

DEXCOM INC  
Form 10-Q  
November 04, 2010

**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 September 30, 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)

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**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 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  (Do not check if a smaller reporting company) 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 November 1, 2010, 58,733,727 shares of the Registrant's common stock were outstanding.

**DexCom, Inc.**

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## DexCom, Inc.

## Consolidated Balance Sheets

(In thousands except par value data)

(Unaudited)

	September 30, 2010	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,529	\$ 3,577
Short-term marketable securities, available-for-sale	24,380	24,439
Accounts receivable, net	5,102	3,490
Inventory	6,353	2,641
Restricted cash	1,664	
Prepaid and other current assets	1,460	2,773
<b>Total current assets</b>	<b>44,488</b>	<b>36,920</b>
Property and equipment, net	9,240	6,422
Restricted cash	275	2,414
Other assets	102	1,192
<b>Total assets</b>	<b>\$ 54,105</b>	<b>\$ 46,948</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 7,075	\$ 5,745
Accrued payroll and related expenses	5,623	4,406
Current portion of long-term debt	750	900
Current portion of deferred revenue	3,560	7,745
<b>Total current liabilities</b>	<b>17,008</b>	<b>18,796</b>
Long-term portion of deferred revenue	881	
Other liabilities	972	840
Long-term debt, net of current portion		45,757
<b>Total liabilities</b>	<b>18,861</b>	<b>65,393</b>
Commitments and contingencies (Note 4)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 5,000 shares authorized; no shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively		
Common stock, \$0.001 par value, 100,000 authorized; 59,000 and 58,718 shares issued and outstanding, respectively, at September 30, 2010; and 46,324 and 46,045 shares issued and outstanding, respectively, at December 31, 2009		
	60	46
Additional paid-in capital	371,789	272,730
Accumulated other comprehensive loss	(39)	(13)
Accumulated deficit	(336,566)	(291,208)
<b>Total stockholders' equity (deficit)</b>	<b>35,244</b>	<b>(18,445)</b>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 54,105</b>	<b>\$ 46,948</b>

See accompanying notes

## DexCom Inc.

## Consolidated Statements of Operations

(In thousands except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Product revenue	\$ 10,776	\$ 4,620	\$ 26,583	\$ 11,404
Development grant and other revenue	888	2,639	6,412	7,818
<b>Total revenue</b>	<b>11,664</b>	<b>7,259</b>	<b>32,995</b>	<b>19,222</b>
Product cost of sales	6,982	4,589	18,440	12,738
Development and other cost of sales	1,206	1,805	3,101	6,930
<b>Total cost of sales</b>	<b>8,188</b>	<b>6,394</b>	<b>21,541</b>	<b>19,668</b>
<b>Gross margin (deficit)</b>	<b>3,476</b>	<b>865</b>	<b>11,454</b>	<b>(446)</b>
Operating expenses				
Research and development	6,161	3,496	16,325	10,122
Selling, general and administrative	10,377	8,948	30,533	25,803
<b>Total operating expenses</b>	<b>16,538</b>	<b>12,444</b>	<b>46,858</b>	<b>35,925</b>
<b>Operating loss</b>	<b>(13,062)</b>	<b>(11,579)</b>	<b>(35,404)</b>	<b>(36,371)</b>
Interest income	20	93	73	323
Interest expense	(44)	(2,037)	(1,540)	(5,947)
Loss on debt extinguishment upon conversion of convertible debt	(312)		(8,487)	
<b>Net loss</b>	<b>\$ (13,398)</b>	<b>\$ (13,523)</b>	<b>\$ (45,358)</b>	<b>\$ (41,995)</b>
<b>Basic and diluted net loss per share</b>	<b>\$ (0.23)</b>	<b>\$ (0.29)</b>	<b>\$ (0.81)</b>	<b>\$ (0.96)</b>
Shares used to compute basic and diluted net loss per share	58,200	45,919	55,707	43,797

See accompanying notes

## DexCom, Inc.

## Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2010	2009
<b>Operating activities</b>		
Net loss	\$ (45,358)	\$ (41,995)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,716	1,903
Share-based compensation	7,363	6,212
Non-cash restructuring benefit		(362)
Accretion and amortization related to investments, net	572	763
Accretion related to convertible debt discount	1,059	3,562
Loss on debt extinguishment upon conversion of convertible debt	8,487	
Amortization of debt issuance costs	36	178
Changes in operating assets and liabilities:		
Accounts receivable	(1,612)	(1,369)
Inventory	(3,712)	514
Prepaid and other assets	2,421	535
Restricted cash	475	1,631
Accounts payable and accrued liabilities	1,296	136
Accrued payroll and related expenses	1,217	1,445
Deferred revenue	(3,304)	(3,318)
Deferred rent and other liabilities	132	(51)
Net cash used in operating activities	(29,212)	(30,216)
<b>Investing activities</b>		
Purchase of available-for-sale marketable securities	(43,688)	(53,597)
Proceeds from the maturity of available-for-sale marketable securities	43,041	35,483
Purchase of property and equipment	(4,534)	(2,529)
Net cash used in investing activities	(5,181)	(20,643)
<b>Financing activities</b>		
Net proceeds from issuance of common stock	37,061	46,231
Repayment of equipment loan	(675)	(1,706)
Net cash provided by financing activities	36,386	44,525
Effect of exchange rate changes on cash and cash equivalents	(41)	(4)
Increase (decrease) in cash and cash equivalents	1,952	(6,338)
Cash and cash equivalents, beginning of period	3,577	12,700
Cash and cash equivalents, ending of period	\$ 5,529	\$ 6,362
<b>Non-cash investing and financing transactions:</b>		
Conversion of convertible notes to common stock	\$ 47,033	\$

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 Food and Drug Administration ( 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. 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 first generation blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, and are continuing 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, 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 and nine months ended September 30, 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 consolidated 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%, 70%, 70%, 40%, 30% and 25% of base salary for our Chief Executive Officer, Chief Operating Officer, Chief Technical Officer, our Senior Vice President of Clinical and Regulatory Affairs, 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. With respect to the CEO, generally, 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, generally, 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

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U.S. and abroad. An allowance for refunds for returned products is determined by analyzing the timing and amounts of past refund activity.

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**DexCom, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**(Unaudited)**

***Share-Based Compensation***

We recorded \$2.3 million and \$2.1 million in share-based compensation expense during the three months ended September 30, 2010 and 2009, respectively, and \$7.3 million and \$6.2 million during the nine months ended September 30, 2010 and 2009, respectively. At September 30, 2010, unrecognized estimated compensation costs related to non-vested stock options, restricted stock and restricted stock units totaled \$17.7 million and is expected to be recognized through 2014. We utilize the Black-Scholes option-pricing model as the method of valuation for stock options granted and we use the grant date fair value of our common stock for valuing restricted stock unit awards.

***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, organizations 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, 2009 and 2010, 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 freight on board ( FOB ) shipping point (free carrier ( 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.

We shipped product directly to certain distributors' customers and recognized \$3.4 million and \$8.2 million in revenue, which represents 29% and 25% of our revenues for the three and nine months ended September 30, 2010, respectively. 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 \$1.2 million and \$3.0 million in revenue from these arrangements for the three and nine months ended September 30, 2010, respectively. We monitor shipments to, and on-hand inventory levels of, these distributors, and at September 30, 2010 these distributors had limited amounts of our product in their

inventory.

