DEXCOM INC
Form 10-Q
November 02, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2011

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 000-51222

DEXCOM, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0857544**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

6340 Sequence Drive

San Diego, California	**92121**
(Address of Principal Executive Offices)	**(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 x 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 x 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 x
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 x

As of October 28, 2011, 67,510,344 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)

	September 30, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 17,523	$ 4,889
Short-term marketable securities, available-for-sale	79,794	42,224
Accounts receivable, net	9,003	6,671
Inventory	6,455	8,112
Restricted cash	0	775
Prepaid and other current assets	2,457	2,690
Total current assets	115,232	65,361
Property and equipment, net	12,524	10,763
Restricted cash	939	939
Other assets	98	101
Total assets	$ 128,793	$ 77,164
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 6,045	$ 5,350
Accrued payroll and related expenses	6,961	5,730
Current portion of long-term debt	0	525
Current portion of deferred revenue	1,737	3,524
Total current liabilities	14,743	15,129
Other liabilities	985	1,042
Total liabilities	15,728	16,171
Commitments and contingencies (Note 4)		
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; no shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	0	0
Common stock, $0.001 par value, 100,000 authorized; 67,783 and 67,500 issued and outstanding, respectively, at September 30, 2011; and 62,360 and 62,078 shares issued and outstanding, respectively, at December 31, 2010	68	62
Additional paid-in capital	491,964	407,375
Accumulated other comprehensive loss	(94)	(66)
Accumulated deficit	(378,873)	(346,378)
Total stockholders equity	113,065	60,993
Total liabilities and stockholders equity	$ 128,793	$ 77,164

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,	
	2011	**2010**	**2011**	**2010**
Product revenue	$ 16,656	$ 10,776	$ 44,974	$ 26,583
Development grant and other revenue	1,598	888	8,871	6,412
Total revenue	18,254	11,664	53,845	32,995
Product cost of sales	9,230	6,982	25,933	18,440
Development and other cost of sales	860	1,206	2,761	3,101
Total cost of sales	10,090	8,188	28,694	21,541
Gross profit	8,164	3,476	25,151	11,454
Operating expenses				
Research and development	8,231	6,161	21,515	16,325
Selling, general and administrative	13,241	10,377	36,203	30,533
Total operating expenses	21,472	16,538	57,718	46,858
Operating loss	(13,308)	(13,062)	(32,567)	(35,404)
Interest income	31	20	82	73
Interest expense	(1)	(44)	(10)	(1,540)
Loss on debt extinguishment upon conversion of convertible debt	0	(312)	0	(8,487)
Net loss	$ (13,278)	$ (13,398)	$ (32,495)	$ (45,358)
Basic and diluted net loss per share	$ (0.20)	$ (0.23)	$ (0.50)	$ (0.81)
Shares used to compute basic and diluted net loss per share	67,397	58,200	64,910	55,707

See accompanying notes

DexCom, Inc.

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
Operating activities		
Net loss	$ (32,495)	$ (45,358)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	2,696	1,716
Share-based compensation	9,933	7,363
Accretion and amortization related to investments, net	610	572
Accretion of non-cash interest expense related to convertible notes	0	1,059
Loss on debt extinguishment upon conversion of convertible debt	0	8,487
Amortization of debt issuance costs	0	36
Changes in operating assets and liabilities:		
Accounts receivable	(2,332)	(1,612)
Inventory	1,657	(3,712)
Prepaid and other assets	518	2,421
Restricted cash	775	475
Accounts payable and accrued liabilities	695	1,296
Accrued payroll and related expenses	1,231	1,217
Deferred revenue	(1,787)	(3,304)
Deferred rent and other liabilities	(57)	132
Net cash used in operating activities	(18,556)	(29,212)
Investing activities		
Purchase of available-for-sale marketable securities	(78,044)	(43,688)
Proceeds from the maturity of available-for-sale marketable securities	39,576	43,041
Purchase of property and equipment	(4,457)	(4,534)
Net cash used in investing activities	(42,925)	(5,181)
Financing activities		
Net proceeds from issuance of common stock	74,662	37,061
Repayment of equipment loan	(525)	(675)
Net cash provided by financing activities	74,137	36,386
Effect of exchange rate changes on cash and cash equivalents	(22)	(41)
Increase in cash and cash equivalents	12,634	1,952
Cash and cash equivalents, beginning of period	4,889	3,577
Cash and cash equivalents, end of period	$ 17,523	$ 5,529
Non-cash investing and financing transactions:		
Conversion of convertible notes to common stock	$ 0	$ 47,033

See accompanying notes

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DexCom, Inc.

Notes to Consolidated Financial Statements

(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Organization and Business

DexCom, Inc. is a medical device company focused on the design, development and commercialization of continuous glucose monitoring (CGM) 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.

