaborative, licensing and other arrangements that we may establish; and

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the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

To achieve commercial success for the SEVEN PLUS and our future products, we must continue to develop and grow our sales and marketing organization and enter into partnerships or other arrangements to market and sell our products. We currently employ a small direct sales force to market our products in the United States. In the United States, our sales force calls directly on healthcare providers and patients throughout the country to initiate sales of our products. Our sales organization competes with the experienced, larger and well-funded marketing and sales operations of our competitors. In March 2011, we completed a modest increase in the size of our sales force, and may not be able to successfully manage our increasingly dispersed sales force, or increase our product sales in the new territories. We have also entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. Our U.S. distribution partnerships are focused on accessing underrepresented regions and, in some instances, third-party payors that contract exclusively with distributors. Our European distribution partners call directly on healthcare providers to market and sell our products in Europe. Because of the competition for their services, we may be unable to partner with or retain additional qualified distributors. Further, we may not be able to enter into agreements with distributors on commercially reasonable terms, if at all.

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

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

recruit and retain adequate numbers of effective and experienced sales personnel;

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

establish and maintain successful sales and marketing and education programs that educate endocrinologists, physicians and diabetes educators so they can appropriately inform their patients about our products; and

manage geographically disbursed sales and marketing operations.

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

We have entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. We have entered into a distribution agreement with Edgepark, as amended, pursuant to which we generated approximately 26% of our revenue during the three months ended March 31, 2011. There can be no assurances that this relationship will continue or that we will be able to maintain this volume of sales from this relationship in the future. A substantial decrease or loss of these sales could have a material adverse effect on our operating performance. Additionally, to the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services in the United States or Europe, our product margins could be lower than if we directly marketed and sold our products. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we cannot predict whether these efforts will be successful. In addition, market acceptance of our products by physicians and patients in Europe will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use. If we are unable to do so, we may not be able to generate product revenue from our sales efforts in Europe. Finally, if we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate adequate product revenue and may not become profitable.

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

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although CMS released 2008 Alpha-Numeric HCPCS codes applicable to each of the three components of our continuous glucose monitoring systems, to date, our approved products are not reimbursed by virtue of a national coverage decision by Medicare. It is not known when, if ever, Medicare will adopt a national coverage decision with respect to continuous glucose monitoring devices. Until any such coverage decision is adopted by Medicare, reimbursement of our products will generally be limited to those patients covered by third-party payors that have adopted coverage policies for continuous glucose monitoring devices. As of May 2011, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with six of those third-party payors for the purchase of our products by their members. However, patients without insurance that covers our products will have to bear the financial cost of them. In the United States, patients using existing single-point finger stick devices are generally reimbursed all or part of the product cost by Medicare or other third-party payors. The commercial success of our products in both domestic and international markets will be substantially dependent on whether third-party reimbursement is widely available for patients that use them. While many third party payors have adopted some form of coverage policy on continuous glucose monitoring devices, those coverage policies frequently require significant medical documentation in order for patients to obtain reimbursement, and as a result, we have experienced difficulty in improving the efficiency of our customer service group. In addition, Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, they may not cover or provide adequate payment for our products. In order to obtain additional reimbursement arrangements, we may have to 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. Furthermore, we are unable to predict what effect the current or any future healthcare reform will have on our business, or the effect these matters will have on our customers. Our initial dependence on the commercial success of the SEVEN PLUS makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, unless government and other third-party payors provide adequate coverage and reimbursement for the SEVEN PLUS, patients may not use our products.

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

We may never receive FDA approval or clearance to market our next generation ambulatory system, or the GlucoClear, our blood-based in-vivo automated glucose monitoring system, or any other continuous glucose monitoring system under development.

Our SEVEN PLUS systems are classified by the FDA as premarket approval, or PMA, medical devices. We are continuing to seek approval for the next generation of our ambulatory system, and are responding to FDA s requests for additional data in support of that application. The PMA process requires us to prove the safety and efficacy of our ambulatory system to the FDA s satisfaction. This process can be expensive, prolonged and uncertain, requires detailed and comprehensive scientific and human clinical data, and may never result in the FDA granting a PMA. We cannot predict when, if ever, the next generation of our ambulatory system will obtain FDA approval.

We also intend to seek approvals for the products that integrate our continuous glucose monitoring technology into the insulin delivery systems of Animas and Insulet, respectively, but cannot predict when, if ever, those products will be approved.