**DexCom, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**(Unaudited)**

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 obligate us to multiple deliverables (for example, license rights, provision of research and development services and manufacture of clinical materials) in exchange for our right to receive various forms of consideration, including 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. We review the estimated period of our performance obligations on a periodic basis and update the recognition period, as appropriate. 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.



**DexCom, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)**

Under the collaboration agreement with Edwards, which provided us with a development grant, we recognized \$856,000 and \$6.0 million in development grant and other revenue, which represents 7% and 18% of our total revenues for the three and nine months ended September 30, 2010, respectively.

**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 September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
Net loss	(\$ 13,398)	(\$ 13,523)	(\$ 45,358)	(\$ 41,995)
Unrealized gain (loss) on short-term available-for-sale marketable securities	9	(32)	15	(10)
Foreign currency translation gain (loss)	(43)	5	(41)	(4)
Comprehensive loss	(\$ 13,432)	(\$ 13,550)	(\$ 45,384)	(\$ 42,009)

**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.

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 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.



**DexCom, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)*****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 September 30, 2010 (in thousands):

	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Cash equivalents	\$ 3,693			\$ 3,693
Marketable securities, available for sale	\$ 24,380			\$ 24,380
Restricted cash	\$ 1,939			\$ 1,939

We have maintained only Level 1 financial assets during the three and nine months ended September 30, 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 \$0 and \$26.6 million at September 30, 2010 and December 31, 2009, respectively. We recorded non-cash interest expense relating to the amortization of the debt discount in the amounts of \$51,000 and \$1.2 million for the three months ended September 30, 2010 and 2009, respectively, and \$1.1 million and \$3.6 million for the nine months ended September 30, 2010 and 2009, respectively. We recorded an interest expense adjustment relating to the contractual coupon payments in the

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amount of (\$20,000) for the three months ended September 30, 2010 and interest expense relating to the contractual coupon payments in the amount of \$713,000 for the three months ended September 30, 2009, and \$559,000 and \$2.1 million for the nine months ended September 30, 2010 and 2009, respectively. As of September 15, 2010, we completed conversions of all Notes that remained outstanding. In aggregate, we have issued 7,928,555 shares of common stock, par value \$0.001, in exchange for the conversion of \$60,000,000 of total principal amount of the Notes, and no Notes remain outstanding as of September 15, 2010.

**DexCom, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)**

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.

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):

	September 30, 2010	December 31, 2009
Principal of convertible notes	\$	\$ 60,000
Unamortized debt discount		(14,768)
<b>Net carrying amount of convertible notes</b>	<b>\$</b>	<b>\$ 45,232</b>

***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 September 30, 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)

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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 September 30, 2010.

## DexCom, Inc.

## Notes to Consolidated Financial Statements (Continued)

(Unaudited)

**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 September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Options outstanding to purchase common stock	8,385	7,714	8,385	7,714
Restricted stock and restricted stock units	520	41	520	41
Convertible senior notes		7,692		7,692
Total	8,905	15,447	8,905	15,447

**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):

	September 30, 2010			Estimated Market Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government agencies	\$ 18,478	\$ 10	\$	\$ 18,488
Corporate debt	5,891	2	(1)	5,892
Total	\$ 24,369	\$ 12	\$ (1)	\$ 24,380

	December 31, 2009			Estimated Market Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government agencies	\$ 16,198	\$ 7	\$ (10)	\$ 16,195

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Commercial paper	8,244	1	(1)	8,244
<b>Total</b>	<b>\$ 24,442</b>	<b>\$ 8</b>	<b>\$ (11)</b>	<b>\$ 24,439</b>

*Inventory*

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
Raw materials	\$ 3,934	\$ 1,613
Work-in-process	529	398
Finished goods	1,890	630
<b>Total</b>	<b>\$ 6,353</b>	<b>\$ 2,641</b>

## DexCom, Inc.

## Notes to Consolidated Financial Statements (Continued)

(Unaudited)

*Accounts Payable and Accrued Liabilities*

	September 30, 2010	December 31, 2009
Accounts payable trade	\$ 4,138	\$ 2,600
Accrued tax, audit, and legal fees	930	761
Clinical trials	71	238
Accrued interest on convertible debt		831
Accrued other including warranty	1,936	1,315
Total	\$ 7,075	\$ 5,745

*Accrued Warranty*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Beginning balance	\$ 429	\$ 63	\$ 129	\$ 71
Charges to costs and expenses	460	457	1,733	777
Costs incurred	(455)	(387)	(1,428)	(715)
Ending balance	\$ 434	\$ 133	\$ 434	\$ 133

**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 were 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 was due semiannually on March 15 and September 15 of each year at a rate of 4.75% per year. The Notes were 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.

For the nine months ended September 30, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of approximately 7.9 million shares of our common stock, par value \$0.001 per share, in exchange for \$60.0 million in aggregate principal amount of the Notes previously held by the exchanging holders, and no Notes remain outstanding as of September 30, 2010. We incurred a loss on the extinguishment of the Notes in the amount of \$312,000 and \$8.5 million for the three and nine months ended September 30, 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 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.



**DexCom, Inc.****Notes to Consolidated Financial Statements (Continued)****(Unaudited)*****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 September 30, 2010, we had total borrowings of \$750,000 under the *Loan Agreement* pursuant to the 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 September 30, 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 September 30, 2010, were as follows (in thousands):

<b>Fiscal Year Ending</b>	
Remainder of 2010	\$ 29
2011	48
Total	\$ 77

Total rent expense for the three and nine months ended September 30, 2010 was \$522,000 and \$1.4 million, respectively.

In August 2010, we entered into a First Amendment to Office Lease (the *Agreement*) with Kilroy Realty, L.P. with respect to facilities in the buildings at 6340 Sequence Drive and 6310 Sequence Drive, each in San Diego, California (the *Buildings*).

Under the *Agreement*, we have leased approximately 102,844 square feet of space in the *Buildings*, and retain the right and obligation to lease an additional 25,971 square feet in the *Buildings*. The lease term on the *Buildings* extends through November 30, 2016. The annual rent payable by us for the *Buildings* under the *Agreement* will be as follows:

<b>Period</b>	<b>Annual Rent Amount</b>
9/1/10 - 8/31/11	\$ 1,870,651
9/1/11 - 8/31/12	\$ 1,938,481
9/1/12 - 8/31/13	\$ 2,473,509

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9/1/13 - 8/31/14	\$ 2,561,323
9/1/14 - 8/31/15	\$ 2,638,568
9/1/15 - 8/31/16	\$ 2,717,471
9/1/16 - 11/30/16	\$ 699,501

In addition, under the Agreement, we are obligated to pay a share of the real estate taxes and operating costs for the Buildings. Provided we are not in default under the Agreement and the Agreement is still in effect, we generally have the right to extend the lease for an additional five years by giving notice to the landlord prior to the end of the initial term of the lease.

The total obligation for rent under the life of all leases is \$14.9 million, excluding real estate taxes and operating costs.