Basis of Presentation

We have incurred operating losses since our inception and have an accumulated deficit of $378.9 million at September 30, 2011. As of September 30, 2011, we had available cash, cash equivalents and short-term investments totaling $97.3 million, excluding $0.9 million of restricted cash, and working capital of $100.5 million. Our ability to transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. If events or circumstances occur such that we do not meet our operating plan as expected, we may be required to reduce planned increases in compensation related expenses or other operating expenses which could have an adverse impact on our ability to achieve our intended business objectives. We believe our working capital resources will be sufficient to fund our operations through at least September 30, 2012.

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, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2010 included in the Annual Report on Form 10-K filed by us with the Securities and Exchange Commission on March 3, 2011.

Reclassification

Restricted cash in the amount of $0.7 million as of December 31, 2010 has been reclassified from short-term restricted cash to long-term restricted cash to conform to current year presentation. This reclassification had no impact on our Consolidated Statements of Operations, Consolidated Statements of Stockholders Equity or Consolidated Statements of Cash Flows.

Principles of Consolidation

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

Segment Reporting

An operating segment is identified as a component of a business that has discrete financial information available, and one that the chief operating decision maker must decide the level of resource allocation directed to the segment. In addition, the guidance for segment reporting indicates certain quantitative thresholds. We consider our operations to be, and manage our business as, one operating segment.

Use of Estimates

The preparation of consolidated financial statements in conformity with 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, 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 2011 bonus plan s authorized target bonus amounts of up to 100%, 90%, 75%, 45%, 35% and 30% of base salary for our Chief Executive Officer, our President, for each of our Chief Operating Officer and Chief Technical Officer, our Senior Vice Presidents, our Vice Presidents and the remainder of our non-sales management employees, respectively, to be awarded from the bonus pool based on the weighted average achievement of certain objectives. For our eligible employees, generally, 60% of any bonus

paid under the 2011 Plan is based on achieving certain annual revenue goals, 20% is based on achieving targeted operating loss goals and 20% is based on achieving certain performance milestones. Clinical trial expenses are accrued based on estimates of progress under related contracts and include initial set up costs as well as ongoing monitoring over multiple sites in the U.S. and abroad. An allowance for refunds for returned products is determined by analyzing the timing and amounts of past refund activity.

Share-Based Compensation

We recorded $3.7 million and $2.3 million in share-based compensation expense during the three months ended September 30, 2011 and 2010, respectively, and $9.9 million and $7.3 million during the nine months ended September 30, 2011 and 2010, respectively. At September 30, 2011, unrecognized estimated compensation costs related to unvested stock options, restricted stock and restricted stock units totaled $29.4 million and are expected to be recognized through 2015. We utilize the Black-Scholes option-pricing model as the method of valuation for share-based awards 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, Israel and in portions of Europe. Components are individually priced and can be purchased separately or together. We receive payment directly from patients who use our products, as well as from distributors and third-party payors. Our 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 durable system price is not dependent upon the purchase of any amount of disposable sensors.

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 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.

We have entered into a distribution agreement with RGH Enterprises, Inc., or Edgepark, as amended on March 29, 2011, as well as agreements with 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 $3.0 million and $10.6 million in revenue, which represents 17% and 20% of our total revenues for the three and nine months ended September 30, 2011, respectively, compared to $3.4 million and $8.2 million in revenue, which represented 29% and 25% of our total revenues for same periods in 2010. With respect to other distributors which stock inventory of our product and fulfill orders from their inventory, we shipped product to these distributors and recognized $5.3 million and $11.7 million in revenue from these arrangements, which represents 29% and 22% of our total revenues for the three and nine months ended September 30, 2011, respectively, compared to $1.2 million and $3.0 million in revenue from these arrangements, which represented 10% and 9% of our total revenues for the same periods in 2010. We monitor shipments to, and on-hand inventory levels of, these distributors, and at September 30, 2011 these distributors had limited amounts of our product in their inventory.

We have collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing our technologies. The terms of these agreements typically include multiple deliverables by us

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(for example, license rights, provision of research and development services and manufacture of clinical materials) in exchange for consideration to us of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development milestones and royalties in the form of a designated percentage of product sales or profits. With the exception of royalties, these types of consideration are classified as development grant and other revenue in our consolidated statements of operations and are generally recognized over the service period except for substantive milestone payments, which are generally recognized when the milestone is achieved.

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 after January 1, 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.

For transactions containing multiple element arrangements entered into prior to January 1, 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.

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, are 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.

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Comprehensive Loss

We report all components of comprehensive loss, including net loss, in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and other comprehensive 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 loss. Our comprehensive loss is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	($ 13,278)	($ 13,398)	($ 32,495)	($ 45,358)
Unrealized gain (loss) on short-term available-for-sale marketable securities	(12)	9	(6)	15
Foreign currency translation gain (loss)	19	(43)	(22)	(41)
Comprehensive loss	($ 13,271)	($ 13,432)	($ 32,523)	($ 45,384)

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, 2010, we had federal and state tax net operating loss carryforwards of approximately $237.6 million and $169.4 million, respectively. The federal and state tax loss carryforwards will begin to expire in 2019 and 2013, respectively, unless previously utilized. We also had federal and state research and development tax credit carryforwards of approximately $3.1 million and $5.6 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. This limitation will likely result in the expiration prior to use of approximately $2.1 million of U.S. income tax credits and approximately $9.2 million of state net operating loss carryforwards. The related deferred tax assets have been removed from the components of our deferred tax assets. The tax benefits related to the remaining federal and state net operating losses and tax credit carryforwards may be further limited or lost if future cumulative changes in ownership exceed 50% within any three-year period.