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In addition, we will seek 510(k) clearance from the FDA for future GlucoClear products, and are working with Edwards to formulate the next steps for these submissions. The 510(k) process would require us to establish (including through pre-clinical testing, bench testing, and/or potentially clinical data) that our GlucoClear system is substantially equivalent in terms of indication, technological characteristics, and performance to one or more legally marketed devices eligible to be cited as predicates in the 510(k) process. We cannot predict whether the FDA will classify the GlucoClear as a 510(k) or PMA product, nor can we predict when, if ever, the GlucoClear will obtain FDA clearance or approval.

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

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

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

If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support additional PMA or 510(k) applications, we may be unable to commercialize our continuous glucose monitoring systems under development, including our next generation ambulatory system, our GlucoClear system or our systems being developed in collaboration with Animas and Insulet, which could impair our financial position.

We are continuing to seek approval for our next generation ambulatory system, and have been requested to provide additional data in support of that application. We also intend to seek approvals for the products that integrate our continuous glucose monitoring technology into the insulin delivery systems of Animas and Insulet, respectively. In addition, we will seek 510(k) clearance from the FDA for future GlucoClear products, and are working with Edwards to formulate the next steps for these submissions. The GlucoClear may ultimately be classified by the FDA as either a 510(k) or PMA product, and we may consequently be requested to provide additional data in support of the GlucoClear application.

To support these and any future additional PMA or 510(k) applications we must successfully complete pre-clinical studies, bench-testing, and clinical trials that we believe will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the studies and trials may be inadequate to support approval of a PMA or 510(k) application and the FDA may request additional clinical data in support of those applications, which may result in significant additional clinical expenses and may delay product approvals. While we have in the past obtained, and may in the future obtain, an Investigational Device Exemption, or IDE, prior to commencing clinical trials for our continuous glucose monitoring systems, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial to be sufficient to support approval of a PMA or 510(k) application, even if the trial s intended safety and efficacy endpoints are achieved. Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations, including 510(k) submissions, by hiring new investigators and increasing the frequency and scope of its inspections of manufacturing facilities. In January 2011, the FDA announced that it will, in the course of 2011, endeavor to streamline its 510(k) review process. We cannot predict the effect of such procedural changes and cannot ascertain if such changes will have a substantive impact on the approval of our products. If we fail to adequately respond to the increased scrutiny and streamlined 510(k) submission process, our business may be adversely impacted.

Unexpected changes to the FDA or foreign regulatory approval processes could also delay or prevent the approval of our products submitted for review. The data drawn from our clinical trials may not be sufficient to support approval of our products or additional or expanded indications. Medical device stock prices have declined significantly in certain circumstances where companies have failed to meet expectations in regards to the timing of regulatory approval. If the FDA s response causes product approval delays, or is not favorable for any of our products, our stock price could decline substantially.

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The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA or 510(k) application, for numerous reasons, including, but not limited to, the following:

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

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

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

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

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

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

Comprehensive healthcare legislation, signed into law in March 2010, imposes stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, with which we may need to comply, and enhanced penalties for non-compliance with the new healthcare regulations. The impact and durability of this legislation, in its current form, remains unclear, and costs of compliance with this legislation, or any future amendments thereto, could result in certain risks and expenses that we may have to assume. Other political and regulatory influences are also subjecting our industry to significant changes, and we cannot predict whether new regulations will emerge at the federal or state level, or abroad. The U.S. government may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect reimbursement for healthcare products such as the SEVEN PLUS. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current U.S. Presidential administration or Congress.

In addition, the comprehensive healthcare reform legislation recently adopted by Congress and subsequently signed into law includes an annual excise tax on the sale of medical devices equal to 2.3% of the price of the device starting on January 1, 2013, which would likely include our SEVEN PLUS and GlucoClear systems. The exact impact of this excise tax, including whether our products would be considered medical devices and how such a tax would be assessed, is not currently clear. As a result of such tax, our future operating results could be harmed, which in turn could cause the price of our stock to decline, Additionally, because of the uncertainty surrounding these issues, the impact of this tax has not been reflected in our forward guidance.

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

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

billing for services;

financial relationships with physicians and other referral sources;

inducements and courtesies given to physicians and other health care providers and patients;

labeling products;

quality of medical equipment and services;

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

medical device reporting;

false claims; and

professional licensure.

