

DEXCOM INC  
Form 10-Q  
May 05, 2010  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10 - Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2010

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-51222

**DEXCOM, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

**6340 Sequence Drive**

**San Diego, California**  
(Address of Principal Executive offices)

**92121**  
(Zip Code)

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

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

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or

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for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer  Smaller Reporting Company   
(Do not check if a smaller

reporting company)

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of April 29, 2010, 57,438,342 shares of the Registrant's common stock were outstanding.

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**DexCom, Inc.**

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**Table of Contents****DexCom, Inc.****Consolidated Balance Sheets****(In thousands except par value data)****(Unaudited)**

	<b>March 31, 2010</b>	<b>December 31, 2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 10,700	\$ 3,577
Short-term marketable securities, available-for-sale	39,221	24,439
Accounts receivable, net	3,801	3,490
Inventory, net	3,851	2,641
Prepaid and other current assets	1,436	2,773
Total current assets	59,009	36,920
Property and equipment, net	6,880	6,422
Restricted cash	2,189	2,414
Other assets	236	1,192
Total assets	\$ 68,314	\$ 46,948
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 5,112	\$ 5,745
Accrued payroll and related expenses	4,048	4,406
Current portion of long-term debt	900	900
Current portion of deferred revenue	5,768	7,745
Total current liabilities	15,828	18,796
Other liabilities	791	840
Long-term debt, net of current portion	4,968	45,757
Total liabilities	21,587	65,393
Commitments and contingencies (Note 4)		
Stockholders equity (deficit):		
Preferred stock, \$0.001 par value, 5,000 shares authorized; no shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively		
Common stock, \$0.001 par value, 100,000 authorized; 57,717 and 57,436 issued and outstanding, respectively, at March 31, 2010; and 46,324 and 46,045 shares issued and outstanding, respectively, at December 31, 2009	58	46
Additional paid-in capital	358,190	272,730
Accumulated other comprehensive loss	(40)	(13)
Accumulated deficit	(311,481)	(291,208)
Total stockholders equity (deficit)	46,727	(18,445)
Total liabilities and stockholders equity (deficit)	\$ 68,314	\$ 46,948

See accompanying notes



**Table of Contents****DexCom Inc.****Consolidated Statements of Operations****(In thousands except per share data)****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Product revenue	\$ 6,764	\$ 2,672
Development grant and other revenue	2,781	2,540
<b>Total revenue</b>	<b>9,545</b>	<b>5,212</b>
Product cost of sales	5,140	3,522
Development and other cost of sales	946	1,953
<b>Total cost of sales</b>	<b>6,086</b>	<b>5,475</b>
<b>Gross margin (deficit)</b>	<b>3,459</b>	<b>(263)</b>
Operating expenses		
Research and development	4,739	3,171
Selling, general and administrative	9,794	7,903
<b>Total operating expenses</b>	<b>14,533</b>	<b>11,074</b>
<b>Operating loss</b>	<b>(11,074)</b>	<b>(11,337)</b>
Interest income	30	123
Interest expense	(1,299)	(1,928)
Loss on debt extinguishment upon conversion of convertible debt	(7,930)	
<b>Net loss</b>	<b>\$ (20,273)</b>	<b>\$ (13,142)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.40)</b>	<b>\$ (0.33)</b>
Shares used to compute basic and diluted net loss per share	51,291	39,569

See accompanying notes

**Table of Contents****DexCom, Inc.****Consolidated Statements of Cash Flows****(In thousands)****(Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating activities</b>		
Net loss	\$ (20,273)	\$ (13,142)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	500	652
Share-based compensation	2,275	2,041
Non-cash restructuring benefit		(362)
Accretion and amortization related to investments, net	154	191
Accretion related to convertible debt discount	919	1,135
Loss on debt extinguishment upon conversion of convertible debt	7,930	
Amortization of debt issuance costs	6	52
Changes in operating assets and liabilities:		
Accounts receivable	(311)	(227)
Inventory	(1,210)	81
Prepaid and other assets	2,395	402
Restricted cash	225	568
Accounts payable and accrued liabilities	(663)	(463)
Accrued payroll and related expenses	(358)	72
Deferred revenue	(1,977)	(399)
Deferred rent and other liabilities	(49)	27
Net cash used in operating activities	(10,437)	(9,372)
<b>Investing activities</b>		
Purchase of available-for-sale marketable securities	(32,265)	(45,361)
Proceeds from the maturity of available-for-sale marketable securities	17,202	7,000
Purchase of property and equipment	(958)	(950)
Net cash used in investing activities	(16,021)	(39,311)
<b>Financing activities</b>		
Net proceeds from issuance of common stock	33,814	45,810
Repayment of equipment loan	(225)	(568)
Net cash provided by financing activities	33,589	45,242
Effect of exchange rate changes on cash and cash equivalents	(8)	17
Increase (decrease) in cash and cash equivalents	7,123	(3,424)
Cash and cash equivalents, beginning of period	3,577	12,700
Cash and cash equivalents, ending of period	\$ 10,700	\$ 9,276
<b>Non-cash investing and financing transactions:</b>		
Conversion of convertible notes to common stock	\$ 41,483	\$