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**DexCom, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**(Unaudited)**

***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 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 filed appeal briefs in each of the cases. In response to those appeal briefs, each of the two examiners' answers maintained all rejections and Abbott has filed reply briefs in both cases and the Patent Office has heard Abbott's oral arguments. We also filed second and third reexamination requests 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 Patent Office has ordered reexamination for each of the two patents. For one of those patents, Abbott filed a petition to vacate the Reexamination Order, and we filed an opposition to Abbott's petition. The Patent Office has not issued any decision on Abbott's petition. With regard to the three patents subsequently asserted, all three have been issued one or more Certificates of Reexamination and subsequently re-entered the reexamination process. For one of the three patents, the Patent Office issued a Notice of Intent to Issue a Reexamination Certificate on September 2, 2010. For the second patent, Abbott submitted a response to a non-final Office Action on August 30, 2010. For the third patent, we submitted one reexamination request, which was ordered only for the originally issued claims by the Patent Office in March 2010, which is waiting for further action from the Patent Office. We submitted another reexamination request for that third patent. In response, the Patent Office ordered reexamination of certain, but not all, claims issued in the Reexamination Certificate in August 2010. We submitted a petition to seek the director's review of the examiners' refusal to order reexamination of certain claims issued in the Reexamination Certificate. The Patent Office has not issued any decision on the petition yet.

In 2008, 2009 and 2010, 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. An oral hearing has been set for December 1, 2010 in one of the proceedings.



**DexCom, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**(Unaudited)**

In 2010, Abbott filed reexamination requests seeking to invalidate an additional five of our patents in the Patent Office. All of the five reexamination requests have been granted and non-final rejections have been issued in two of the five requests.

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 and operational activities including materials used in our glucose monitoring systems. As of September 30, 2010, we had purchase commitments with vendors totaling \$4.6 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.

***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 2008 we received \$500,000. In January 2009 we received \$250,000. We recorded \$25,000 and \$164,000 in revenue for the three and nine months ended September 30, 2010, compared to \$70,000 and \$209,000 for the same period in 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 to which we were entitled, under the original agreement, to receive upon receipt of a CE Mark for the first commercializable product outside of the U.S. ( OUS ).

***Edwards Lifesciences LLC***

On November 10, 2008, and as amended on May 5, 2009, we entered into a Collaboration Agreement (the Collaboration 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 Collaboration Agreement, as amended, 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 for product development costs and milestones related to regulatory approvals

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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 Collaboration Agreement provides Edwards with an exclusive license under our intellectual property to the critical care sector 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 \$1.3 million and \$2.9 million during the three and nine months ended September 30, 2010, respectively. We recorded \$856,000 and \$6.0 million in development grant and other revenue for the three and nine months ended September 30, 2010, respectively, compared to \$2.6 million and \$7.6 million for the same periods in 2009, respectively.

**DexCom, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**(Unaudited)**

**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.

**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 reliably manufacture products in commercial quantities at an acceptable cost, possible delays in our research and development programs or in product approvals, failure to comply with regulatory requirements, uncertainties related to healthcare reform in the United States, 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 Européenne) 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 first generation blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, and are continuing 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, estimates that 285 million people around the world have diabetes, 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.

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 September 2010 estimates that our current share of the continuous glucose monitoring system market in the United States is at 47%. The report analyzed responses from 300 panel members who were asked what brand and model of continuous glucose monitoring system they used. 43% of respondents used our SEVEN PLUS product and 4% 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 materially 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. In addition, we are continuing to seek approval for our fourth generation ambulatory system, and are responding to FDA's requests for additional data in support of that application. We expect our fourth generation system 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 (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 achieve clinical endpoints and regulatory requirements and to overcome technology challenges, and our development timelines may be delayed due to extended regulatory approval timelines, scheduling issues with patients and investigators, requests from 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 November 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 six 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 and liberalize 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 future generations 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 are seeking regulatory approval for a fourth generation sensor platform using advanced membrane technologies that are more scalable and reliable. Over the longer term, we plan to develop 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. On June 1, 2010, we also received a warning letter dated May 21, 2010 from the FDA requiring us to file medical device reports (MDRs) in accordance with the MDR regulations for complaints involving sensor wire fractures underneath a patient's skin. The warning letter also recommended that we add certain warnings and precautions statements to the labeling, patient education brochures, and our company website regarding the appropriate use of the SEVEN and SEVEN PLUS Systems, including that they are not approved for use in children under age 18, pregnant women, or persons on dialysis. In response to the warning letter and the Form 483 inspectional observations, we have taken steps to address the observations to achieve substantial compliance with the FDA regulatory requirements applicable to a commercial medical device manufacturer. In October 2010, we were subject to a follow-up site inspection by the FDA, and upon completion of that inspection, we were notified by the inspector that there were no 483 inspectional observations. We also received written notification dated November 1, 2010 from the FDA that we adequately addressed all issues cited in the warning letter.

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.

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, within negotiated contractual terms with respect to purchases covered by insurance payors, or with the issuance of a purchase order or letter of credit for certain distributors and institutions.

From inception through September 30, 2010, we generated \$79.3 million of product and development grant and other (non-product) revenue, and we have incurred net losses in each year since our inception in May 1999. From inception through September 30, 2010, we had an accumulated deficit of \$336.6 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 September 30, 2010, we had an outstanding balance of \$750,000 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 September 30, 2010, we generated \$59.5 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 September 30, 2010, we recognized \$19.8 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. 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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**Results of Operations**

*Quarter Ended September 30, 2010 Compared to September 30, 2009*

**Revenue, Cost of Sales and Gross Margin**

Product revenues increased \$6.2 million to \$10.8 million for the three months ended September 30, 2010 compared to \$4.6 million for the three months ended September 30, 2009 based primarily on increased sales volume. Product cost of sales increased \$2.4 million to \$7.0 million for the three months ended September 30, 2010 compared to \$4.6 million for the three months ended September 30, 2009. The increased product cost of sales associated with additional product sales was offset primarily by increased manufacturing absorption for the three months ended September 30, 2010 as compared to the same period in 2009. The product gross margin of \$3.8 million for the three months ended September 30, 2010 increased \$3.8 million compared to \$31,000 for the same period in 2009, primarily due to increased revenue and increased manufacturing absorption. During the three months ended September 30, 2010, we increased inventory levels to meet sales forecast requirements and in anticipation of Flextronics' relocation of its production site from California to China. The increase in our inventory levels resulted in additional absorption of manufacturing costs and a corresponding improvement in product gross margin.

Development grant and other revenues decreased \$1.8 million to \$888,000 for the three months ended September 30, 2010 compared to \$2.6 million for the three months ended September 30, 2009. Development and other cost of sales decreased \$600,000 to \$1.2 million for the three months ended September 30, 2010 compared to \$1.8 million for the three months ended September 30, 2009. The decrease in development grant and other revenues during the three months ended September 30, 2010 was based on longer than expected development and regulatory review timelines under our collaboration arrangements with Edwards and Animas. The decrease in costs associated with development was primarily due to fewer development obligations during the quarter with respect to our collaboration arrangements.

**Research and Development.** Research and development expense increased \$2.7 million to \$6.2 million for the three months ended September 30, 2010, compared to \$3.5 million for the three months ended September 30, 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. Increased research and development costs include \$1.1 million in additional salaries, bonus, and payroll related costs, \$392,000 in additional share-based compensation, and \$185,000 in additional clinical trial costs.