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

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

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

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

We currently have limited resources, facilities and experience in commercially manufacturing sufficient quantities of product to meet expected demand. In the past, we have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support our commercialization efforts. From time to time, we have also experienced brief periods of backorder and, at times, have had to limit the efforts of our sales force to introduce our products to new customers. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts, however, there can be no assurances that supply will not be constrained in the future. In order to produce our products in the quantities we anticipate will be necessary to meet market demand, we will need to increase our manufacturing capacity by a significant factor over the current level. In addition, we will have to modify our manufacturing design and process if and when our next generation sensor technologies are approved and commercialized. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, materials procurement, manufacturing site expansion, problems with production yields and quality control and assurance. Developing commercial-scale manufacturing facilities will require the investment of substantial additional funds and the hiring and retention of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. Also, the scaling of manufacturing capacity is subject to numerous risks and uncertainties, and may lead to variability in product quality or reliability, increased construction timelines, as well as resources required to design, install and maintain manufacturing equipment, among others, all of which can lead to unexpected delays in manufacturing output. In addition, any changes to our manufacturing processes may require FDA submission and approval and our facilities may have to undergo additional inspections by the FDA and corresponding state agencies. We cannot assure you that we will be able to develop and expand our manufacturing process and operations or obtain FDA and state agency approval of our facilities in a timely manner or at all. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand and our business will suffer.

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

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

Since our commercial launch in 2006, we have experienced periodic field failures, including reports of broken sensors or sensors that become lodged beneath a patient s skin, as well as reports that a sensor fails to provide glucose values for a full seven days. We do not believe these failures necessitated device explant, other procedures, or non-standard clinical treatment or intervention. To comply with the FDA s medical device reporting requirements, we have filed reports of all such broken or lodged sensors. Although we believe we have taken and are taking appropriate actions aimed at reducing or eliminating field failures, there can be no assurances that we will not experience additional failures going forward.

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

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

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our products are technologically complex and it is difficult to develop alternative supply sources;
- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;
- our suppliers may make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products;
- we may have difficulty locating and qualifying alternative suppliers for our single-source supplies;
- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner;
- our suppliers may make obsolete components that are critical to our products; and
- our suppliers may encounter financial hardships unrelated to our demand for components, including those related to changes in global economic conditions, which could inhibit their ability to fulfill our orders and meet our requirements.

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

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

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

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

Any product for which we obtain marketing approval will be subject to continual review and periodic inspections by the FDA and other regulatory bodies, which may include inspection of our manufacturing processes, post-approval clinical data and promotional activities for such product. The FDA s medical device reporting, or MDR, regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned and, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury. We and our suppliers are also required to comply with the FDA s Quality System Regulation, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, selection and oversight of suppliers or contractors, quality assurance, labeling, packaging, storage, complaint handling, shipping and servicing of our products. The FDA enforces the QSR through unannounced inspections. We currently manufacture our devices at our headquarters facilities in San Diego, California. In these facilities we have more than 8,000 square feet of laboratory space and approximately 10,000 square feet of controlled environment rooms. In February 2010, our facility was subject to a post-approval inspection by the FDA. After the close of the inspection, the FDA investigator issued a Form 483 identifying several inspectional observations. Subsequent to the inspection, we also received a warning letter from the FDA requiring us to file MDRs in accordance with the MDR regulations for complaints involving sensor wire fractures underneath a patient s skin. The warning letter also recommended that we add certain warnings and precautions statements to the labeling, patient education brochures, and our company website regarding the appropriate use of the SEVEN PLUS system, including that they are not approved for use in children under age 18, pregnant women, or persons on dialysis. In response to the warning letter and the Form 483 inspectional observations, we have taken corrective action to address the observations to achieve substantial compliance with the FDA regulatory requirements applicable to a commercial medical device manufacturer. In October 2010, we were subject to a follow-up site inspection by the FDA, and upon completion of that inspection, we were notified by the inspector that there were no 483 inspectional observations. We also received written notification dated November 1, 2010 from the FDA that we adequately addressed all issues cited in the warning letter.

In March 2009, the Federal Communications Commission, or FCC, established a bifurcated Medical Implant Communications System, or MICS, band which requires device manufacturers whose products will operate in the main MICS band to either manufacture their devices using listen-before-transmit technology, or to transmit on a side band outside the main MICS band at lower power. Although the SEVEN PLUS does not comply with existing MICS band listen-before-transmit requirements, the FCC granted a waiver to allow us to continue marketing and operating our SEVEN PLUS through March 2013, which we believe will provide adequate time to design an alternative method of wireless communication.

Compliance with ongoing regulatory requirements can be complex, expensive and time-consuming. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions:

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

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

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

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

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

As further described in Part II, Item 1 Legal Proceedings of this quarterly report, Abbott Diabetes Care, Inc., or Abbott, has filed a patent infringement lawsuit against us, claiming that our continuous glucose monitor infringes certain patents held by Abbott. We have requested, and the Patent Office has granted, reexamination of each of the patents cited in this lawsuit. On September 30, 2007, the court granted our motion to stay the case pending conclusion of the reexamination proceedings in the Patent Office relating to all seven patents asserted against us.