Fair Value Measurements

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

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

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

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

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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, 2011 (in thousands):

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 15,382	0	0	$ 15,382
Marketable securities, available for sale				
U.S. government agencies	$ 60,163	0	0	$ 60,163
Commercial paper	$ 6,494	0	0	$ 6,494
Corporate debt	$ 13,137	0	0	$ 13,137
Total marketable securities, available for sale	$ 79,794			$ 79,794
Restricted cash	$ 939	0	0	$ 939

We have maintained only Level 1 financial assets during the three and nine months ended September 30, 2011.

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.

Recent Accounting Guidance

In April 2010, the FASB reached a consensus on the Milestone Method of Revenue Recognition which provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The updated guidance is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. We adopted the provisions of the guidance as of January 1, 2011 on a prospective basis. The prospective application had no impact on our consolidated financial statements for the nine months ended September 30, 2011.

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,	
	2011	2010	2011	2010
Options outstanding to purchase common stock	7,852	8,385	7,852	8,385
Unvested restricted stock and restricted stock units	1,896	520	1,896	520
Total	9,748	8,905	9,748	8,905

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, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
U.S. government agencies	$ 60,165	$ 6	$ (8)	$ 60,163
Commercial paper	6,495	0	(1)	6,494
Corporate debt	13,149	1	(13)	13,137
Total	$ 79,809	$ 7	$ (22)	$ 79,794

	December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Market Value
U.S. government agencies	$ 32,231	$ 2	$ (10)	$ 32,223
Commercial paper	4,996	0	0	4,996
Corporate debt	5,006	1	(2)	5,005
Total	$ 42,233	$ 3	$ (12)	$ 42,224

Inventory

	September 30, 2011	December 31, 2010
Raw materials	$ 3,139	$ 5,041
Work-in-process	1,420	575
Finished goods	1,896	2,496
Total	$ 6,455	$ 8,112

Accounts Payable and Accrued Liabilities

	September 30, 2011	December 31, 2010
Accounts payable trade	$ 2,652	$ 1,758
Accrued tax, audit, and legal fees	899	783
Clinical trials	279	134
Accrued other including warranty	2,215	2,675
Total	$ 6,045	$ 5,350

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Accrued Warranty

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Beginning balance	$ 446	$ 429	$ 435	$ 129
Charges to costs and expenses	392	460	1,375	1,733
Costs incurred	(454)	(455)	(1,426)	(1,428)
Ending balance	$ 384	$ 434	$ 384	$ 434

4. Commitments and Contingencies

Leases

In April 2006, we entered into an office lease agreement for facilities located in San Diego, California. In August 2010, we entered into a First Amendment to Office Lease (the Lease Amendment) with respect to facilities in the buildings at 6340 Sequence Drive and 6310 Sequence Drive, each in San Diego, California (the Buildings). Under the Lease Amendment, we have leased additional space in the Buildings, and retain the right and obligation to lease additional space 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. These facility leases have annual rental increases ranging from approximately 2.5% to 4.0%. The difference between the straight-line expense over the term of the lease and actual amounts paid are recorded as deferred rent. In September 2008, our subsidiary in Sweden entered into a three year lease for a small shared office space, which was renewed for a three year term and has a quarterly adjustment clause for rent to increase or decrease in proportion to changes in consumer prices. Rental obligations, excluding real estate taxes, operating costs, and tenant improvement allowances, under all lease agreements as of September 30, 2011 were as follows (in thousands):

Fiscal Year Ending	
Remainder of 2011	$ 486
2012	2,121
2013	2,507
2014	2,591
2015	2,665
Thereafter	2,511
Total	$ 12,881

Total rent expense for the three and nine months ended September 30, 2011 was $0.6 million and $2.0 million, respectively, compared to $0.5 million and $1.4 million, respectively, for the same periods of 2010.

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.

In connection with this litigation five of Abbott s seven patents that are the subject of the litigation 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, canceling claims and/or seeking to add new claims. Regarding the remaining two patents, Abbott has appealed the decisions of final rejection to the Federal Circuit, the cases have been consolidated and their Brief has recently been filed.

In addition, since 2008, Abbott has copied claims from certain of our applications, and stated that it may seek to provoke an interference with certain of our pending applications in the Patent Office. If interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also since 2008, Abbott has filed 30 reexamination requests seeking to invalidate 29 of our patents. Fifteen of the 30 reexamination requests are in various stages at the Patent Office, and 15 have been issued a Certificate of Reexamination. We have filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented in the reexaminations, seeking to amend certain claims to overcome the prior art presented in the reexaminations, canceling claims and/or seeking to add new claims. It is possible that the Patent Office may determine that some or all of the claims of our patents subject to the reexamination are invalid. Additionally, Abbott has filed an Opposition to three of our European patents.