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See accompanying notes



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**DexCom, Inc.**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

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

***Organization and Business***

DexCom, Inc. is a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems for ambulatory use by people with diabetes and by healthcare providers in the hospital for the treatment of both diabetic and non-diabetic patients. Unless the context requires otherwise, the terms we, us, our, the company, or DexCom refer to DexCom, Inc. and its subsidiary. We received approval from the FDA and commercialized our first product in 2006. In 2007, we received approval and began commercializing our second generation system, the SEVEN<sup>®</sup>, and on February 13, 2009, we received approval for our third generation system, the SEVEN PLUS, which is designed for up to seven days of continuous use, and we began commercializing this product in the first quarter of 2009. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, and on September 30, 2009, we received CE Mark approval for the SEVEN PLUS. We initiated a limited commercial launch in the European Union in 2008 and 2009. To address the in-hospital patient population, we entered into an exclusive agreement with Edwards Lifesciences LLC, or Edwards, to develop jointly and market a specific product platform for the in-hospital glucose monitoring market, with an initial focus on the development of an intravenous sensor specifically for the critical care market. On October 30, 2009, we received CE Mark approval for our blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, but have yet to seek approval for this system from the FDA. In partnership with Edwards, we initiated a limited launch of the blood-based, in-vivo automated glucose monitoring system, which we have branded as the GlucoClear<sup>®</sup>, in Europe in 2009.

***Basis of Presentation***

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ( U.S. GAAP ) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation (except for the changes in estimates described below), have been included. Operating results for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2009 included in the Annual Report on Form 10-K filed by us with the Securities and Exchange Commission on March 9, 2010.

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

***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates. Significant estimates include excess or obsolete inventories, warranty accruals, employee bonus, clinical study expenses, trade show expenses, allowances for returned product, allowance for bad debt, valuation of the liability component of our convertible notes, and share-based compensation expense. Excess and obsolete inventories are estimated by identifying the amount of on hand and on order materials compared to expected future sales, taking into account clinical trial and development usage along with new product introductions. Employee bonus estimates are based, in part, on the 2010 bonus plan s authorized target bonus amounts of up to 80%, 50%, 45%, 40%, 30% and 25% of base salary for our Chief Executive Officer, Chief Administrative Officer, our Senior Vice President of Operations, our Senior Vice President of Clinical and Regulatory Affairs and Quality Assurance, our Vice Presidents and the remainder of our non-sales management employees, respectively, to be awarded from the bonus pool based on the weighted average achievement of certain objectives. For our CEO, the amount of any bonus awarded under the 2010 Plan will be predicated on achieving targeted revenue goals and targeted operating



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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 and 25% is based on achieving certain operating expense goals. For the remainder of our 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. Clinical trial expenses are accrued based on estimates of progress under related contracts and include initial set up costs as well as ongoing monitoring over multiple sites in the U.S. and abroad. An allowance for refunds for returned products is determined by analyzing the timing and amounts of past refund activity.

***Share-Based Compensation***

We recorded \$2.3 million and \$2.0 million in share-based compensation expense during the three months ended March 31, 2010 and 2009, respectively. At March 31, 2010, unrecognized estimated compensation costs related to non-vested stock options, restricted stock and restricted stock units totaled \$19.7 million and is expected to be recognized through 2014. We utilize the Black-Scholes option-pricing model as the method of valuation for share-based awards granted.

***Revenue Recognition***

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

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

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

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

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We shipped product directly to certain distributors customers and recognized \$2.0 million in revenue, which represents 21% of our revenues for the three months ended March 31, 2010. With respect to other distributors which stock inventory of our product and fulfill orders from their inventory, we shipped product to these distributors and recognized \$836,000 in revenue from these arrangements for the three months ended March 31, 2010. We monitor shipments to, and on-hand inventory levels of, these distributors, and at March 31, 2010 these distributors had limited amounts of our product in their inventory.

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

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

For transactions containing multiple element arrangements entered into or materially modified during 2010, we consider deliverables as separate units of accounting and recognize deliverables as revenue upon delivery only if (i) the deliverable has stand-alone value and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery of the undelivered item(s) is probable and substantially controlled by us. We allocate consideration to the separate units of accounting using the relative selling price method, in which allocation of consideration is based on vendor-specific objective evidence ( VSOE ) if available, third party evidence ( TPE ), or if VSOE or TPE is not available, management s best estimate of a stand alone selling price for elements. See *Recent Accounting Pronouncements* in Note 1 of the notes to the consolidated financial statements for additional information related to our adoption of authoritative guidance for revenue recognition for multiple-deliverable revenue arrangements.