Five of the patents described above has one or more associated reexamination requests in various stages at the Patent Office. Two of the patents are in the appeal process and the other three patents have been issued one or more Certificates of Reexamination and those three patents are undergoing additional reexamination at the Patent Office. With regard to the two patents in the appeal process, the Board of Patent Appeals and Interferences within the Patent Office has recently rendered decisions. We believe these decisions are favorable to us; however, Abbott may seek judicial review of the decisions. The remaining two patents have been issued Certificates of Reexamination.

Since 2008, Abbott has copied claims from certain of our applications, and stated that it may seek to provoke an interference with certain of our pending applications in the Patent Office. If an interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also since 2008, Abbott has filed reexamination requests seeking to invalidate eighteen of our patents in the Patent Office. Fifteen of the eighteen reexamination requests are in various stages at the Patent Office. If the Patent Office were to determine in the reexamination that some or all of the claims of our patents are invalid, it could have a significant impact on our ability to protect aspects of our technology.

Although it is our position that Abbott s assertions of infringement have no merit, and that the potential interference and reexamination requests have no merit, the outcome of the litigation and interference or reexamination requests cannot be assessed currently with any certainty. We may not successfully defend ourselves against the claims made by Abbott or prevail in the litigation. Subject to the stay of litigation, if Abbott were to seek and obtain a preliminary or permanent injunction, it could force us to stop making, using, selling or offering to sell our products. The technology at issue in our litigation with Abbott is currently used in our products, including SEVEN PLUS, our only current ambulatory product that is approved for commercial sale, and our GlucoClear system for in-hospital use. If we were forced to stop selling these products, our business and prospects would suffer. In addition, defending against this action could have a number of harmful effects on our business, including those discussed in the following risk factor, regardless of the final outcome of such litigation. For example, we have incurred, and expect to continue to incur, significant costs in defending the action.

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

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

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

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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 one or more of our products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

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

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

Our success and our ability to compete are dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright and trademark law, and trade secrets and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. In addition, proposed regulations may limit our ability to file continuing patent applications and pursue patent claims in the Patent Office.

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

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

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

The market for glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. In selling the SEVEN PLUS, we compete directly with Roche Diabetes Care, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; the MediSense and TheraSense divisions of Abbott Laboratories; and Bayer Corporation, each of which manufactures and markets products for the single-point finger stick device market. Collectively, these companies currently account for substantially all of the worldwide sales of self-monitored glucose testing systems. Several companies are developing or marketing short-term continuous glucose monitoring products that will compete directly with our products. To date, in addition to us, three other companies, Cygnus, Medtronic and Abbott, have received approval from the FDA to market continuous glucose monitors. We believe that one of the products, originally developed and marketed by Cygnus, is no longer actively marketed. In addition, we believe that others, including Bayer, are developing invasive and non-invasive continuous glucose monitoring systems. Most of the companies developing or marketing competing devices are publicly traded or divisions of publicly-traded companies, and these companies enjoy several competitive advantages, including:

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

As a result, we may not be able to compete effectively against these companies or their products.

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

On November 10, 2008, we entered into a Collaboration Agreement with Edwards pursuant to which we have agreed to develop jointly and to market the GlucoClear, a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital. Under the Collaboration Agreement, we expect to receive payments for various milestones related to regulatory approvals and commercial readiness of the product. In addition, we also expect to receive either a profit-sharing payment of 10% of commercial sales of the product, or a royalty of 6% of commercial sales of the product. The Collaboration Agreement provides Edwards with an exclusive license to our intellectual property that relates to blood-based glucose sensors in the critical care sector of the hospital market. However, this collaboration may not result in the development of products that achieve regulatory approval in the United States or commercial success, which would result in various penalties to us under the Collaboration Agreement, up to and including delay or loss of some or all of our milestone payments and rights to any profit-sharing or royalties. On October 30, 2009, we received CE Mark approval for the first generation GlucoClear that we developed in collaboration with Edwards. Although Edwards commenced market evaluations during 2009, this product did not generate significant revenue during 2010 and we do not expect this product to generate significant revenue during 2011. We will seek 510(k) clearance from the FDA for future GlucoClear products, and are working with Edwards to formulate the next steps for these submissions. We cannot predict whether the FDA will classify the GlucoClear as a 510(k) or PMA product, nor can we predict when, if ever, the GlucoClear will obtain FDA clearance or approval.