Although it is our position that Abbott s assertions of infringement have no merit, and that the potential interference, reexamination requests and oppositions have no merit, neither the outcome of the litigation nor the amount and range of potential fees associated with the litigation, potential interference, reexamination requests or oppositions can be assessed, and as of September 30, 2011, no amounts have been accrued.

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 manufacturing and development activities including materials used in our glucose monitoring systems. As of September 30, 2011, we had purchase commitments with vendors totaling $14.1 million due within one year. There are no material 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, we entered into a joint development agreement with Animas Corporation (Animas), as amended on January 12, 2009, July 30, 2009 and June 7, 2011 (the Animas Amendments) to integrate our continuous glucose monitoring technology into Animas insulin pumps. Under the terms of the amended agreement, Animas will contribute up to $1.1 million to DexCom to offset certain development, clinical and regulatory expenses. The agreement is non-exclusive in the United States, but exclusive outside the United States and does not impact either party s existing third-party development agreements. In January of 2008 we received $0.5 million from Animas to offset development and other expenses. In January of 2009 we received an additional $0.3 million. We recorded $25,000 and $0.1 million in development grant and other revenue during the three and nine months ended September 30, 2011, respectively, compared to $25,000 and $0.2 million during the same periods in 2010, respectively, related to consideration previously received for development efforts. 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 were 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, which was earned in December 2010, and we received this $1.0 million milestone payment in January 2011. We were also entitled to receive an additional one-time $4.0 million milestone payment and a $0.3 million development payment upon the first regulatory body approval outside the United States for the new system, which was earned in May 2011. We received the $4.0 million milestone payment in June 2011.

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 Lifesciences LLC (Edwards). Pursuant to the Collaboration Agreement, we and Edwards agreed to

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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 and manufacturing readiness. We will also receive either a profit-sharing payment of up to 10% on the product s gross profits, 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 an additional $10.0 million during 2009 and 2010. We recorded $0.6 million and $1.7 million in development grant and other revenue related to consideration previously received for development efforts for the three and nine months ended September 30, 2011, respectively, compared to $0.9 million and $6.0 million for the same periods in 2010, respectively.

Each of the milestones related to the Collaboration Agreement is considered to be substantive. In determining whether each milestone is substantive, we considered whether the consideration earned by achieving the milestone should (i) be commensurate with either (a) our performance to achieve the milestone or (b) the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) relate solely to past performance and (iii) be reasonable relative to all deliverables and payment terms in the arrangement. We did not recognize any consideration for milestones related to the Collaboration Agreement for the three and nine months ended September 30, 2011.

6. Stockholder s Equity

Follow-on Stock Offering

In May 2011, we completed a follow-on public stock offering of 4,700,000 shares of our common stock for net proceeds of approximately $70.9 million.

7. Subsequent Events

On November 1, 2011, we entered into a non-exclusive Research and Development Agreement (the Agreement) with Roche Diagnostics Operations, Inc. (Roche) to integrate a future generation of our continuous glucose monitoring technology with Roche s next generation Accu-Chek® insulin delivery system in the United States. Under the terms of the Agreement, we are entitled to receive up to $1.0 million to offset certain development, clinical and regulatory expenses. We are also entitled to receive an initial milestone payment of $0.5 million as a result of the execution of the Agreement, and up to an additional $2.5 million upon the achievement of certain milestones as set forth in the Agreement.

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

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

Overview

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

Ambulatory Product Line: SEVEN® PLUS

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

In-Hospital Product Line: GlucoClear®

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 (Conformité Européene) approval for our first generation blood-based in-vivo automated glucose monitoring system in Europe, which we have branded the GlucoClear, for use by healthcare providers in the hospital, and will seek approval for future GlucoClear products from the FDA. In partnership with Edwards, we initiated a very limited launch of the GlucoClear system in Europe in 2009.

Background

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, and the Centers for Disease Control, or CDC, estimates that diabetes affects 25.8 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 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 as a result of diabetes.

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 estimated 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 were meeting ADA standards for glucose control (A1c), and only 37% of people with diabetes were 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 patients with diabetes 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

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Summary Report from August 2011 estimated that our share of the continuous glucose monitoring system market in the United States was at 56%. The report analyzed responses from 414 panel members who were asked what brand and model of continuous glucose monitoring system they used.

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. In March 2011, we completed a modest increase in the size of our sales organization. We believe our direct, highly-specialized and focused sales organization is sufficient for us to support our sales efforts.