For transactions containing multiple element arrangements entered into prior to 2010, we considered deliverables as separate units of accounting and recognized deliverables as revenue upon delivery only if (i) the deliverable had stand-alone value, (ii) if the arrangement included a general right of return relative to the delivered item(s), delivery of the undelivered item(s) was probable and substantially controlled by us, and (iii) the fair value of the undelivered performance obligations could be determined. In those instances when objective and reliable evidence of fair value existed for the undelivered items but not for the delivered items, the residual method was used to allocate the arrangement consideration. Under the residual method, the amount of arrangement consideration allocated to the delivered items equaled the total arrangement consideration less the aggregate fair value of the undelivered items. If we were unable to establish stand-alone value for delivered items or when fair value of undelivered items had not been established, revenue was deferred until all elements were delivered and services had been performed, or until fair value could objectively be determined for any remaining undelivered elements.

We use judgment in estimating the value allocable to product revenues or development grant and other revenue based on our estimate of the fair value attributable to the related deliverables. For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement are recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. The cumulative amount of revenue earned is limited to the cumulative amount of payments received as of the period ending date.

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

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

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Under the collaboration agreement with Edwards, which provided us with a development grant, we recognized \$2.6 million in development grant and other revenue, which represents 27% of our total revenues for the three months ended March 31, 2010.

**Warranty Accrual**

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

**Foreign Currency**

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

**Comprehensive Loss**

We report all components of comprehensive income (loss), including net income (loss), in the consolidated financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments and foreign currency translation adjustments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). Our comprehensive loss is as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Net loss	\$ (20,273)	\$ (13,142)
Unrealized loss on short-term available-for-sale marketable securities	(19)	(54)
Foreign currency translation gain (loss)	(8)	17
Comprehensive loss	\$ (20,300)	\$ (13,179)

**Inventory**

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

**Income Taxes**

At December 31, 2009, we had federal and state tax net operating loss carryforwards of approximately \$203.2 million and \$138.3 million, respectively. The federal and state tax loss carryforwards will begin to expire in 2019 and 2011, respectively, unless previously utilized. We also had federal and state research and development tax credit carryforwards of approximately \$2.3 million and \$4.7 million, respectively. The federal research and development tax credit will begin to expire in 2019, unless previously utilized.

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Utilization of net operating losses and credit carryforwards are subject to an annual limitation due to ownership change limitations provided by Section 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state provisions. An ownership change limitation occurred as a result of the stock offering completed in February 2009. The limitation will likely result in approximately \$2.1 million of U.S. income tax credits and

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approximately \$9.2 million of state net operating loss carryforwards that will expire unused. The related deferred tax assets have been removed from the components of our deferred tax assets. The tax benefits related to the remaining federal and state net operating losses and tax credit carryforwards may be further limited or lost if future cumulative changes in ownership exceed 50% within any three-year period.

**Fair Value Measurements**

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

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

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

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

The following table represents our fair value hierarchy for our financial assets (cash equivalents and investments) measured at fair value on a recurring basis as of March 31, 2010 (in thousands):

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Cash equivalents	\$ 3,538			\$ 3,538
Marketable securities, available for sale	\$ 39,221			\$ 39,221
Restricted cash	\$ 2,189			\$ 2,189

We have maintained only Level 1 financial assets during the three months ended March 31, 2010.

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

**Convertible Debt Instruments**

In May 2008, the FASB issued authoritative guidance for accounting for convertible debt instruments that may be settled in cash upon conversion. The authoritative guidance requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability and equity components of the instrument. The debt would be recognized at the present value of its cash flows discounted using our nonconvertible debt borrowing rate. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The authoritative guidance also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The effective date of the authoritative guidance is for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. On January 1, 2009, we adopted the provisions of the authoritative guidance which resulted in a reduction to the historical carrying value of the 4.75% convertible senior notes (the Notes) due in 2027 on our balance sheet of \$26.6 million, a reduction to the carrying value of the debt issuance costs of \$1.2 million, and a corresponding increase to paid in capital as of the date of issuance. Our estimated non-convertible borrowing rate of 19.5% was applied to the notes and coupon interest using a present value technique to arrive at the fair value of the liability component. The adoption of the authoritative guidance also resulted in an increase in accumulated deficit of \$6.2 million and a corresponding net decrease to the carrying value of the debt discount and issuance costs as of January 1, 2009. The carrying amount of the equity component was \$1.6 million and \$26.6 million at March 31, 2010 and December 31, 2009, respectively. We recorded non-cash interest expense relating to the amortization of the debt discount in the amounts of \$919,000 and \$1.1 million for the three months ended March 31, 2010 and 2009, respectively. We recorded interest expense relating to the contractual coupon payments in the amounts of \$535,000 and \$713,000 for the three months ended March 31, 2010 and 2009, respectively.

We account for the conversion of our Notes in accordance with the authoritative guidance, in which a gain (loss) on the extinguishment of debt upon conversion is calculated as the difference between the carrying value and the fair value of the Notes on the conversion date. Determining the fair value of the liability component requires the use of accounting estimates and assumptions which are judgmental in nature and could have a significant impact on the valuation.





