DEXCOM INC
Form 8-K
January 14, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) January 13, 2010

DexCom, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**000-51222**	**33-0857544**
(State or other jurisdiction of incorporation)	**(Commission file number)**	**(I.R.S. Employer Identification No.)**

6340 Sequence Drive San Diego, CA 92121	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code (858) 200-0200

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(e) On January 13, 2010, the Board of Directors of DexCom, Inc., which is referred to in this Report as the Company, DexCom, we, us, or our approved a bonus plan for fiscal 2010 (the 2010 Plan) for the Company s management and select individual contributors, including its chief executive officer, chief financial officer and its other named executive officers (together, the Named Executive Officers) pursuant to which the Named Executive Officers are eligible for cash bonus awards if the Company attains specified financial and performance targets. The target bonus for the Chief Executive Officer (the CEO) is 80% of his base salary; the target bonus for the Company s Chief Administrative Officer is 50% of his base salary; the target bonus for the Company s Senior Vice President of Operations is 45% of his base salary; the target bonus for the Company s Senior Vice President of Clinical, Regulatory and Quality is 40% of his base salary; the target bonus for the Company s Vice Presidents is 30% of their respective base salaries, and the target bonus for the remainder of the Company s management employees and select contributors is 25% of their respective base salaries.

For the Company s CEO, the amount of any bonus awarded under the 2010 Plan will be predicated on achieving targeted revenue goals and targeted operating expense goals. With respect to the CEO, generally speaking, 75% of any bonus paid under the 2010 Plan is based on achieving certain annual revenue goals (the Revenue Component) and 25% is based on achieving certain operating expense goals (the Operating Results Component). Under the 2010 Plan, no portion of the Revenue Component shall be paid to the CEO unless the Company meets a specified minimum revenue target for fiscal 2010. Upon achievement of this minimum revenue target, the CEO will receive a bonus award of 80% of his targeted Revenue Component. Upon achievement of 100% of the Company s revenue target for fiscal 2010, the CEO will receive a bonus award of 100% of his targeted Revenue Component. If the Company exceeds its fiscal 2010 revenue target, the CEO will receive a bonus at various stepped up amounts up to a maximum of 120% of his targeted Revenue Component. In addition, the Company wishes to incent reduction of its operating expense. No portion of the Operating Results Component shall be paid to the CEO unless the Company meets a specified operating expense result for fiscal 2010. Upon achievement of this operating expense target, the CEO will receive a bonus award of 80% of the targeted Operating Results Component. Upon achievement of 100% of the Company s operating expense target for fiscal 2010, the CEO will receive a bonus award of 100% of the Operating Results Component. If the Company achieves a more favorable operating expense result in fiscal 2010 than its operating expense target, the CEO will receive a bonus at various stepped up amounts up to a maximum of 120% of the targeted Operating Results Component.

For the remainder of the Company s eligible employees, the amount of any bonus awarded under the 2010 Plan will be predicated on achieving targeted revenue goals, targeted operating expense goals, and performance milestones. Generally speaking, 60% of any bonus paid under the 2010 Plan is based on achieving certain annual revenue goals, 20% is based on achieving targeted operating expense goals and 20% is based on achieving certain performance milestones (the Performance Component).

Under the 2010 Plan, no portion of the Revenue Component shall be paid unless the Company meets a specified minimum revenue target for fiscal 2010. Upon achievement of this minimum revenue target, each eligible participant will receive a bonus award of 80% of their targeted Revenue Component. Upon achievement of 100% of the Company s revenue target for fiscal 2010, each eligible participant will receive a bonus award of 100% of their targeted Revenue Component. If the Company exceeds its fiscal 2010 revenue target, the Named Executive Officers (not including the CEO) will receive bonuses at various stepped up amounts up to a maximum of 175% of their targeted Revenue Component.

Under the 2010 Plan, no portion of the Operating Results Component shall be paid unless the Company meets a specified operating expense result for fiscal 2010. Upon achievement of this operating expense target, each eligible participant will receive a bonus award of 80% of their targeted Operating Results Component. Upon achievement of 100% of the Company s operating expense target for fiscal 2010, each eligible participant will receive a bonus award of 100% of their targeted Operating Results Component. If the Company achieves operating expense results that are more favorable in fiscal 2010 than its operating expense target, the Named Executive Officers (not including the CEO) will receive bonuses at various stepped up amounts up to a maximum of 175% of their targeted Operating Results Component.

Under the Performance Component, bonus amounts will also be paid to the Named Executive Officers (not including the CEO) for achieving specified corporate milestones. Eligible participants will receive 25% of their targeted Performance Component for achievement of each of four corporate milestones by the Company during fiscal 2010.