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, a subsidiary of Johnson & Johnson, and one with Insulet, and in November 2011, we entered into a development agreement with Roche 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. The Animas insulin pump product augmented with our sensor technology has been branded the Vibe®, and received CE Mark approval in May 2011, which allows Animas to market the Vibe in the countries that recognize CE Mark approvals. In addition, we are continuing to seek approval for our next generation ambulatory system, and, in response to requests from the FDA, are preparing to commence additional clinical trials in support of that application. We expect our next 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 during pregnancy) for our product platform in the future. Further, as described above, we are developing in collaboration with Edwards the GlucoClear, which is 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 services, or CMS, in 2008 released 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 due to 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 2011, the seven largest private third-party payors, in terms of the number of covered lives, have issued policies for the category of continuous glucose monitoring devices allowing for coverage of these devices if certain conditions are met. In addition, we have negotiated contracted rates with six of those third-party payors for the purchase of our SEVEN PLUS system by their members. Many of these coverage policies are restrictive in nature and require the patient to comply with extensive 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 throughout 2011. 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 next generation sensor platform using advanced manufacturing processes that are more scalable and reliable and that produce sensors which are more accurate and durable. 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. These facilities have more than 8,000 square feet of laboratory space and approximately 12,000 square feet of controlled environment rooms. In February 2010, our facility was subject to a post-approval inspection by the FDA. After the close of the inspection, the FDA investigator issued a Form 483 identifying several inspectional observations. Subsequent to the inspection, we also received a warning letter from the FDA requiring us to file medical device reports, or (MDRs), in accordance with the MDR regulations for complaints involving sensor wire fractures underneath a patient s skin. The warning letter also recommended that we add certain warnings and precautions statements to the labeling, patient education brochures, and our company website regarding the appropriate use of the SEVEN PLUS system, including that they are not approved for use in children under age 18, pregnant women, or persons on dialysis. In response to the warning letter and the Form 483 inspectional observations, we have taken corrective action to address the observations to achieve substantial compliance with the FDA regulatory requirements applicable to a commercial medical device manufacturer. In October 2010, we were subject to a follow-up site inspection by the FDA, and upon completion of that inspection, we were notified by the inspector that there were no 483 inspectional observations. We also received written notification dated November 1, 2010 from the FDA that we adequately addressed all issues cited in the warning letter.

There are technical challenges to increasing manufacturing capacity, including equipment design and automation, material procurement, problems with production yields, and quality control and assurance. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts, however there can be no assurances that supply will not be constrained going forward. Additionally, the production of our continuous glucose monitoring systems must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Developing commercial-scale manufacturing facilities has and will continue to require the investment of substantial additional funds and the hiring and retaining of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. Manufacturing is subject to numerous risks and uncertainties described in detail in Risk Factors below.

We manufacture our SEVEN PLUS with components supplied by outside vendors and with parts manufactured by us internally. Key components that we manufacture internally include our wire-based sensors for our SEVEN PLUS. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished SEVEN PLUS systems, which includes a reusable transmitter, a receiver, and disposable sensors.

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

From inception through September 30, 2011, we had generated $148.8 million of product and development grant and services (non-product) revenue, and we have incurred net losses in each year since our inception in May 1999. From inception through September 30, 2011, we had an accumulated deficit of $378.9 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 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. In November 2010, we completed a follow-on public offering of 3,277,500 shares of our common stock for net proceeds of approximately $33.0 million. In May 2011, we completed a follow-on public offering of 4,700,000 shares of our common stock for net proceeds of approximately $70.9 million.

Financial Operations

Revenue

From inception through September 30, 2011, we generated $118.1 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, 2011, we recognized $30.7 million in development grant and other revenue, which includes milestones and services.

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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 control, 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, quality assurance programs, 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, 2011 Compared to September 30, 2010

Revenue, Cost of Sales and Gross Profit

Product revenue increased $5.9 million to $16.7 million for the three months ended September 30, 2011, compared to $10.8 million for the three months ended September 30, 2010 based primarily on increased sales volume of our durable systems and disposable sensors, and higher average per unit selling prices. Product cost of sales increased $2.2 million to $9.2 million for the three months ended September 30, 2011, compared to $7.0 million for the three months ended September 30, 2010. The product gross profit of $7.4 million for the three months ended September 30, 2011 increased $3.6 million compared to $3.8 million for the same period in 2010, primarily due to increased revenue and increased manufacturing absorption.

Development grant and other revenues increased $0.7 million to $1.6 million for the three months ended September 30, 2011, compared to $0.9 million for the three months ended September 30, 2010. Development and other cost of sales decreased $0.3 million to $0.9 million for the three months ended September 30, 2011, compared to $1.2 million for the three months ended September 30, 2010. The increase in development grant and other revenues during the three months ended September 30, 2011 was primarily due to additional services performed, and partially offset by extended revenue recognition timelines related to 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 period with respect to our collaboration arrangements.

Research and Development. Research and development expense increased $2.1 million to $8.2 million for the three months ended September 30, 2011, compared to $6.2 million for the three months ended September 30, 2010. The increase in research and development expense was primarily due to increased development efforts for our future generation ambulatory products. Increased research and development costs include $0.7 million in additional consulting costs, $0.5 million in additional salaries, bonus, and payroll related costs, and $0.4 million in additional share-based compensation.