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

	March 31, 2010	December 31, 2009
Principal of convertible notes	\$ 6,000	\$ 60,000
Unamortized debt discount	(1,332)	(14,768)
<b>Net carrying amount of convertible notes</b>	<b>\$ 4,668</b>	<b>\$ 45,232</b>

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

**Recent Accounting Guidance**

In October 2009, the FASB issued authoritative guidance for multiple-deliverable revenue arrangements that provides amendments to the criteria for separating consideration in multiple-deliverable arrangements. As a result of these amendments, multiple-deliverable revenue arrangements will be separated in more circumstances than under existing U.S. GAAP by establishing a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific objective evidence nor third-party evidence is available. A vendor will be required to determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. This guidance also eliminates the residual method of allocation and will require that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method, which allocates any discount in the overall arrangement proportionally to each deliverable based on its relative selling price. Expanded disclosures of qualitative and quantitative information regarding application of the multiple-deliverable revenue arrangement guidance are also required under the guidance. The guidance does not apply to arrangements for which industry specific allocation and measurement guidance exists, such as long-term construction contracts and software transactions. This guidance is effective for fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We adopted the provisions of the authoritative guidance as of March 31, 2010 on a prospective basis. Prospective application required us to apply the guidance to new arrangements entered into or arrangements materially modified since the beginning of 2010. The prospective application had no impact on our consolidated financial statements for the interim period ended March 31, 2010. There would not have been a material difference in amounts recognized for development grant and other revenue for 2009 if the multiple element arrangements entered into or materially modified during 2009 were subject to the measurement requirements of the amendments of this guidance.

In October 2009, the FASB issued authoritative guidance for certain revenue arrangements that include software elements that reduce the types of transactions that fall within the current scope of software revenue recognition guidance. Existing software revenue recognition guidance requires that its provisions be applied to an entire arrangement when the sale of any products or services containing or utilizing software when the software is considered more than incidental to the product or service. As a result of the amendments included in the guidance, many tangible products and services that rely on software will be accounted for under the multiple-element arrangements revenue recognition guidance rather than under the software revenue recognition guidance. Under the guidance, the following components would be excluded from the scope of software revenue recognition guidance: the tangible element of the product, software products bundled with tangible products where the software components and non-software components function together to deliver the product's essential functionality, and undelivered components that relate to software that is essential to the tangible product's functionality. The guidance also provides direction on how to allocate transaction consideration when an arrangement contains both deliverables within the scope of software revenue guidance (software deliverables) and deliverables not within the scope of that guidance (non-software deliverables). The guidance is effective for fiscal years beginning on or after June 15, 2010 and early adoption is permitted. We must elect the same transition method for this guidance as that chosen for the guidance for multiple-deliverable revenue arrangements. We adopted the provisions of the authoritative guidance as of March 31, 2010 on a prospective basis. The prospective application had no impact on our consolidated financial statements for the interim period ended March 31, 2010.

**Table of Contents****2. Net Loss Per Common Share**

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

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

	Three Months Ended March 31,	
	2010	2009
Options outstanding to purchase common stock	8,560	7,137
Restricted stock and restricted stock units	437	59
Convertible senior notes	769	7,692
Total	9,766	14,888

**3. Financial Statement Details (in thousands)***Short Term Marketable Securities, Available for Sale*

Short term investment securities, consisting solely of debt securities with contractual maturities of less than one year were as follows (in thousands):

	March 31, 2010			Estimated Market Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government agencies	\$ 33,831	\$ 1	\$ (18)	\$ 33,814
Commercial paper	2,998			2,998
Corporate debt	2,414		(5)	2,409
Total	\$ 39,243	\$ 1	\$ (23)	\$ 39,221

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

*Inventory*

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	<b>March 31, 2010</b>	<b>December 31, 2009</b>
Raw materials	\$ 1,778	\$ 1,613
Work-in-process	271	398
Finished goods	1,802	630
Total	\$ 3,851	\$ 2,641

**Table of Contents***Accounts Payable and Accrued Liabilities*

	March 31, 2010	December 31, 2009
Accounts payable trade	\$ 2,173	\$ 2,600
Accrued tax, audit, and legal fees	811	761
Clinical trials	189	238
Accrued interest on convertible debt	12	831
Accrued other including warranty	1,927	1,315
 Total	 \$ 5,112	 \$ 5,745

*Accrued Warranty*

	Three Months Ended March 31,	
	2010	2009
Beginning balance	\$ 129	\$ 71
Charges to costs and expenses	803	119
Costs incurred	(528)	(143)
 Ending balance	 \$ 404	 \$ 47

**4. Commitments and Contingencies***Convertible Senior Notes*

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

Interest on the Notes is due semiannually on March 15 and September 15 of each year at a rate of 4.75% per year. The Notes are redeemable by us beginning March 20, 2010 at a price equal to 100% of the principal amount to be redeemed plus accrued and unpaid interest. Holders of the Notes may require us to repurchase the Notes for cash equal to 100% of the principal amount to be repurchased plus accrued and unpaid interest upon the occurrence of certain designated events, including a change of control. In addition, we will have the right to automatically convert the Notes if the closing price of our common stock exceeds 150% of the conversion price, or \$11.70 per share, for at least 20 trading days during any 30-day period. The holders of the Notes may require us to repurchase the Notes for cash on March 15, 2012, March 15, 2017 and March 15, 2022 at a repurchase price equal to 100% of the principal amount, plus accrued and unpaid interest. The Notes contain no financial covenants, and therefore, the note holders do not have protection against adverse changes in our business, and have limited protections in the event of a fundamental change to the Company.