Item 8.01 Other Events.

The following is updated information about DexCom, Inc.

Our Business

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

patients. We received approval from the FDA and commercialized our first product in 2006. In 2007, we received approval and began commercializing our second generation system, the SEVEN, and on February 13, 2009, we received approval for our third generation system, the SEVEN PLUS, which is designed for up to seven days of continuous use, and we began commercializing this product in the first quarter of 2009. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. Our approvals allow for the use of our continuous glucose monitoring systems by adults with diabetes to detect trends and track glucose patterns, to aid in the detection of hypoglycemia and hyperglycemia and to facilitate acute and long-term therapy adjustments. Our approved products must be prescribed by a physician and include a disposable sensor, a transmitter and a small handheld receiver. Our approved products are indicated for use as adjunctive devices to complement, not replace, information obtained from standard home blood glucose monitoring devices and must be calibrated periodically using a standard home blood glucose monitor. The sensor is inserted by the patient and is intended to be used continuously for up to seven days after which it is removed by the patient and may be replaced by a new sensor. Our transmitter and receiver are reusable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark. We initiated a limited commercial launch of the SEVEN in the European Union in 2009. From inception to 2006, we devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. Since 2006, we have devoted considerable resources to the commercialization of our ambulatory continuous glucose monitoring systems, including the SEVEN PLUS, as well as the continued research and clinical development of our technology platform. We have yet to seek approval from the FDA for our blood-based in-vivo automated glucose monitoring system.

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

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

According to the American Diabetes Association, or ADA, one in every ten health care dollars was spent on treating diabetes in 2007, and the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated $174 billion, an increase of $42 billion since 2002. Of the $174 billion in overall expenses, the ADA estimates that approximately $89 billion were costs associated with chronic complications and excess general medical costs, $27 billion were costs associated with diabetes care and $58 billion were indirect medical costs. The ADA also found that average medical expenditures among people with diagnosed diabetes were 2.3 times higher than for people without diabetes.

Continuous glucose monitoring has the potential to enable more people with diabetes to achieve and sustain tight glycemic control. The Diabetes Control and Complications Trial (DCCT) demonstrated that improving blood glucose control lowers the risk of developing diabetes related complications by up to 50%. The study also demonstrated that people with Type 1 diabetes achieved sustained benefits with intensive management. Yet, according to an article published in the *Journal of the American Medical Association* (JAMA) in 2004, less than 50% of diabetes patients are meeting ADA standards for glucose control (A1c), and only 37% of people with diabetes are achieving their glycemic targets. The CDC estimates that as of 2006, only 63.4% of all adults with diabetes were monitoring their blood glucose levels on a daily basis, but that 86.7% of insulin-requiring diabetes patients monitored daily.

Various clinical studies also demonstrate the benefits of continuous glucose monitoring and that continuous glucose monitoring is equally effective in patients who administer insulin through multiple daily injections or through continuous subcutaneous insulin infusion pumps. Results of a Juvenile Diabetes Research Foundation (JDRF) study published in the *New England Journal of Medicine*, and the extension phase of the study, published in *Diabetes Care*, demonstrated that continuous glucose monitoring both improves A1c levels and reduces incidence of hypoglycemia for patients over the age of 25 and for all patients who utilize continuous glucose monitoring regularly.

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

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

We have built a direct sales organization to call on endocrinologists, physicians and diabetes educators who can educate and influence patient adoption of continuous glucose monitoring. We believe that focusing efforts on these participants is important given the instrumental role they each play in the decision-making process for diabetes therapy. In September 2008, we established a wholly owned subsidiary in Sweden and hired a Vice President of International Business Development to begin our expansion outside the United States. To complement our direct sales efforts, we also employ clinical specialists who educate and provide clinical support in the field, and have entered into a limited number of distribution arrangements that allow distributors to sell our products. We believe our direct, highly-specialized and focused sales organization is sufficient for us to support our sales efforts and have no immediate plans to increase the size of the sales organization.