Selling, General and Administrative. Selling, general and administrative expense increased $2.9 million to $13.2 million for the three months ended September 30, 2011, compared to $10.4 million for the three months ended September 30, 2010. The increase was primarily due to higher selling, marketing, 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 $1.2 million in additional salaries, bonus, and payroll related costs, $0.7 million in additional share-based compensation, and $0.3 million in additional facilities costs.

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Interest Income. Interest income increased to $31,000 for the three months ended September 30, 2011, compared to $20,000 for the three months ended September 30, 2010. The increase in interest income was primarily due to higher average interest bearing cash and marketable securities balances during the three months ended September 30, 2011 as compared to the same period of 2010.

Interest Expense. Interest expense decreased $43,000 to $1,000 for the three months ended September 30, 2011, compared to $44,000 for the three months ended September 30, 2010. The decrease in interest expense was primarily due to the conversion of all of the outstanding convertible notes in 2010.

Nine Months Ended September 30, 2011 Compared to September 30, 2010

Revenue, Cost of Sales and Gross Profit

Product revenue increased $18.4 million to $45.0 million for the nine months ended September 30, 2011, compared to $26.6 million for the nine months ended September 30, 2010 based primarily on increased sales volume. Product cost of sales increased $7.5 million to $25.9 million for the nine months ended September 30, 2011, compared to $18.4 million for the nine months ended September 30, 2010. The product gross profit of $19.0 million for the nine months ended September 30, 2011 increased $10.9 million compared to $8.1 million for the same period in 2010, primarily due to increased revenue.

Development grant and other revenues increased $2.5 million to $8.9 million for the nine months ended September 30, 2011, compared to $6.4 million for the nine months ended September 30, 2010. Development and other cost of sales decreased $0.3 million to $2.8 million for the nine months ended September 30, 2011 compared to $3.1 million for the nine months ended September 30, 2010. The increase in revenues associated with development was primarily due to the $4.0 million milestone payment received from Animas for CE Mark approval, and partially offset by extended revenue recognition timelines related to longer than expected development and regulatory review timelines under our collaboration arrangements with Edwards and Animas.

Research and Development. Research and development expense increased $5.2 million to $21.5 million for the nine months ended September 30, 2011, compared to $16.3 million for the nine months ended September 30, 2010. The increase in research and development expense was primarily due to increased development efforts for our ambulatory products. Increased research and development costs include $1.7 million in additional consulting costs, $1.4 million in additional salaries, bonus, and payroll related costs, and $1.2 million in additional share-based compensation.

Selling, General and Administrative. Selling, general and administrative expense increased $5.7 million to $36.2 million for the nine months ended September 30, 2011, compared to $30.5 million for the nine months ended September 30, 2010. The increase was primarily due to higher selling, customer operations, 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 $3.3 million in additional salaries, bonus, and payroll related costs, $0.8 million in additional facilities costs, and $0.6 million in additional share-based compensation.

Interest Income. Interest income was $0.1 million for each of the nine month periods ended September 30, 2011 and 2010, respectively.

Interest Expense. Interest expense decreased $1.5 million to $10,000 for the nine months ended September 30, 2011, compared to $1.5 million for the nine months ended September 30, 2010. 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.

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, 2011, we had an accumulated deficit of $378.9 million and had working capital of $100.5 million. Our cash, cash equivalents and short-term marketable securities totaled $97.3 million, excluding $0.9 million in restricted cash. We have funded our operations primarily from the sale of equity and debt securities and our bank line. 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. In November 2010, we completed a public follow-on offering of 3,277,500 shares of our common stock for net proceeds of approximately $33.0 million. In May 2011, we completed a follow-on public offering of 4,700,000 shares of our common stock for net proceeds of approximately $70.9 million.

***Net Cash Used in Operating Activities*.** Net cash used in operating activities decreased $10.7 million to $18.6 million for the nine months ended September 30, 2011, compared to $29.2 million for the same period in 2010. The decrease in cash used in operations

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was primarily due to $12.9 million in lower net loss, offset by $6.0 million in lower non-cash charges primarily comprised of loss on the extinguishment of debt upon conversion of our convertible notes. Net loss decreased primarily due to increased revenue and improved gross margins.

Net Cash Used In Investing Activities. Net cash used in investing activities was $42.9 million for the nine months ended September 30, 2011, compared to $5.2 million for the same period of 2010. The increase in cash used in investing activities was primarily due to $34.4 million increase in cash used to purchase available-for-sale marketable securities and by a $3.5 million decrease in proceeds from the maturities of short-term marketable securities for the nine months ended September 30, 2011 as compared to the same period in 2010. We invested $4.5 million in equipment to support manufacturing improvements for each of the nine month periods ended September 30, 2011 and 2010, respectively.

Net Cash Provided by Financing Activities**.** Net cash provided by financing activities increased $37.8 million to $74.1 million for the nine months ended September 30, 2011, compared to $36.4 million for the same period of 2010. The increase was primarily due to the $70.9 million in net proceeds generated by the sale of common stock in the follow on public offering completed in May 2011 for the nine months ended September 30, 2011 compared to $33.0 million for the same period of 2010.