For the three months ended March 31, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of approximately 7.2 million shares of our common stock, par value \$0.001 per share, in exchange for \$54.0 million in aggregate principal amount of the Notes previously held by the exchanging holders. We incurred a loss on the extinguishment of the Notes in the amount of \$7.9 million for the three months ended March 31, 2010, which includes the difference between the carrying value and the fair value of the Notes on the conversion date, other consideration given to note holders to induce early conversion and transaction costs incurred with third parties, other than the investors, to settle the conversion of the Notes.

*Call Spread Option*

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In March 2007, we entered into hedge transactions to minimize the potential dilution of our common stock upon conversion of the Notes if our stock price exceeded \$7.80 per share through March 2009. We had the right to purchase a number of shares of common stock equal to the number of shares underlying the \$60 million principal amount of the Notes, at a strike price equal to the conversion price of the Notes, or \$7.80 per share. The call spread options were structured in four tranches with one tranche expiring in each six-month interval for two years from the

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date of March 6, 2007. Each of the four options capped the potential benefit to us at market prices ranging from \$9.00 for the option which expired in September 2007 to \$18.50 for the option which expired in March 2009. The call spread options were separate transactions entered into by us and were not part of the terms of the Notes. Each of the call spread options have expired.

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

*Line of Credit*

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

At March 31, 2010, we had total borrowings of \$1.2 million under the Loan Agreement pursuant to the Facility A Equipment Line and Facility B Equipment Line and none was available for future borrowings. The loan bears an interest rate equal to the lender's prime rate plus 0.25% and at March 31, 2010, the interest rate was 3.5%. Beginning April 2008, terms of the Facility B Equipment Line began to require monthly amortized payments through the maturity date of July 2011. Under the amended Loan Agreement, we continue to grant a security interest in substantially all of our personal property as collateral for the loan and are required to maintain cash balances equal to total outstanding loan balances with the lender.

*Lease*

In January 2007, we entered into a sublease agreement to sublet an existing facility near our corporate headquarters to a third party. Under the terms of the agreement, we sublet approximately 7,000 square feet of facilities space at terms and conditions, including real estate taxes and operating costs, which mirror the original lease agreement. We retain obligations per the original lease. Rental obligations, excluding real estate taxes and operating costs, owed by us, but subject to reimbursement by the subtenant in accordance with the terms of the sublease agreement, as of March 31, 2010, were as follows (in thousands):

<b>Fiscal Year Ending</b>	
Remainder of 2010	86
2011	48
Total	\$ 134

Total rent expense for the three months ended March 31, 2010 was \$440,000.

*Litigation*

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



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redundant of claims Abbott already improperly attempted to inject into the original case, and because the original case is now stayed, Abbott must wait until the court lifts that stay before it can properly ask the court to consider these claims. Alternatively, we asked the court to consolidate the new case with the original case and thereby stay the entirety of the case pending conclusion of the reexamination proceedings in the Patent Office. In February 2007, the Patent Office ordered reexamination of each of the three patents cited in this new lawsuit. On September 30, 2007, the court granted our motion to consolidate the cases and stay the entirety of the case pending conclusion of the reexamination proceedings in the Patent Office relating to all seven patents asserted against us.

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

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

Although it is our position that Abbott's assertions of infringement have no merit, and that the potential interference and reexamination requests have no merit, neither the outcome of the litigation nor the amount and range of potential fees associated with the litigation, potential interference or reexamination requests can be assessed.

From time to time, we are subject to various claims and suits arising out of the ordinary course of business, including commercial and employment related matters. We do not expect that the resolution of these matters would have a material adverse effect on our consolidated financial position.

### *Purchase Commitments*

We are party to various purchase arrangements related to our development activities including materials used in our glucose monitoring systems. As of March 31, 2010, we had purchase commitments with vendors totaling \$4.7 million due within one year. There are no purchase commitments due beyond one year.

## **5. Development Agreements**

### *Insulet Corporation*

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



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*Animas Corporation*

On January 10, 2008, as amended on January 12, 2009 and July 30, 2009 ( the Animas Amendments ), we entered into a joint development agreement with Animas Corporation ( Animas ) to integrate our continuous glucose monitoring technology into Animas insulin pumps. Under the terms of the amended agreement, Animas will contribute up to \$1.1 million to DexCom to offset certain development, clinical and regulatory expenses. The agreement is non-exclusive in the United States, but exclusive outside the United States and does not impact either party's existing third party development agreements. In January of 2008 we received \$500,000. In January of 2009 we received \$250,000. We recorded \$70,000 in development grant and other revenue in each of the three months ended March 31, 2010 and 2009. Pursuant to the Animas Amendments, we will collaborate with Animas to develop a modified version of our transmitter to support a single, global CGM-enabled insulin pump launch by Animas. We are entitled to receive a one-time \$1.0 million milestone payment upon the achievement of performance qualification of a manufacturing line for the modified transmitter and are also entitled to receive an additional one-time \$4.0 million payment upon the first regulatory body approval outside the United States for the new system. By separating the milestone payments into \$1.0 million and \$4.0 million payments as set forth above, the Animas Amendments modify the original \$5.0 million milestone payment that we were entitled to receive upon receipt of a CE Mark for the first commercializable outside of the U.S. ( OUS ) product.