We are leveraging our technology platform to enhance the capabilities of our current products and to develop additional continuous glucose monitoring products. In January 2008, we entered into two separate development agreements, one with Animas Corporation, or Animas, a subsidiary of Johnson & Johnson, and one with Insulet Corporation, or Insulet, to integrate our technology into the insulin pump product offerings of the respective partner, enabling the partner s insulin pump to receive glucose readings from our transmitter and display this information on the pump s screen. We are continuing clinical development of a fourth generation ambulatory product which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, and will be suited for large scale manufacturing. We also intend to seek approval for a pediatric indication (patients under 18 years of age) and a pregnancy indication (diabetes patients who become pregnant and patients who develop gestational diabetes) for our product platform in the future. In addition, we are developing a product platform specifically for the in-hospital glucose monitoring market, with an initial focus on the development of an intravenous sensor specifically for the critical care market. To that end, on November 10, 2008, we entered into a definitive collaboration agreement with Edwards Lifesciences LLC, or Edwards, a global leader in the monitoring of critically ill patients, to develop products for automated monitoring of glucose levels in hospitalized patients. Our development timelines are highly dependent on our clinical trials, and may be delayed due to scheduling issues with patients and investigators, institutional review boards, sensor performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts are successful, the FDA may not approve our products, and if approved, we may not achieve acceptance in the marketplace by physicians and patients.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. On November 2, 2007, the Centers for Medicare and Medicaid, or CMS, released its 2008 Alpha-Numeric HCPCS File, which included three separate codes applicable to each of the three components of our continuous glucose monitoring systems, and HCPCS codes for continuous glucose monitoring became effective on January 1, 2008. HCPCS codes are billing codes used by Medicare and private third-party payors, but do not represent a reimbursement coverage decision by CMS and, 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 January 2010, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage

policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with five of those third-party payors for the purchase of our products by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with documentation and other requirements to demonstrate medical necessity under the policy. In addition, patients who are insured by payors that do not offer coverage for our devices will have to bear the financial cost of the products. We currently employ in-house reimbursement expertise to assist patients in obtaining reimbursement from private third-party payors. We also maintain a field-based reimbursement team charged with calling on third-party private payors to obtain coverage decisions and contracts. We have had formal meetings and have increased our efforts to create coverage policies with third-party payors during 2009 and expect to continue to do so in 2010. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them.

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

Certain statements that we make in this Report may constitute forward-looking statements, including statements concerning our future product development plans. These statements reflect management s expectations about future events, operating plans and performance and speak only as of the date hereof. These forward-looking statements involve a number of risks and uncertainties. Factors that could cause actual results to be materially different from those expressed or implied by any of these forward-looking statements include 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 development programs, the inability of patients to receive adequate reimbursements from third-party payors and inadequate financial and other resources. Also see the risk factors set forth in DexCom s Annual Report on Form 10-K, quarterly reports on Form 10-Q and its other reports filed with the Securities and Exchange Commission. We undertake no obligation to update publicly or revise these forward-looking statements for any reason.

Recent Events

On January 12, 2010, we reported estimated, unaudited product revenues of approximately $6.6 million for the fourth quarter of 2009, up approximately 43% sequentially from the prior quarter. We sold approximately 2,800 starter kits during the fourth quarter of 2009, amounting to an increase of approximately 31% in starter kit sales compared to the third quarter of 2009. Sequentially, sensor revenues were up approximately 50% compared to the third quarter of 2009.

Legal Proceedings

On August 11, 2005, Abbott Diabetes Care, Inc., or Abbott, filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware, seeking a declaratory judgment that our continuous glucose monitor infringes certain patents held by Abbott. In August 2005, we moved to dismiss these claims and filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office, or the Patent Office, and by March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against us in the litigation. On June 27, 2006, Abbott amended its complaint to include three additional patents owned or licensed by Abbott which are allegedly infringed by our continuous glucose monitor. On August 18, 2006, the court granted our motion to stay the lawsuit pending reexamination by the Patent Office of each of the four patents originally asserted by Abbott, and the court dismissed one significant infringement claim. In approving the stay, the court also granted our motion to strike, or disallow, Abbott s amended complaint in which Abbott had sought to add three additional patents to the litigation. Subsequent to the court s August 18, 2006 order striking Abbott s amended complaint, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of the three additional patents it had sought to include in the litigation discussed above. On September 7, 2006, we filed a motion to strike Abbott s new complaint on the grounds that it is redundant of claims Abbott already improperly attempted to inject into the original case, and because the original case is now stayed, Abbott must wait until the court lifts that

stay before it can properly ask the court to consider these claims. Alternatively, we asked the court to consolidate the new case with the original case and thereby stay the entirety of the case pending conclusion of the reexamination proceedings in the Patent Office. In February 2007, the Patent Office ordered reexamination of each of the three patents cited in this new lawsuit. On September 30, 2007, the court granted our motion to consolidate the cases and stay the entirety of the case pending conclusion of the reexamination proceedings in the Patent Office relating to all seven patents asserted against us.

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

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DEXCOM, INC.

Date: January 14, 2010

By: /s/ John Lister
Name: John Lister
Title: Vice President of Legal Affairs