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 to 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 through at least September 30, 2012. 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. Our ability to transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure. If events or circumstances occur such that we do not meet our operating plan as expected, or if we are unable to obtain additional financing, we may be required to reduce planned increases in compensation related expenses or other operating expenses related to research, development, and commercialization activities, which could have an adverse impact on our ability to achieve our intended business objectives.

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

We are party to various purchase arrangements related to components used in manufacturing and research and development activities. As of September 30, 2011, we had purchase commitments with certain vendors totaling approximately $14.1 million due within one year. There are no material 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 U.S. GAAP. 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, Israel and in portions of Europe. 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.

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 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, 2011, we maintained a reserve balance of $26,000 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.

We have entered into a distribution agreement with RGH Enterprises, Inc., or Edgepark, as amended on March 29, 2011, as well as agreements with 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

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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 $3.0 million and $10.6 million in revenue, which represents 17% and 20% of our total revenues for the three and nine months ended September 30, 2011, respectively, compared to $3.4 million and $8.2 million in revenue, which represented 29% and 25% of our total revenues for same periods in 2010. With respect to other distributors which stock inventory of our product and fulfill orders from their inventory, we shipped product to these distributors and recognized $5.3 million and $11.7 million in revenue from these arrangements, which represents 29% and 22% of our total revenues for the three and nine months ended September 30, 2011, respectively, compared to $1.2 million and $3.0 million in revenue from these arrangements, which represented 10% and 9% of our total revenues for the same periods in 2010. We monitor shipments to, and on-hand inventory levels of, these distributors, and at September 30, 2011 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 and are generally recognized over the service period except for substantive milestone payments, which are generally recognized when the milestone is achieved.

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 after January 1, 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.

For transactions containing multiple element arrangements entered into prior to January 1, 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 $1.6 million and $8.9 million in development grant and other revenue for the three and nine months ended September 30, 2011. As of September 30, 2011, we had $1.7 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 share-based awards granted and we use the grant date fair value of our common stock for valuing restricted stock unit awards. We recorded $3.7 million and $2.3 million in share-based compensation expense during the three months ended September 30, 2011 and 2010, respectively, and $9.9 million and $7.3 million during the nine months ended September 30, 2011 and 2010, respectively. As of September 30, 2011, there was $29.4 million of unrecognized compensation cost related to unvested options, restricted stock and restricted stock units that is expected to be recognized as a component of our operating expenses through 2015. 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, are 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 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.

Recent Accounting Pronouncements

In April 2010, the FASB reached a consensus on the Milestone Method of Revenue Recognition which provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. A vendor can recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The updated guidance is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years beginning on or after June 15, 2010, with early adoption permitted. We adopted the provisions of the guidance as of January 1, 2011 on a prospective basis. The prospective application had no impact on our consolidated financial statements for the nine months ended September 30, 2011.

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.

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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.

In connection with this litigation five of Abbott s seven patents that are the subject of the litigation 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, canceling claims and/or seeking to add new claims. Regarding the remaining two patents, Abbott has appealed the decisions of final rejection to the Federal Circuit, the cases have been consolidated and their Brief has recently been filed.

In addition, since 2008, Abbott has copied claims from certain of our applications, and stated that it may seek to provoke an interference with certain of our pending applications in the Patent Office. If interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also since 2008, Abbott has filed 30 reexamination requests seeking to invalidate 29 of our patents. Fifteen of the 30 reexamination requests are in various stages at the Patent Office, and 15 have been issued a Certificate of Reexamination. We have filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented in the reexaminations, seeking to amend certain claims to overcome the prior art presented in the reexaminations, canceling claims and/or seeking to add new claims. It is possible that the Patent Office may determine that some or all of the claims of our patents subject to the reexamination are invalid. Additionally, Abbott has filed an Opposition to three of our European patents.

Although it is our position that Abbott s assertions of infringement have no merit, and that the potential interference, reexamination requests and oppositions have no merit, neither the outcome of the litigation nor the amount and range of potential fees associated with the litigation, potential interference, reexamination requests or oppositions can be assessed, and as of September 30, 2011, no amounts have been accrued.

We may be subject to additional various claims, complaints and legal actions that arise from time to time in the normal course of business. Other than as described above, we do not believe we are party to any currently pending legal proceedings, the outcome of which could have a material adverse effect on our operations or financial position. There can be no assurance that existing or future legal proceedings arising in the ordinary course of business or otherwise will not have a material adverse effect on our business, consolidated financial position, results of operations or cash flows.