We enter into collaborations with third parties related to our SEVEN PLUS that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we enter into collaborative arrangements to develop new products and to pursue new markets, such as our agreements with Animas and Insulet, to integrate our continuous glucose monitoring technology into their respective insulin delivery systems. We have also entered into an OUS Commercialization Agreement, as amended, with Animas pursuant to which Animas retains the exclusive right to develop and market outside the United States an ambulatory insulin pump that is combined with our continuous glucose monitoring technology. These collaborations may not result in the development of products that achieve commercial success and could be terminated prior to developing any products. Accordingly, we cannot assure you that any of our collaborations will result in the successful development of a commercially viable product or result in significant additional future revenues. In addition, our development timelines are highly dependent on our ability to achieve clinical endpoints and regulatory requirements and to overcome technology challenges, and may be delayed due to scheduling issues with patients and investigators, requests from institutional review boards, product performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts are successful, the FDA may not approve the combined products or may require additional product testing and clinical trials before approving the combined products, which would result in product launch delays and additional expense. If approved by the FDA, the combined products may not achieve acceptance in the marketplace by physicians and patients.

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

The SEVEN PLUS does not eliminate the need for single-point finger stick devices and our future products may not be approved for that indication. No precedent for FDA approval of continuous glucose monitoring systems as a replacement for single-point finger stick devices has been established. Accordingly, there is no established study design or agreement regarding performance requirements or measurements in clinical trials for continuous glucose monitoring systems. We have not yet filed for FDA approval for therapeutic or replacement claim labeling and we cannot assure you that we will not experience delays if we do file. If any of our competitors were to obtain replacement claim labeling for a continuous glucose monitoring system, our products may not be able to compete effectively against that system and our business would suffer.

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

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

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

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

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

We may be subject to claims against us even if the apparent injury is due to the actions of others or misuse of the device. Our customers, either on their own or following the advice of their physicians, may use our products in a manner not described in the products labeling and that differs from the manner in which it was used in clinical studies and approved by the FDA. For example, our SEVEN PLUS is designed to be used by a patient continuously for up to seven days, but the patient might be able to circumvent the safeguards designed into the SEVEN PLUS and use the product for longer than seven days. Off-label use of products by patients is common, and any such off-label use of our products could subject us to additional liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

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

Although we believe our promotional materials and training methods are conducted in compliance with FDA and other regulations, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, the FDA could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

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

We take precautions to safeguard our facilities, 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 have begun limited commercial and marketing efforts in Europe and Israel with respect to our SEVEN PLUS and may seek to market our products in other regions in the future. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States on a timely basis, or at all.

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

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

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

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

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the 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. Furthermore, on July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. This new law makes significant changes to corporate governance and executive compensation rules for public companies across all industries. 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.

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

We record compensation expense in the consolidated statement of operations for share-based payments, such as employee stock options, using the fair value method. The requirements of the authoritative guidance for share-based payment have and will continue to have a material effect on our future financial results reported under GAAP and make it difficult for us to accurately predict the impact our future financial results.

For instance, estimating the fair value of share-based payments is highly dependent on assumptions regarding the future exercise behavior of our employees and changes in our stock price. Our share-based payments have characteristics significantly different from those of freely traded options, and changes to the subjective input assumptions of our share-based payment valuation models can materially change our estimates of the fair values of our share-based payments. In addition, the actual values realized upon the exercise, expiration, early termination or forfeiture of share-based payments might be significantly different 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.

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

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

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

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. The method in which we market and sell our products may have an impact on the manner in which we recognize revenue. In addition, changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, as a result of changes approved by the 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. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants

prepare financial statements in accordance with International Financial Reporting Standards, may adversely impact our reported financial results and business, and may further require us to incur greater accounting fees.

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

In March 2006, we entered into our Loan Agreement that provided for a loan to finance various equipment and leasehold improvement expenses. In January 2008, we amended our Loan Agreement to enable us to draw an additional $3.0 million. We are required to repay this additional amount at intervals through July 2011. As of March 31, 2011, we had a total outstanding loan balance under the Loan Agreement of $0.3 million. The Loan Agreement requires us to maintain a minimum cash balance with Square 1 Bank, and also imposes certain limitations on us, including, among others, 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; 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.

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.

Risks Related to This Offering and Our Common Stock

If our stock price fluctuates after this offering, you could lose a significant part of your investment.

Historically, the market price of our common stock has fluctuated considerably and often. Since the beginning of 2010, the closing price of our common stock on the NASDAQ Global Market has been as high as $16.72 per share and as low as $8.56 per share.

The market price of our common stock is influenced by many factors that are beyond our control, including the following:

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

variations in quarterly operating results;

future sales of our common stock by our stockholders;

investor perception of us and our industry;

announcements by us or our competitors of significant agreements, acquisitions or capital commitments;

changes in market valuation or earnings of our competitors;

general economic conditions;

regulatory actions;

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legislation and political conditions; and

terrorist acts.