**Selling, General and Administrative.** Selling, general and administrative expense increased \$1.4 million to \$10.4 million for the three months ended September 30, 2010, compared to \$8.9 million for the three months ended September 30, 2009. The increase was primarily due to higher selling, customer service, and information technology costs to support revenue growth and the continued commercialization of our products. Major elements of increased selling, general, and administrative expenses include \$845,000 in additional salaries, bonus, and payroll related costs, \$217,000 in additional commissions, and \$203,000 in additional tradeshow expense.

**Interest Income.** Interest income decreased \$73,000 to \$20,000 for the three months ended September 30, 2010, compared to \$93,000 for the three months ended September 30, 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 September 30, 2010 as compared to the same period of 2009.

**Interest Expense.** Interest expense decreased \$2.0 million to \$44,000 for the three months ended September 30, 2010, compared to \$2.0 million for the three months ended September 30, 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% senior convertible notes (the Notes) issued in March of 2007, and lower coupon interest expense relating to the Notes outstanding as a result of the conversions of the Notes that occurred during the three months ended September 30, 2010.

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

For the three months ended September 30, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of approximately 512,814 shares of our common stock, par value \$0.001 per share, in exchange for \$4.0 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 \$312,000 for the three months ended September 30, 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.



*Nine Months Ended September 30, 2010 Compared to September 30, 2009*

***Revenue, Cost of Sales and Gross Margin***

Product revenues increased \$15.2 million to \$26.6 million for the nine months ended September 30, 2010 compared to \$11.4 million for the nine months ended September 30, 2009 based primarily on increased sales volume. Product cost of sales increased \$5.7 million to \$18.4 million for the nine months ended September 30, 2010 compared to \$12.7 million for the nine months ended September 30, 2009. The increased product cost of sales associated with additional product sales was offset primarily by increased manufacturing absorption for the nine months ended September 30, 2010 as compared to the same period in 2009. The product gross margin of \$8.1 million for the nine months ended September 30, 2010 increased \$9.5 million compared to a loss of \$1.3 million for the same period in 2009, primarily due to increased revenue, better direct labor utilization, and increased manufacturing absorption. During the nine months ended September 30, 2010, we increased inventory levels to meet sales forecast requirements and in anticipation of a contract manufacturer that will relocate the production of certain hardware components to an alternate facility. The increase in our inventory levels resulted in additional absorption of manufacturing costs and a corresponding improvement in product gross margin.

Development grant and other revenues decreased \$1.4 million to \$6.4 million for the nine months ended September 30, 2010 compared to \$7.8 million for the nine months ended September 30, 2009. Development and other cost of sales decreased \$3.8 million to \$3.1 million for the nine months ended September 30, 2010 compared to \$6.9 million for the nine months ended September 30, 2009. The decrease in development grant and other revenues during the nine months ended September 30, 2010 was based on longer than expected development and regulatory review timelines under our collaboration arrangements with Edwards and Animas. The decrease in costs associated with development was primarily due to fewer development obligations during the quarter with respect to our collaboration arrangements.

***Research and Development.*** Research and development expense increased \$6.2 million to \$16.3 million for the nine months ended September 30, 2010, compared to \$10.1 million for the nine months ended September 30, 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. Increased research and development costs include \$3.2 million in additional salaries, bonus, and payroll related costs, \$794,000 in additional share-based compensation, and \$513,000 in additional facilities costs.

***Selling, General and Administrative.*** Selling, general and administrative expense increased \$4.7 million to \$30.5 million for the nine months ended September 30, 2010, compared to \$25.8 million for the nine months ended September 30, 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 \$3.1 million in additional salaries, bonus, and payroll related costs, \$368,000 in additional tradeshow expense and \$360,000 in additional depreciation expense.

***Interest Income.*** Interest income decreased \$250,000 to \$73,000 for the nine months ended September 30, 2010, compared to \$323,000 for the nine months ended September 30, 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 nine months ended September 30, 2010 as compared to the same period of 2009.

***Interest Expense.*** Interest expense decreased \$4.4 million to \$1.5 million for the nine months ended September 30, 2010, compared to \$5.9 million for the nine months ended September 30, 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, and lower coupon interest expense relating to lower principle notes outstanding as a result of the conversions of the notes that occurred during the nine months ended September 30, 2010.

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

For the nine months ended September 30, 2010, we completed exchanges with prior holders of our issued and outstanding Notes, under which we issued an aggregate of approximately 7.9 million shares of our common stock, par value \$0.001 per share, in exchange for \$60.0 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 \$8.5 million for the nine months ended September 30, 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 September 30, 2010, we had an accumulated deficit of \$336.6 million and had working capital of \$27.5 million. Our cash, cash equivalents and short-term marketable securities totaled \$29.9 million, excluding \$1.9 million in restricted cash. We have funded our operations primarily from the sale of equity and debt securities and our bank line. As of September 30, 2010 we had a total of \$750,000 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 decreased \$1.0 million to \$29.2 million for the nine months ended September 30, 2010, compared to \$30.2 million for the same period in 2009. The decrease in cash used in operating activities was due to \$7.0 million in additional non-cash charges primarily comprised of loss on the extinguishment of debt upon conversion of our Notes, offset by \$3.4 million in higher net loss and \$2.6 million in additional changes in operating assets and liabilities.

**Net Cash Used In Investing Activities.** Net cash used in investing activities was \$5.2 million for the nine months ended September 30, 2010, compared to \$20.6 million for the same period of 2009. The decrease in cash used in investing activities was primarily due to \$9.9 million decrease in cash used to purchase available-for-sale marketable securities and by \$7.6 million increase in proceeds from the maturities of short-term marketable securities for the nine months ended September 30, 2010 as compared to the same period in 2009. We invested \$4.5 million and \$2.5 million in equipment to support manufacturing improvements for the nine months ended September 30, 2010 and 2009, respectively.

**Net Cash Provided by Financing Activities.** Net cash provided by financing activities decreased \$8.1 million to \$36.4 million for the nine months ended September 30, 2010, compared to \$44.5 million for the same period of 2009. The decrease was primarily due to the \$33.0 million in net proceeds generated by the sale of common stock in the follow on public offering completed in January 2010 for the nine months ended September 30, 2010 compared to \$45.6 million in the same period of 2009.

### *Operating Capital and Capital Expenditure Requirements*

We anticipate that we will continue to incur net losses for the foreseeable future as we incur expenses to continue expand the commercialization of our approved products, develop additional continuous glucose monitoring products, and expand our marketing, manufacturing and corporate infrastructure.