*Edwards Lifesciences LLC*

On November 10, 2008, and as amended on May 5, 2009, we entered into a Collaboration Agreement (the Agreement ) with Edwards. Pursuant to the Agreement, we and Edwards agreed to develop jointly and to market an in-hospital automatic blood glucose monitoring system. Under the terms of the Agreement, Edwards was obligated to pay us an upfront fee of \$13.0 million. In addition, we are entitled to receive up to \$22.0 million, as amended, over the next two years for product development costs and milestones related to regulatory approvals and manufacturing readiness. We will also receive either a profit-sharing payment of up to 10% of commercial sales of the product, or a royalty of up to 6% of commercial sales of the product. The Agreement provides Edwards with an exclusive license under our intellectual property in the hospital market. Edwards will be responsible for global sales and marketing, and we will initially be responsible for manufacturing. In November 2008 we received \$13.0 million. We received \$667,000 during the three months ended March 31, 2010. We recorded \$2.6 million in development grant and other revenue for the three months ended March 31, 2010, compared to \$2.5 million for the same period in 2009.

**6. Stockholder's Equity**

*Follow-on Stock Offering*

In January 2010, we completed a follow-on public stock offering of 4,025,000 shares of our common stock for net proceeds of approximately \$33.0 million.

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

*This document, including the following Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that are based upon current expectations. These forward-looking statements fall within the meaning of the federal securities laws that relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may, will, expect, plan, anticipate, believe, estimate, intend, potential or continue or the negative of these terms or other comparable terminology. Forward-looking statements involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in our forward-looking statements as a result of many factors, including product performance, a lack of acceptance in the marketplace by physicians and patients, the inability to manufacture products in commercial quantities at an acceptable cost, possible delays in our research and development programs, the inability of patients to receive reimbursements from third-party payors, inadequate financial and other resources, global economic conditions, and the other risks set forth below under Risk Factors and elsewhere in this report. We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results.*

**Overview**

We are a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems for ambulatory use by people with diabetes and for use by healthcare providers in the hospital for the treatment of both diabetic and non-diabetic patients. We received approval from the FDA and commercialized our first product in 2006. In 2007, we received approval and began commercializing our second generation system, the SEVEN, and on February 13, 2009, we received approval for our third generation system, the SEVEN PLUS, which is designed for up to seven days of continuous use, and we began commercializing this product in the first quarter of 2009. There are various differences between the SEVEN and the SEVEN PLUS. As compared to the SEVEN, the SEVEN PLUS incorporates additional user interface and algorithm enhancements that are intended to make its glucose monitoring function more accurate and customizable. Our ambulatory product approvals allow for the use of our continuous glucose monitoring systems by adults with diabetes to detect trends and track glucose patterns, to aid in the detection of hypoglycemia and hyperglycemia and to facilitate acute and long-term therapy adjustments. Our approved ambulatory products must be prescribed by a physician and include a disposable sensor, a transmitter and a small handheld receiver. Our approved ambulatory products are indicated for use as adjunctive devices to complement, not replace, information obtained from standard home blood glucose monitoring devices and must be calibrated periodically using a standard home blood glucose monitor. The sensor is inserted by the patient and is intended to be used continuously for up to seven days after which it is removed by the patient and may be replaced by a new sensor. Our transmitter and receiver are reusable. On November 26, 2008, we received CE Mark (Conformité Européene) approval for the SEVEN, enabling commercialization of the SEVEN system in the European Union and the countries in Asia and Latin America that recognize the CE Mark, and on September 30, 2009, we received CE Mark approval for the SEVEN PLUS. We initiated a limited commercial launch in the European Union and Israel in 2008 and 2009. To address the in-hospital patient population, we entered into an exclusive agreement with Edwards to develop jointly and market a specific product platform for the in-hospital glucose monitoring market, with an initial focus on the development of an intravenous sensor specifically for the critical care market. On October 30, 2009, we received CE Mark approval for our blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, but have yet to seek approval for this system from the FDA. In partnership with Edwards, we initiated a limited launch of the blood-based, in-vivo automated glucose monitoring system, which we have branded the GlucoClear, in Europe in 2009. From inception to 2006, we devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. Since 2006, we have devoted considerable resources to the commercialization of our ambulatory continuous glucose monitoring systems, including the SEVEN PLUS, as well as the continued research and clinical development of our technology platform.