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

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

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

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

our inability to manufacture an adequate supply of product at appropriate quality levels and acceptable costs;

possible delays in our research and development programs or in the completion of any clinical trials;

a lack of acceptance of our products in the marketplace by physicians and patients;

the inability of patients to receive reimbursements from third-party payors;

failures to comply with regulatory requirements, which could lead to withdrawal of products from the market;

our failure to continue the commercialization of any of our continuous glucose monitoring systems;

inadequate financial and other resources; and

global economic conditions.

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

This offering may cause the market price of our common stock to decline, perhaps significantly, even if our business is doing well, and the volatility of our trading price may increase around the time of this offering. The market price of our common stock could also decline as a result of our sale of shares in this offering or the perception that sales of our shares are likely to occur in the future. This might also make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Also, we may issue securities in connection with future financings and acquisitions, and those shares could dilute the holdings of other stockholders, including the investors in this offering.

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

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

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

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

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

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

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FORWARD-LOOKING INFORMATION

This prospectus and documents incorporated herein by reference contain forward-looking statements that involve risks and uncertainties. All statements other than statements of historical fact contained in this prospectus or any documents incorporated by reference in this prospectus, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including anticipates, believes, can, continue, could, estimates, expects, intends, may, plans, potential, predicts, should or wil terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under Risk Factors or elsewhere in this prospectus or any documents incorporated by reference in this prospectus. Our actual results and the timing of events could differ materially from those anticipated in our forward-looking statements as a result of many factors, including product performance, a lack of acceptance in the marketplace by physicians and patients, the inability to manufacture products in commercial quantities at an acceptable cost, possible delays in our research and development programs, the inability of patients to receive reimbursements from third-party payors, inadequate financial and other resources, global economic conditions, and the other risks outlined under Risk Factors or elsewhere in this prospectus or any documents incorporated by reference in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment; new risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this prospectus. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled Risk Factors or elsewhere in this prospectus could negatively affect our business, operating results, financial condition and stock price. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this prospectus to conform our statements to actual results or changed expectations.

USE OF PROCEEDS

Except as described in any prospectus supplement, we currently intend to use the net proceeds from the sale of securities under this prospectus for working capital and general corporate purposes, including, without limitation, additions to our working capital and capital expenditures, repayment of any outstanding indebtedness, and, while we have no present understandings, commitments, or agreements to do so, potential acquisitions of, or investments in, companies and technologies that complement our business.

PLAN OF DISTRIBUTION

We may sell the securities referenced in this prospectus in any one or more of the following methods:

- direct sales to purchasers;
- to or through underwriters or dealers;
- through designated agents;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

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settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

broker-dealers may agree with us to sell a specified number of such securities at a stipulated price per security;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

A prospectus supplement will set forth the specific terms of the offering of the securities covered by this prospectus, including:

the name or names of any underwriters, dealers or agents, if any, and the amounts of securities underwritten or purchased by each of them;

any over-allotment options under which underwriters, if any, may purchase additional securities from us;

any underwriting discounts or commissions or agency fees and other items constituting underwriters or agents compensation, if applicable;

the public offering price of the securities and the proceeds to us and any discounts, commissions or concessions allowed or reallowed or paid to dealers; and

any securities exchanges or markets on which the securities will be listed.

Underwriters may offer and sell the securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions described above. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters obligations to purchase the securities will be subject to certain conditions precedent. The underwriters will be obligated to purchase all of the securities they have committed to purchase if they purchase any of the securities. We may use underwriters with whom we have a material relationship. We will describe the nature of any such relationship in a prospectus supplement, naming the underwriter.

We may sell securities through agents from time to time. A prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment.

Any dealers or agents that are involved in selling the securities may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at a public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Agents and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof. Agents and underwriters may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

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LEGAL MATTERS

The validity of the securities offered under this prospectus will be passed upon for us by Fenwick & West LLP, Mountain View, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements and our schedule included in our Annual Report on Form 10-K for the year ended December 31, 2010, and the effectiveness of our internal control over financial reporting as of December 31, 2010, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

INCORPORATION OF DOCUMENTS BY REFERENCE

This prospectus incorporates by reference some of the reports, proxy and information statements and other information that we have filed with the SEC under the Securities Exchange Act of 1934, or the Exchange Act. This means that we are disclosing important business and financial information to you by referring you to those documents. Unless expressly incorporated into this prospectus, a Current Report (or portion thereof) furnished, but not filed, on Form 8-K shall not be incorporated by reference into this prospectus. We incorporate by reference the documents listed below and any future filings made with the SEC under sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until all of the securities offered by this prospectus are sold.