We believe that our cash, cash equivalents, short-term marketable securities balances, and projected cash contributions from existing partnership arrangements will be sufficient to meet our anticipated cash requirements with respect to the continued scale-up of our commercialization activities, research and development activities, including clinical trials, the expansion of our marketing, manufacturing and corporate infrastructure, and to meet our other anticipated cash needs for at least the next twelve months. If our available cash, cash equivalents and short-term marketable securities are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain an additional credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. Additionally, there can be no assurance that we will be successful in obtaining additional cash contributions from future partnership arrangements. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the development of continuous glucose monitoring technologies, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including, but not limited to:

the revenue generated by sales of our approved products and other future products;

the expenses we incur in manufacturing, developing, selling and marketing our products;

the quality levels of our products and services;

the third party reimbursement of our products for our customers;

our ability to efficiently scale our manufacturing operations to meet demand for our current and any future products;

the costs, timing and risks of delays of additional regulatory approvals;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including, but not limited to, defending the patent infringement lawsuit filed against us by Abbott;

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

the success of our research and development efforts;

the emergence of competing or complementary technological developments;

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

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

***Contractual Obligations***

In April 2006, we entered into an office lease agreement for approximately 66,400 square feet of additional facilities located in San Diego, California. In connection with the lease, we entered into a \$664,000 letter of credit to secure future payments under the lease and paid a security deposit in the amount of \$89,640 in April 2006. In August 2010, we entered into a First Amendment to Office Lease (the Agreement) with respect to facilities in the buildings at 6340 Sequence Drive and 6310 Sequence Drive, each in San Diego, California (the Buildings). Under the Agreement, we have leased approximately 102,844 square feet of space in the Buildings, and retain the right and obligation to lease an additional 25,971 square feet in the Buildings. The lease term for the Buildings extends through November 2016 and we have a five-year option to renew the lease upon the expiration of the initial term. Excluding real estate taxes and operating costs, we are required to make total future monthly payments for all of our real estate obligations for the period from September 2010 through November 2016 totaling \$14.9 million.

We are party to various purchase arrangements related to components used in production and research and development activities. As of September 30, 2010, we had purchase commitments with certain vendors totaling approximately \$4.6 million due within one year. There are no purchase commitments due beyond one year.

***Off-Balance Sheet Arrangements***

We have not engaged in any off-balance sheet activities.

***Critical Accounting Policies and Estimates***

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we

believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our annual report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

***Revenue Recognition***

We sell durable systems and disposable units 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. Components are individually priced and can be purchased separately or together. The SEVEN PLUS durable system includes a transmitter, a receiver, a power cord, data management software and a USB cable. Disposable sensors for use with the SEVEN PLUS 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 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 the 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 a 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 the SEVEN PLUS durable system and a package of four disposable sensors may return the SEVEN PLUS durable system for any reason within thirty days of purchase and receive a full refund of their purchase price. At September 30, 2010, we maintained a reserve balance of \$37,000 relating to this program. 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. Our distributors typically have a limited time frame 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. We have no intention of refunding or unwinding a prior sale and view any potential product non-conformity solely as a warranty issue.

We shipped product directly to certain distributors' customers and recognized \$3.4 million and \$8.2 million in revenue, which represents 29% and 25% of our revenues for the three and nine months ended September 30, 2010, respectively. 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 \$1.2 million and \$3.0 million in revenue from these arrangements for the three and nine months ended September 30, 2010. We monitor shipments to, and on-hand inventory levels of, these distributors, and at September 30, 2010 these distributors had limited amounts of our product in their inventory.

During 2008, we entered into collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing our technologies. The terms of these agreements obligate us to multiple deliverables (for example, license rights, provision of research and development services, and manufacture of clinical materials) in exchange for our right to receive various forms of consideration including non-refundable license fees, funding of research and development activities, payments based upon achievement of development milestones and royalties in the form of a designated percentage of product sales or profits. With the exception of royalties, these types of consideration 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 and 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. We review the estimated period of our performance obligations on a periodic basis and update the recognition period as appropriate. 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 required 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.

During the first quarter of 2008, we entered into a development agreement with Animas, as amended on January 12, 2009 and July 30, 2009, which provided us with a development grant. During the fourth quarter of 2008, we entered into a collaboration agreement with Edwards, as amended on May 5, 2009, which provided us with a development grant. We recognized \$888,000 and \$6.4 million in development grant and other revenue for the three and nine months ended September 30, 2010, respectively. As of September 30, 2010, we had \$4.4 million in deferred revenue relating to our development and other agreements.

#### ***Share-Based Compensation***

We measure and recognize compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants including employee stock options, restricted stock, restricted stock units and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values. We utilize the Black-Scholes option-pricing model as our method of valuation for stock options granted and we use the grant date fair value of our common stock for valuing restricted stock unit awards. Share-based compensation expense recognized for the three and nine months ended September 30, 2010 was \$2.3 million and \$7.3 million, respectively, compared to \$2.1 million and \$6.2 million, respectively, for the three and nine months ended September 30, 2009. As of September 30, 2010, there was \$17.7 million of unrecognized compensation cost related to unvested options, restricted stock and restricted stock units that we expect to be recognized as a component of our operating expenses through 2014. Compensation costs will be adjusted for future changes in estimated forfeitures.

#### ***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.

### ***Income Taxes***

In July 2006, the Financial Accounting Standards Board ( FASB ) issued authoritative guidance for accounting for uncertainty in income taxes, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, the authoritative guidance provides detail on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. Only tax positions that meet the more likely than not recognition threshold at the effective date may be recognized upon adoption of the authoritative guidance.

### ***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 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 \$0 and \$26.6 million at September 30, 2010 and December 31, 2009, respectively. We recorded non-cash interest expense relating to the amortization of the debt discount in the amounts of \$51,000 and \$1.2 million for the three months ended September 30, 2010 and 2009, respectively, and \$1.1 million and \$3.6 million for the nine months ended September 30, 2010 and 2009, respectively. We recorded an interest expense adjustment relating to the contractual coupon payments in the amount of (\$20,000) for the three months ended September 30, 2010 and interest expense relating to the contractual coupon payments in the amount of \$713,000 for the three months ended September 30, 2009, and \$559,000 and \$2.1 million for the nine months ended September 30, 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. For the nine month period ended September 30, 2010, we applied non-convertible debt borrowing rates between 10.5% and 13.0% to the notes and coupon interest using a present value technique to determine the fair value of the liability components at conversion.

### ***Recent Accounting Pronouncements***

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 September 30, 2010. There would not have been a material difference in amounts recognized for development 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 reduces 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 September 30, 2010.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

#### ***Interest Rate Risk***

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including money market funds, U.S. Treasury debt and corporate debt securities. Due to the short-term nature of our investments, we believe that we have no material exposure to interest rate risk.

#### ***Foreign Currency Risk***

To date we have recorded no product sales in other than U.S. dollars. We have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### ***Evaluation of Disclosure Controls and Procedures***

Regulations under the Securities Exchange Act of 1934 require public companies to maintain disclosure controls and procedures, which are defined to mean a company's controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and timely communicated to management, including our Chief Executive Officer and Chief Financial Officer, recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures. Based on their evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective for this purpose.

***Changes in Internal Control Over Financial Reporting***

There were no changes in our internal control over financial reporting during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

***Limitation on Effectiveness of Controls***

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

## PART II OTHER INFORMATION

### ITEM 1. 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 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 filed appeal briefs in each of the cases. In response to those appeal briefs, each of the two examiners' answers maintained all rejections and Abbott has filed reply briefs in both cases and the Patent Office has heard Abbott's oral arguments. We also filed second and third reexamination requests 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 Patent Office has ordered reexamination for each of the two patents. For one of those patents, Abbott filed a petition to vacate the Reexamination Order, and we filed an opposition to Abbott's petition. The Patent Office has not issued any decision on Abbott's petition. With regard to the three patents subsequently asserted, all three have been issued one or more Certificates of Reexamination and subsequently re-entered the reexamination process. For one of the three patents, the Patent Office issued a Notice of Intent to Issue a Reexamination Certificate on September 2, 2010. For the second patent, Abbott submitted a response to a non-final Office Action on August 30, 2010. For the third patent, we submitted one reexamination request, which was ordered only for the originally issued claims by the Patent Office in March 2010, which is waiting for further action from the Patent Office. We submitted another reexamination request for that third patent. In response, the Patent Office ordered reexamination of certain, but not all, claims issued in the Reexamination Certificate in August 2010. We submitted a Petition to seek the director's review of the examiners' refusal to order reexamination of certain claims issued in the Reexamination Certificate. The Patent Office has not issued any decision on the petition yet.