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

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

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

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

Various clinical studies also demonstrate the benefits of continuous glucose monitoring and that continuous glucose monitoring is equally effective in patients who administer insulin through multiple daily injections or through use of continuous subcutaneous insulin infusion pumps. Results of a Juvenile Diabetes Research Foundation (JDRF) study published in the *New England Journal of Medicine* in 2008, and the extension phase of the study, published in *Diabetes Care* in 2009, demonstrated that continuous glucose monitoring improved A1c levels and reduced incidence of hypoglycemia for patients over the age of 25 and for all patients of all ages who utilized continuous glucose monitoring regularly.

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

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

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

We are leveraging our technology platform to enhance the capabilities of our current products and to develop additional continuous glucose monitoring products. In January 2008, we entered into two separate development agreements, one with Animas Corporation, or Animas, a subsidiary of Johnson & Johnson, and one with Insulet

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Corporation, or Insulet, to integrate our technology into the insulin pump product offerings of the respective partner, enabling the partner's insulin pump to receive glucose readings from our transmitter and display this information on the pump's screen. In addition, we are continuing clinical development of a fourth generation ambulatory product which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, and will be suited for large scale manufacturing. We also intend to seek approval for a pediatric indication (patients under 18 years of age) and a pregnancy indication (diabetes patients who become pregnant and patients who develop gestational diabetes) for our product platform in the future. In addition, as described above we are developing, in collaboration with Edwards, a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital. Our development timelines are highly dependent on our ability to overcome technology challenges, clinical trials, and may be delayed due to scheduling issues with patients and investigators, institutional review boards, sensor performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts are successful, the FDA may not approve our products, and if approved, we may not achieve acceptance in the marketplace by physicians and patients.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although the Centers for Medicare and Medicaid, or CMS, released 2008 Alpha-Numeric Healthcare Common Procedure Coding System ( 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 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 and expect to continue to do so in 2010. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them on a widespread basis.

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

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

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

From inception through March 31, 2010, we had generated \$55.9 million of product and development grant and services (non-product) revenue, and we have incurred net losses in each year since our inception in May 1999. From inception through March 31, 2010, we had an accumulated deficit of \$311.5 million. We expect our losses to continue as we proceed with our commercialization and research and development activities. We have financed our operations primarily through offerings of equity securities and convertible debt. In April 2005, we completed our initial public offering in which we sold 4,700,000 shares of common stock for net proceeds of \$50.5 million. In March 2006, we entered into a Loan Agreement, which was subsequently amended in January 2008. As of March 31, 2010, we had an outstanding balance of \$1.2 million under the Loan Agreement. In May 2006, we completed a follow-on public offering of 2,117,375 shares of our common stock for net proceeds of \$47.0 million. In March 2007, we issued an aggregate principal amount of \$60.0 million of 4.75% Convertible Senior Notes due in 2027. In February 2009, we completed a follow-on public offering of 15,994,000 shares of our common stock for net proceeds of approximately \$45.6 million. In January 2010, we completed a follow-on public offering of 4,025,000 shares of our common stock for net proceeds of approximately \$33.0 million.

## **Financial Operations**

### ***Revenue***

From inception through March 31, 2010, we generated \$39.7 million in product revenue from the sale of our continuous glucose monitoring systems. We expect that revenues we generate from the sales of our products will fluctuate from quarter to quarter. During the first quarter of 2008, we entered into a joint development agreement with Animas and we recognize development grant and other revenue received pursuant to that agreement ratably over the term of the development period. During the fourth quarter of 2008, we entered into a collaboration agreement with Edwards and we recognize development grant and other revenue received pursuant to that agreement ratably over the term of the development period. From inception through March 31, 2010, we recognized \$16.2 million in development grant and other revenue, which includes milestones and services.

### ***Cost of Sales***

Product cost of sales includes direct labor and materials costs related to each product sold or produced, including assembly, test labor and scrap, as well as factory overhead supporting our manufacturing operations. Factory overhead includes facilities, material procurement and control, manufacturing engineering, quality assurance, supervision and management. These costs are primarily salary, fringe benefits, share-based compensation, facility expense, supplies and purchased services. The majority of our costs are currently fixed due to our relatively low production volumes compared to our potential capacity. All of our manufacturing costs are included in product cost of sales. Development and other cost of sales consists primarily of salaries, fringe, facilities, and supplies directly attributable to our development contracts.

### ***Research and Development***

Our research and development expenses primarily consist of engineering and research expenses related to our continuous glucose monitoring technology, clinical trials, regulatory expenses, materials and products for clinical trials. Until December 31, 2005 our manufacturing costs were included in research and development expense. Research and development expenses are primarily related to employee compensation, including salary, fringe benefits, share-based compensation, and temporary employee expenses. We also incur significant expenses to operate our clinical trials including clinical site reimbursement, clinical trial product and associated travel expenses. Our research and development expenses also include fees for design services, contractors and development materials.

### ***Selling, General and Administrative***

Our selling, general and administrative expenses primarily consist of salary, fringe benefits and share-based compensation for our executive, financial, sales, marketing and administrative functions. Other significant expenses include trade show expenses, sales samples, insurance, professional fees for our outside legal counsel and independent auditors, litigation expenses and consulting expenses.