- our annual report on Form 10-K for the fiscal year ended December 31, 2010;
- our quarterly report on Form 10-Q for the quarterly periods ended March 31, 2011;
- our proxy statement on Schedule 14A filed with the SEC on April 18, 2011, with respect to our 2011 Annual Meeting of Stockholders;
- our current report on Form 8-K/A filed on January 4, 2011;
- our current report on Form 8-K filed on March 23, 2011;
- our current report on Form 8-K filed on April 1, 2011;
- our current report on Form 8-K filed on May 3, 2011 (excluding the information furnished therein pursuant to Item 2.02); and
- the description of our common stock and preferred stock purchase rights contained in a registration statement on Form 8-A, filed March 25, 2005, including any amendment or report filed for the purpose of updating such description.

Any statements made in a document incorporated by reference in this prospectus are deemed to be modified or superseded for purposes of this prospectus to the extent that a statement in this prospectus or in any other subsequently filed document, which is also incorporated by reference, modifies or supersedes the statement. Any statement made in this prospectus is deemed to be modified or superseded to the extent a statement in any subsequently filed document, which is incorporated by reference in this prospectus, modifies or supersedes such statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

The information relating to us contained in this prospectus should be read together with the information in the documents incorporated by reference. In addition, certain information, including financial information, contained in this prospectus or incorporated by reference in this prospectus should be read in conjunction with documents we have filed with the SEC.

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We will provide to each person, including any beneficial holder, to whom a prospectus is delivered, at no cost, upon written or oral request, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. Requests for documents should be directed to John Lister, DexCom, Inc., 6340 Sequence Drive, San Diego, California 92121, telephone number (858) 200-0200. Exhibits to these filings will not be sent unless those exhibits have been specifically incorporated by reference in such filings.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the information requirements of the Exchange Act and file reports, proxy statements and other information with the SEC. We are required to file electronic versions of these documents with the SEC. Our reports, proxy statements and other information can be inspected and copied at prescribed rates at the Public Reference Room of the SEC located at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. The SEC also maintains a website that contains reports, proxy and information statements and other information, including electronic versions of our filings. The website address is *http://www.sec.gov*. Our SEC filings are also available free of charge at our website at *http://www.dexcom.com.*

You should note that where we summarize in this prospectus the material terms of any contract, agreement or other document filed as an exhibit to the registration statement, the summary information provided in this prospectus is less complete than the actual contract, agreement or document. You should refer to the exhibits to the registration statement for copies of the actual contract, agreement or document.

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Common Stock

PROSPECTUS

May 4, 2011

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the estimated costs and expenses, other than any underwriting discounts and commission, payable by us in connection with the offering of the securities being registered. All amounts shown are estimates, except for the registration fee.

SEC registration fee	$	
Accounting fees and expenses		*
Legal fees and expenses		*
Printing and miscellaneous expenses		*
Total	$	*

The SEC registration fee is being deferred pursuant to Rules 456(b) and 457(r).

* These expenses depend on the securities offered and the number of issuances and cannot be estimated at this time.

Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation s board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act.

As permitted by the Delaware General Corporation Law, the Registrant s restated certificate of incorporation includes a provision that eliminates the personal liability of its directors for monetary damages for breach of fiduciary duty as a director, except for liability:

for any breach of the director s duty of loyalty to the Registrant or its stockholders,

for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law,

under section 174 of the Delaware General Corporation Law (regarding unlawful dividends and stock purchases), or

for any transaction from which the director derived an improper personal benefit.

As permitted by the Delaware General Corporation Law, the Registrant s restated bylaws provide that:

the Registrant is required to indemnify its directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to very limited exceptions,

the Registrant may indemnify its other employees and agents as set forth in the Delaware General Corporation Law,

the Registrant is required to advance expenses, as incurred, to its directors and officers in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to very limited exceptions, and

the rights conferred in the bylaws are not exclusive.

The Registrant has entered into Indemnification Agreements with its directors and officers to provide such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in the Registrant s restated certificate of incorporation and restated bylaws and to provide additional procedural protections. At present, there is no pending litigation or proceeding involving a director, officer or employee of the Registrant regarding which indemnification is sought.

The Registrant has directors and officers liability insurance for securities matters.

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See also the undertakings set out in response to Item 17 hereof.