In 2008, 2009 and 2010, 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. An oral hearing has been set for December 1, 2010 in one of the proceedings.

In 2010, Abbott filed reexamination requests seeking to invalidate an additional five of our patents in the Patent Office. All of the five reexamination requests have been granted and non-final rejections have been issued in two of the five requests.

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.

## **ITEM 1A. RISK FACTORS**

### **Factors that May Affect our Financial Condition and Results of Operations**

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

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 by patients age eighteen or older 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 first generation blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital, branded the GlucoClear, and are continuing to seek approval for this system from the FDA. In partnership with Edwards, we initiated a limited launch of 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.

We expect that sales of our SEVEN PLUS, which consists of a handheld receiver, reusable transmitter and disposable sensor, will account for substantially all of our product revenue for the foreseeable future. From inception through September 30, 2010, product revenues total approximately \$59.5 million. We have limited experience in selling our products and we might be unable to successfully commercialize our products on a wide scale for a number of reasons, including:

market acceptance of our products by physicians and patients will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use;

our FDA and other regulatory submissions may be delayed, or approved with limited product labeling;

we may not be able to manufacture our products in commercial quantities or at an acceptable cost;

patients do not generally receive broad reimbursement from third-party payors for their purchase of our products since many payors require that a patient meet specific medical criteria to qualify for reimbursement, which may reduce widespread use of our products;

the limited size of our sales force and our relative inexperience in marketing, selling and distributing our products;

we may not have adequate financial or other resources to successfully commercialize our products;

the uncertainties associated with establishing and qualifying new manufacturing facilities;

our SEVEN PLUS is not labeled as a replacement for the information that is obtained from single-point finger stick devices;

patients will need to incur the costs of our SEVEN PLUS in addition to single-point finger stick devices;

the introduction and market acceptance of competing products and technologies;

our inability to obtain sufficient quantities of supplies at appropriate quality levels from our sole source and other key suppliers;

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

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

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

**We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.**

We have incurred net losses in each year since our inception in May 1999, including a net loss of \$45.4 million for the nine months ended September 30, 2010. As of September 30, 2010, we had an accumulated deficit of \$336.6 million. We have financed our operations primarily through private placements of our equity and debt securities and our public offerings, and have devoted a substantial portion of our resources to research and development relating to our continuous glucose monitoring systems, including our in-hospital product development, and more recently, we have incurred significant sales and marketing and manufacturing expenses associated with the commercialization of the SEVEN PLUS. In addition, we expect our research and development expenses to increase in connection with our clinical trials and other development activities related to our products, including our next generation sensor and the GlucoClear. We also expect that our general and administrative expenses will continue to increase due to the additional operational and regulatory burdens applicable to public healthcare and medical device companies. As a result, we expect to continue to incur significant operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

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

Our operations and performance depend on worldwide economic conditions, which, since 2008, have deteriorated significantly in the United States and other countries, and may remain depressed or volatile for the foreseeable future. These conditions may make it difficult for our customers and potential customers to afford our products, and could cause our customers to stop using our products or to use them less

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frequently. If that were to occur, we would experience a decrease in revenue and our performance would be negatively impacted. We cannot predict the timing, strength or duration of any economic slowdown or subsequent economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse affect on our financial condition and operating results.



**We may require additional funding to continue the commercialization of our SEVEN PLUS or the development and commercialization of our next generation and other continuous glucose monitoring systems, including the blood-based in-vivo automated glucose monitoring system.**

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our products, including further development of our direct sales force and expansion of our manufacturing capacity, and on research and development, including conducting clinical trials for our blood-based in-vivo automated blood glucose monitoring system as well as our next generation continuous glucose monitoring sensors and systems. For the nine months ended September 30, 2010, our net cash used in operating activities was \$29.2 million, compared to \$30.2 million for the same period in 2009, and as of September 30, 2010, we had working capital of \$27.5 million comprised of \$31.8 million in cash, cash equivalents and short-term marketable securities, and includes \$1.9 million in restricted cash. We expect that our cash used by operations will increase significantly in each of the next several years, and, although we recently completed a follow-on public offering of 4,025,000 shares of our common stock for net proceeds to the company of approximately \$33.0 million, we may need additional funds to continue the commercialization of our products and for the development and commercialization of our next generation sensors and systems. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

the revenue generated by sales of our products and other future products;

the costs, timing and risks of delay of additional regulatory approvals;

the expenses we incur in manufacturing, developing, selling and marketing our products;

our ability to scale our manufacturing operations to meet demand for our current and any future products;

the costs to produce our continuous glucose monitoring systems;

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

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

the success of our research and development efforts;

the emergence of competing or complementary technological developments;

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

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

If adequate funds are not available, we may not be able to commercialize our products at the rate we desire and we may have to delay development or commercialization of our other products or license to third parties the rights to commercialize products or technologies that we

would otherwise seek to commercialize. We also may have to reduce sales, marketing, customer support or other resources devoted to our products. Any of these factors could harm our financial condition.

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

Comprehensive healthcare legislation, signed into law in March 2010, imposes stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, with which we may need to comply, and enhanced penalties for non-compliance with the new healthcare regulations. The U.S. government may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect reimbursement for healthcare products such as the SEVEN PLUS. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current U.S. Presidential administration or Congress.

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

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

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

billing for services;

financial relationships with physicians and other referral sources;

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

quality of medical equipment and services;

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

medical device reporting;

false claims;

professional licensure; and

labeling products.

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

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

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

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

To achieve commercial success for the SEVEN PLUS and our future products, we must continue to develop and grow our sales and marketing organization and enter into partnerships or other arrangements to market and sell our products. We currently employ a small direct sales force to market our products in the United States. In the United States, our sales force calls directly on healthcare providers and patients throughout the

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country to initiate sales of our products. Our sales organization competes with the experienced, larger and well-funded marketing and sales operations of our competitors. We have also entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. Our U.S. distribution partnerships are focused on accessing underrepresented regions and, in some instances, regional third-party payors that contract exclusively with distributors. Our European distribution partners call directly on healthcare providers to market and sell our products in Europe. Because of the competition for their services, we may be unable to partner with or retain additional qualified distributors. Further, we may not be able to enter into agreements with distributors on commercially reasonable terms, if at all.

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

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

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

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

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

manage geographically disbursed sales and marketing operations.

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

We have entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. To the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services in the United States or Europe, our product margins could be lower than if we directly marketed and sold our products. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we cannot predict whether these efforts will be successful. In addition, market acceptance of our products by physicians and patients in Europe will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use. If we are unable to do so, we may not be able to generate product revenue from our sales efforts in Europe. Finally, if we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate adequate product revenue and may not become profitable.