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**Table of Contents****Results of Operations*****Quarter Ended March 31, 2010 Compared to March 31, 2009******Revenue, Cost of Sales and Gross Margin***

Product revenues increased \$4.1 million to \$6.8 million for the three months ended March 31, 2010 compared to \$2.7 million for the three months ended March 31, 2009 based primarily on increased sales volume and higher average per unit selling prices. Product cost of sales increased \$1.6 million to \$5.1 million for the three months ended March 31, 2010 compared to \$3.5 million for the three months ended March 31, 2009. The increased product cost of sales associated with additional product sales was offset primarily by increased manufacturing absorption for the three months ended March 31, 2010 as compared to the same period in 2009. The product gross margin of \$1.6 million for the three months ended March 31, 2010 increased \$2.4 million compared to a loss of \$850,000 for the same period in 2009, primarily due to increased revenue, better direct labor utilization, and increased manufacturing absorption. During the quarter ended March 31, 2010, we increased inventory levels to meet current and forecasted requirements which resulted in additional absorption of manufacturing costs and a corresponding improvement in product gross margin.

Development grant and other revenues increased \$241,000 to \$2.8 million for the three months ended March 31, 2010 compared to \$2.5 million for the three months ended March 31, 2009. Development and other cost of sales decreased \$1.0 million to \$946,000 for the three months ended March 31, 2010 compared to \$2.0 million for the three months ended March 31, 2009. The increase in revenues associated with development was primarily due to additional services performed during the quarter ended March 31, 2010. The decrease in costs associated with development was primarily due to less development efforts on our collaboration arrangements.

***Research and Development.*** Research and development expense increased \$1.6 million to \$4.7 million for the three months ended March 31, 2010, compared to \$3.2 million for the three months ended March 31, 2009. The increase in research and development expense was primarily due to increased development efforts for our ambulatory products and decreased activity with respect to our development and collaboration agreements. Changes in research and development expense include \$107,000 in higher development costs and \$430,000 in higher clinical and regulatory and quality assurance costs. Increased research and development costs include \$992,000 in additional salaries, bonus, and payroll related costs, \$146,000 in additional facilities costs, and \$128,000 in additional share-based compensation.

***Selling, General and Administrative.*** Selling, general and administrative expense increased \$1.9 million to \$9.8 million for the three months ended March 31, 2010, compared to \$7.9 million for the three months ended March 31, 2009. The increase was primarily due to higher selling, customer service, and international development costs to support revenue growth and the continued commercialization of our products. Major elements of increased selling, general, and administrative expenses include \$1.2 million in additional salaries, bonus, and payroll related costs, \$140,000 in additional allowance for doubtful accounts, and \$123,000 in additional share-based compensation.

***Interest Income.*** Interest income decreased \$93,000 to \$30,000 for the three months ended March 31, 2010, compared to \$123,000 for the three months ended March 31, 2009. The decrease in interest income was primarily due to lower average interest bearing cash and marketable securities balances and lower yields earned on those balances during the three months ended March 31, 2010 as compared to the same period of 2009.

***Interest Expense.*** Interest expense decreased \$629,000 to \$1.3 million for the three months ended March 31, 2010, compared to \$1.9 million for the three months ended March 31, 2009. The decrease in interest expense was primarily due to lower non-cash interest expense relating to the accretion of the debt discount for the 4.75% convertible notes issued in March of 2007 as a result of the conversions of the notes that occurred during the three months ended March 31, 2010.

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### **Loss on Debt Extinguishment upon Conversion of Convertible Debt**

For the three months ended March 31, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of approximately 7.2 million shares of our common stock, par value \$0.001 per share, in exchange for \$54.0 million in aggregate principal amount of the Notes previously held by the exchanging holders. We incurred a loss on the extinguishment of the Notes in the amount of \$7.9 million for the three months ended March 31, 2010, which includes the difference between the carrying value and the fair value of the Notes on the conversion date, other consideration given to note holders to induce early conversion and transaction costs incurred with third parties, other than the investors, to settle the conversion of the Notes.

### **Liquidity and Capital Resources**

We are in the early commercialization stage and have incurred losses since our inception in May 1999. As of March 31, 2010, we had an accumulated deficit of \$311.5 million and had working capital of \$43.2 million. Our cash, cash equivalents and short-term marketable securities totaled \$49.9 million, excluding \$2.2 million in restricted cash. We have funded our operations primarily from the sale of equity and debt securities and our bank line. As of March 31, 2010 we had a total of \$1.2 million outstanding under our amended bank equipment loan that we are required to repay through July 2011. In January 2010, we completed a follow-on public offering of 4,025,000 shares of our common stock for net proceeds of approximately \$33.0 million.

***Net Cash Used in Operating Activities.*** Net cash used in operating activities increased \$1.1 million to \$10.4 million for the three months ended March 31, 2010, compared to \$9.4 million for the same period in 2009. The increase in cash used in operations was primarily due to \$7.1 million in higher net loss, offset by \$8.1 million in additional non-cash charges primarily comprised of loss on the extinguishment of debt upon conversion of our Notes.