Reference is made to the following documents regarding relevant indemnification provisions described above and elsewhere in the Registration Statement on Form S-1:

		Incorporated by Reference				
Exhibit Number	**Exhibit Document**	**Form**	**File No.**	**Date of First Filing**	**Exhibit Number**	**Provided Herewith**
3.01	Registrant s Restated Certificate of Incorporation.	S-1/A	333-122454	March 3, 2005	3.03	
3.02	Registrant s Amended and Restated Bylaws.	8-K	000-51222	May 22, 2009	99.01	
10.01	Form of Indemnity Agreement between Registrant and each of its directors and executive officers.	S-1	333-122454	February 1, 2005	10.01	

Item 16. Exhibits

		Incorporated by Reference				
Exhibit Number	**Exhibit Document**	**Form**	**File No.**	**Date of First Filing**	**Exhibit Number**	**Provided Herewith**
1.01*	Form of Underwriting Agreement for shares of common stock.					
3.01	Registrant s Restated Certificate of Incorporation.	S-1/A	333-122454	March 3, 2005	3.03	
3.02	Registrant s Amended and Restated Bylaws.	8-K	000-51222	May 22, 2009	99.01	
4.01	Form of Specimen Certificate for Registrant s common stock.	S-1/A	333-122454	March 24, 2005	4.01	
4.02	Form of Rights Agreement, between DexCom, Inc. and American Stock Transfer & Trust Company, including the Certificate of Designations of Series A Junior Participating Preferred Stock, Summary of Stock Purchase Rights and Forms of Right Certificate attached thereto as Exhibit A, B and C, respectively.	S-1/A	000-51222	March 24, 2005	4.03	
5.01	Opinion of Fenwick & West LLP regarding legality of the securities being registered.					X
23.01	Consent of Fenwick & West LLP (included in Exhibit 5.01).					X
23.02	Consent of Independent Registered Public Accounting Firm.					X
24.01	Power of Attorney (see page II-5 of this registration statement).					X

* To be filed, when and if necessary, as an exhibit to a current report on Form 8-K and incorporated by reference or by post-effective amendment.

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Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum aggregate offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

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(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(8) That, for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(9) That, for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on this 4th day of May, 2011.

DEXCOM, INC.

By: /s/ Terrance H. Gregg
Terrance H. Gregg
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Terrance H. Gregg and Jess Roper, and each of them, or his true and lawful attorneys-in-fact and agents with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post- effective amendments) to this Registration Statement on Form S-3, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done with respect to this Registration Statement, including post-effective amendments, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the date indicated.

Name	Title	Date
Principal Executive Officer and Director:		
/s/ Terrance H. Gregg Terrance H. Gregg	Chief Executive Officer and Director	May 4, 2011
Principal Financial Officer and Principal Accounting Officer:		
/s/ Jess Roper Jess Roper	Chief Financial Officer	May 4, 2011
Additional Directors:		
/s/ Jonathan T. Lord Jonathan T. Lord, M.D.	Chairman of the Board of Directors	May 4, 2011
/s/ Nicholas Augustinos Nicholas Augustinos	Director	May 4, 2011
/s/ Martin Doordan	Director	May 4, 2011

Martin Doordan		
/s/ Barbara Kahn		
	Director	May 4, 2011
Barbara Kahn		

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Name	Title	Date
/s/ KEVIN SAYER Kevin Sayer	President and Director	May 4, 2011
/s/ JAY SKYLER Jay Skyler, M.D.	Director	May 4, 2011
/s/ ERIC TOPOL Eric Topol, M.D.	Director	May 4, 2011

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EXHIBIT INDEX

Exhibit Number	Exhibit Document	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
1.01*	Form of Underwriting Agreement for shares of common stock.					
3.01	Registrant s Restated Certificate of Incorporation.	S-1/A	333-122454	March 3, 2005	3.03	
3.02	Registrant s Amended and Restated Bylaws.	8-K	000-51222	May 22, 2009	99.01	
4.01	Form of Specimen Certificate for Registrant s common stock.	S-1/A	333-122454	March 24, 2005	4.01	
4.02	Form of Rights Agreement, between DexCom, Inc. and American Stock Transfer & Trust Company, including the Certificate of Designations of Series A Junior Participating Preferred Stock, Summary of Stock Purchase Rights and Forms of Right Certificate attached thereto as Exhibit A, B and C, respectively.	S-1/A	000-51222	March 24, 2005	4.03	
5.01	Opinion of Fenwick & West LLP regarding legality of the securities being registered.					X
23.01	Consent of Fenwick & West LLP (included in Exhibit 5.01).					X
23.02	Consent of Independent Registered Public Accounting Firm.					X
24.01	Power of Attorney (see page II-5 of this registration statement).					X

* To be filed, when and if necessary, as an exhibit to a current report on Form 8-K and incorporated by reference or by post-effective amendment.