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

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

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

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

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

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

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

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

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

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

our products are technologically complex and it is difficult to develop alternative supply sources;

we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;

our suppliers may make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products;

we may have difficulty locating and qualifying alternative suppliers for our single-source supplies;

switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

our suppliers may encounter financial hardships unrelated to our demand for components, including those related to changes in global economic conditions, which could inhibit their ability to fulfill our orders and meet our requirements.

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

**If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support additional PMA or 510(k) applications, we may be unable to commercialize our continuous glucose monitoring systems under development, which could impair our financial position.**



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Our SEVEN PLUS systems are classified by the FDA as PMA medical devices. The GlucoClear has not yet been classified by the FDA. Before submitting any additional PMA or 510(k) applications we must successfully complete pre-clinical studies, bench-testing, and clinical trials that we believe will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the studies and trial may be inadequate to support approval of a PMA or 510(k) application and the FDA may request additional clinical data in support of those applications, which may result in significant additional clinical expenses and may delay product approvals. While we have in the past obtained, and may in the future obtain, an Investigational Device Exemption, or IDE, prior to commencing clinical trials for our continuous glucose monitoring systems, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial to be sufficient to support approval of a PMA or 510(k) application, even if the trial's intended safety and efficacy endpoints are achieved. Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations, including 510(k) submissions, by hiring new investigators and increasing the frequency and scope of its inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. Unexpected changes to the FDA or foreign regulatory approval processes could also delay or prevent the approval of our products submitted for review. The data drawn from our clinical trials may not be sufficient to support approval of our products or additional or expanded indications. Medical device stock prices have declined significantly in certain circumstances where companies have failed to meet expectations in regards to the timing of regulatory approval. If the FDA's response causes product approval delays, or is not favorable for any of our products, our stock price could decline substantially.

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

the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;

patients do not enroll in clinical trials at the rate we expect;

patients do not comply with trial protocols;

patient follow-up does not occur at the rate we expect;

patients experience adverse side effects;

patients die during a clinical trial, even though their death may not be related to our products;

institutional review boards, or IRBs, and third-party clinical investigators may delay or reject our trial protocol;

third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the investigator agreements, clinical trial protocol, good clinical practices or other FDA or IRB requirements;

the company or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;

third-party clinical investigators have significant financial interests related to the company or study that FDA deems to make the study results unreliable, or the company or investigators fail to disclose such interests;

regulatory inspections of our clinical trials or manufacturing facilities may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;

changes in governmental regulations, policies or administrative actions;

the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and

the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

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

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

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

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

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

Pursuant to the Collaboration Agreement entered into with Edwards, we are jointly developing the GlucoClear, a blood-based in-vivo automated glucose monitoring system. We are continuing to seek FDA approval for this device, and are working with Edwards on responding to the FDA's requests for additional data. We cannot predict when, if ever, the GlucoClear will obtain FDA approval. The regulatory approval process for this device, and any other continuous glucose monitoring system in development involves, among other things, successfully completing clinical trials and obtaining either prior 510(k) clearance or prior approval from the FDA through the PMA process. The 510(k) process would require us to establish (including through pre-clinical testing, bench testing, and/or potentially clinical data) that our blood-based in vivo automated glucose monitoring system (or any other devices we may seek to develop) are substantially equivalent in terms of indication, technological characteristics, and performance to one or more legally marketed devices eligible to be cited as predicates in the 510(k) process. The PMA process requires us to prove the safety and efficacy of our continuous blood glucose monitoring system to the FDA's satisfaction. This process can be expensive and uncertain, requires detailed and comprehensive scientific and human clinical data, generally takes one to three years after a PMA application is filed and may never result in the FDA granting a PMA. The FDA can refuse to grant us 510(k) clearance or delay, limit or deny approval of a PMA application for many reasons, including:

our systems may not be deemed by the FDA to be substantially equivalent to appropriate predicate devices;

our systems may not satisfy the FDA's safety or efficacy requirements;

the data from our pre-clinical studies and clinical trials may be insufficient to support approval;

the manufacturing process or facilities we use may not meet applicable requirements; and

changes in FDA approval policies or adoption of new regulations may require additional data.

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

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

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

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

Any product for which we obtain marketing approval will be subject to continual review and periodic inspections by the FDA and other regulatory bodies, which may include inspection of our manufacturing processes, post-approval clinical data and promotional activities for such

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product. The FDA's medical device reporting, or MDR, regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned and, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury. We and our suppliers are also required to comply with the FDA's Quality System Regulation, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, selection and oversight of suppliers or contractors, quality assurance, labeling, packaging, storage, complaint handling, shipping and servicing of our products. The FDA enforces the QSR through unannounced inspections. We currently manufacture our devices at our headquarters facility 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 investigator issued a Form 483 identifying several inspectional observations. Subsequent to the inspection, we also received a warning letter from the FDA requiring us to file medical device reports (MDRs) in accordance with the MDR regulations for complaints involving sensor wire fractures underneath a patient's skin. The warning letter also recommended that we add certain warnings and precautions statements to the labeling, patient education brochures, and our company website regarding the appropriate use of the SEVEN and SEVEN PLUS Systems, including that they are not approved for use in children under age 18, pregnant women, or persons on dialysis. In response to the warning letter and the Form 483 inspectional observations, we have taken corrective action to address the observations to achieve substantial compliance with the FDA regulatory requirements applicable to a commercial medical device manufacturer. In October 2010, we were subject to a follow-up site inspection by the FDA, and upon completion of that inspection, we were notified by the inspector that there were no 483 inspectional observations. We also received written notification dated November 1, 2010 from the FDA that we adequately addressed all issues cited in the warning letter.

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

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

warning letters or untitled letters that require corrective action;

fines and civil penalties;

unanticipated expenditures;

delays in approving or refusal to approve our continuous glucose monitoring systems;

FDA refusal to issue certificates to foreign governments needed to export our products for sale in other countries;

suspension or withdrawal of approval by the FDA or other regulatory bodies;

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

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

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

the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

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

On August 11, 2005, Abbott Diabetes Care, Inc., or Abbott, filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware, seeking a declaratory judgment that our 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 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. In response to those appeal briefs, each of the two examiner's answers maintained all rejections and Abbott has filed reply briefs in both cases, and the Patent Office has heard Abbott's oral arguments. We also filed second and third reexamination requests 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 Patent Office has ordered reexamination for each of the two patents. For one of those patents, Abbott filed a petition to vacate the Reexamination Order, and we filed an opposition to Abbott's petition. The Patent Office has not issued any decision on Abbott's petition. With regard to the three patents subsequently asserted, all three have been issued one or more Certificates of Reexamination and subsequently re-entered the reexamination process. For one of the three patents, the Patent Office issued a Notice of Intent to Issue a Reexamination Certificate on September 2, 2010. For the second patent, Abbott submitted a response to a non-final Office Action on August 30, 2010. For the third patent, we submitted one Reexamination Request, which was ordered only for the originally issued claims by the Patent Office in March 2010, which is waiting for further action from the Patent Office. We submitted another reexamination request for that third patent. In response, the Patent Office ordered reexamination of certain, but not all, claims issued in the Reexamination Certificate in August 2010. We submitted a petition to seek the director's review of the examiners' refusal to order reexamination of certain claims issued in the Reexamination Certificate. The Patent Office has not issued any decision on the petition yet.

