

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
Assets		
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
Total current assets	44,488	36,920
Property and equipment, net	9,240	6,422
Restricted cash	275	2,414
Other assets	102	1,192
Total assets	\$ 54,105	\$ 46,948
Liabilities and stockholders' equity		
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
Total current liabilities	17,008	18,796
Long-term portion of deferred revenue	881	
Other liabilities	972	840
Long-term debt, net of current portion		45,757
Total liabilities	18,861	65,393
Commitments and contingencies (Note 4)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 5,000 shares authorized; no shares issued and outstanding at 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)
Total stockholders' equity (deficit)	35,244	(18,445)
Total liabilities and stockholders' equity (deficit)	\$ 54,105	\$ 46,948

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
Total revenue	11,664	7,259	32,995	19,222
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
Total cost of sales	8,188	6,394	21,541	19,668
Gross margin (deficit)	3,476	865	11,454	(446)
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
Total operating expenses	16,538	12,444	46,858	35,925
Operating loss	(13,062)	(11,579)	(35,404)	(36,371)
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)	
Net loss	\$ (13,398)	\$ (13,523)	\$ (45,358)	\$ (41,995)
Basic and diluted net loss per share	\$ (0.23)	\$ (0.29)	\$ (0.81)	\$ (0.96)
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
Operating activities		
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)
Investing activities		
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)
Financing activities		
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
Non-cash investing and financing transactions:		
Conversion of convertible notes to common stock	\$ 47,033	\$

See accompanying notes

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

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

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
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)
Net carrying amount of convertible notes	\$	\$ 45,232

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
Total	\$ 24,442	\$ 8	\$ (11)	\$ 24,439

Inventory

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

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):

Fiscal Year Ending	
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:

Period	Annual Rent Amount
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.

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 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, 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.

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