In 2008, 2009 and 2010, 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. An oral hearing has been set for December 1, 2010 in one of the proceedings.

In 2010, Abbott filed reexamination requests seeking to invalidate an additional five of our patents in the Patent Office. All of the five reexamination requests have been granted and non-final rejections have been issued in two of the five requests.

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. No assurances can be given that we will prevail in the lawsuit or that we can successfully defend ourselves against the claims made by Abbott, and we expect to incur significant costs in defending the action, which could have a material adverse effect on our business and our results of operations regardless of the final outcome of such litigation. Subject to the stay, Abbott could immediately seek a preliminary injunction that, if granted, would force us to stop making, using, selling or offering to sell our products. Our SEVEN PLUS is our only current ambulatory product that is approved for commercial sale, and if we were forced to stop selling it or our blood-based in-vivo automated glucose monitoring system for in-hospital use, our business and prospects would suffer. We cannot assure you that Abbott will not file for a preliminary injunction, that we would be successful in defending against such an action if filed or that we can successfully defend ourselves against the claim. In addition, defending against this action could have a number of harmful effects on our business, including those discussed in the following risk factor, regardless of the final outcome of such litigation.

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



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

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

Any infringement or misappropriation claim, including the claim brought by Abbott, could cause us to incur significant costs, could place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign our products to avoid infringement. Even if we are able to redesign our products to avoid an infringement claim, we may not receive FDA approval for such changes in a timely manner or at all. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling or offering to sell one or more of our products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

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

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

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

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

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

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

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

significantly greater name recognition;

established relations with healthcare professionals, customers and third-party payors;

established distribution networks;

additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products; and

greater financial and human resources for product development, sales and marketing, and patent litigation.

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

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

On November 10, 2008, we entered into a Collaboration Agreement with Edwards pursuant to which we have agreed to develop jointly and to market a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital. Under the Collaboration Agreement, we expect to receive payments for various milestones related to regulatory approvals and commercial readiness of the product. In addition, we also expect to receive either a profit-sharing payment of 10% of commercial sales of the product, or a royalty of 6% of commercial sales of the product. The Collaboration Agreement provides Edwards with an exclusive license to our intellectual property that relates to blood-based glucose sensors in the critical care sector of the hospital market. However, this collaboration may not result in the development of products that achieve regulatory approval in the United States or commercial success, which would result in various penalties to us under the Collaboration Agreement, up to and including delay or loss of some or all of our milestone payments and rights to any profit-sharing or royalties. On October 30, 2009, we received CE Mark approval for the first generation GlucoClear that we developed in collaboration with Edwards. Although Edwards commenced market evaluations during 2009, we do not expect this product to generate significant revenue during 2010. We are continuing to seek approval from the FDA for this product, and are working with Edwards on responding to the FDA's requests for additional data. We cannot predict when, if ever, the GlucoClear will obtain FDA approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

We take precautions to safeguard our facilities, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

**We may be liable for contamination or other harm caused by materials that we handle, and changes in environmental regulations could cause us to incur additional expense.**

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

**Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.**

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

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

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

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

**We have incurred and will incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.**

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission, or SEC, will result in increased costs to us as we evaluate the implications of any new rules and regulations and respond to new requirements under such rules and regulations. We are required to comply with many of these rules and regulations, and will be required to comply with additional rules and regulations in the future. Furthermore, on July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. While this new law is primarily focused on bank reform and consumer protection, it also makes significant changes to corporate governance and executive compensation rules for public companies across all industries. As an early commercialization stage company with limited capital and human resources, we will need to divert management's time and attention away from our business in order to ensure compliance with these regulatory requirements. This diversion of management's time and attention may have a material adverse effect on our business, financial condition and results of operations.

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

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

For instance, estimating the fair value of share-based payments is highly dependent on assumptions regarding the future exercise behavior of our employees and changes in our stock price. Our share-based payments have characteristics significantly different from those of freely traded options, and changes to the subjective input assumptions of our share-based payment valuation models can materially change our estimates of the fair values of our share-based payments. In addition, the actual values realized upon the exercise, expiration, early termination or forfeiture of share-based payments might be significantly different than our estimates of the fair values of those awards as determined at the date of grant. Moreover, we rely on third parties that supply us with information or help us perform certain calculations that we employ to estimate the fair value of share-based payments. If any of these parties do not perform as expected or make errors, we may inaccurately calculate actual or estimated compensation expense for share-based payments.

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



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

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

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. The method in which we market and sell our products may have an impact on the manner in which we recognize revenue. In addition, changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, as a result of changes approved by the Financial Accounting Standards Board, or FASB, on January 1, 2006 we began recording compensation expense in our statements of operations for equity compensation instruments, including employee stock options, using the fair value method. Our reported financial results beginning for the first quarter of 2006 and for all foreseeable future periods will be negatively and materially impacted by this accounting change. Other potential changes in existing taxation rules related to stock options and other forms of equity compensation could also have a significant negative effect on our reported results.

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

In March 2006, we entered into our Loan Agreement that provided for a loan to finance various equipment and leasehold improvement expenses. In January 2008, we amended our Loan Agreement to enable us to draw an additional \$3.0 million. We are required to repay this additional amount at intervals through July 2011. As of September 30, 2010, we had a total outstanding loan balance under the Loan Agreement of \$750,000. The Loan Agreement requires us to maintain a minimum cash balance with Square 1 Bank, and also imposes certain limitations on us, including, among others, limitations on our ability to:

transfer all or any part of our businesses or properties, other than transfers done in the ordinary course of business;

engage in any business other than the businesses in which we are currently engaged;

relocate our chief executive offices or state of incorporation;

change our legal name or fiscal year;

replace our chief executive officer or chief financial officer;

merge or consolidate with or into any other business organizations, with certain exceptions;

permit any person to beneficially own a sufficient number of shares entitling such person to elect a majority of our board of directors;

incur additional indebtedness, with certain exceptions;

incur liens with respect to any of our properties, with certain exceptions;



store any equipment or inventory in which the lender has any interest with any bailee, warehousemen or similar third party unless the third party has been notified of the lender's security interest, or  
Complying with these covenants may make it more difficult for us to successfully execute our business strategy and compete against companies who are not subject to such restrictions.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

*Unregistered Sales of Equity Securities*

Not applicable.

*Use of Proceeds*

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. (REMOVED AND RESERVED)**

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

The following exhibits are filed as a part of this report.

Exhibit Number	Exhibit Description	Incorporated by Reference			Provided Herewith
		Form	File No.	Date of First Filing	
10.27	First Amendment to Office Lease between DexCom, Inc. and Kilroy Realty, L.P., dated August 18, 2010.				X
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).				X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).				X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*				X
32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*				X

\* This certification is not deemed filed for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that DexCom specifically incorporates it by reference.

**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 thereunto duly authorized.

DEXCOM, INC.  
(Registrant)

Dated: November 4, 2010

By:

/s/ TERRANCE H. GREGG  
**Terrance H. Gregg,**  
**President and Chief Executive Officer**

Dated: November 4, 2010

By:

/s/ JESS ROPER  
**Jess Roper,**  
**Chief Financial Officer**