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 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, 2011, product revenues total approximately $118.1 million. We have relatively limited experience in selling our products and we might be unable to successfully expand the commercialization of our products on a wide scale for a number of reasons, including:

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

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

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

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

We have incurred net losses in each year since our inception in May 1999, including a net loss of $32.5 million for the nine months ended September 30, 2011. As of September 30, 2011, we had an accumulated deficit of $378.9 million. We have financed our operations primarily through private placements of our equity and debt securities and our public offerings, and have devoted a substantial portion of our resources to research and development relating to our continuous glucose monitoring systems, including our in-hospital product development, and more recently, we have incurred significant sales and marketing and manufacturing expenses

associated with the commercialization of the SEVEN PLUS. In addition, we expect our research and development expenses to increase in connection with our clinical trials and other development activities related to our products, including our next generation sensor, sensor augmented insulin pump collaborations, and the GlucoClear. We also expect that our general and administrative expenses will continue to increase due to the additional operational and regulatory burdens applicable to public healthcare and medical device companies. As a result, we expect to continue to incur significant operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders equity.

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

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

We may require additional funding to continue the commercialization of our SEVEN PLUS or the development and commercialization of our next generation and other continuous glucose monitoring systems, including the GlucoClear and our sensor augmented insulin pump systems developed in collaboration with Animas, Insulet and Roche.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our products, including growth of our manufacturing capacity, and on research and development, including conducting clinical trials for our GlucoClear in-hospital system as well as our next generation ambulatory continuous glucose monitoring sensors and systems. For the nine months ended September 30, 2011, our net cash used in operating activities was $18.6 million, compared to $29.2 million for the same period in 2010, and as of September 30, 2011, we had working capital of $100.5 million comprised of $98.3 million in cash, cash equivalents and short-term marketable securities, and includes $0.9 million in restricted cash. We expect that our cash used by operations will increase significantly in each of the next several years, and, although we recently completed a follow-on public offering of 4,700,000 shares of our common stock for net proceeds to the company of approximately $70.9 million, we may need additional funds to continue the commercialization of our products and for the development and commercialization of our next generation sensors and systems. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

- the revenue generated by sales of our products and other future products;
- the costs, timing and risks of delay of additional regulatory approvals;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- our ability to scale our manufacturing operations to meet demand for our current and any future products;
- the costs to produce our continuous glucose monitoring systems;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

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

the success of our research and development efforts;

the emergence of competing or complementary technological developments;

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

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

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

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

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

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

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

- recruit and retain adequate numbers of effective and experienced sales personnel;
- effectively train our sales personnel in the benefits and risks of our products;
- establish and maintain successful sales, marketing and education programs that educate endocrinologists, physicians and diabetes educators so they can appropriately inform their patients about our products; and
- manage geographically disbursed sales and marketing operations.

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

We have entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. We have entered into a distribution agreement with Edgepark, as amended, pursuant to which we generated approximately 21% of our revenue during the nine months ended September 30, 2011. There can be no assurances that this relationship will continue or that we will be able to maintain this volume of sales from this relationship in the future. A substantial decrease or loss of these sales could have a material adverse effect on our operating performance. Additionally, to the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services in the United States or Europe, our product margins could be lower than if we directly marketed and sold our products. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we cannot predict whether these efforts will be successful. In addition, market acceptance of our products by physicians and patients in Europe will largely depend on our ability to demonstrate their relative safety, efficacy, reliability, cost-effectiveness and ease of use. If we are unable to do so, we may not be able to generate product revenue from our sales efforts in Europe. Finally, if we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate adequate product revenue and may not become profitable.

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

products or any future products from third-party payors, we will be unable to generate significant revenue.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Although CMS in 2008 released Alpha-Numeric HCPCS codes applicable to each of the three components of our continuous glucose monitoring systems, to date, our approved products are not reimbursed by virtue of a national coverage decision

by Medicare. It is not known when, if ever, Medicare will adopt a national coverage decision with respect to continuous glucose monitoring devices. Until any such coverage decision is adopted by Medicare, reimbursement of our products will generally be limited to those patients covered by third-party payors that have adopted policies for continuous glucose monitoring devices allowing for coverage of these devices if certain conditions are met. As of November 2011, the seven largest private third-party payors, in terms of the number of covered lives, have issued coverage policies for the category of continuous glucose monitoring devices. In addition, we have negotiated contracted rates with six of those third-party payors for the purchase of our products by their members. However, patients without insurance that covers our products will have to bear the financial cost of them. In the United States, patients using existing single-point finger stick devices are generally reimbursed all or part of the product cost by Medicare or other third-party payors. The commercial success of our products in both domestic and international markets will be substantially dependent on whether third-party reimbursement is widely available for patients that use them. While many third-party payors have adopted some form of coverage policy on continuous glucose monitoring devices, those coverage policies frequently require significant medical documentation in order for patients to obtain reimbursement, and as a result, we have experienced difficulty in improving the efficiency of our customer service group. In addition, Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, they may not cover or provide adequate payment for our products. In order to obtain additional reimbursement arrangements, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. Our revenue may be limited by the continuing efforts of government and third-party payors to contain or reduce the costs of healthcare through various increasingly sophisticated means, such as requiring prospective reimbursement and second opinions, purchasing in groups, or redesigning benefits. Furthermore, we are unable to predict what effect the current or any future healthcare reform will have on our business, or the effect these matters will have on our customers. Our initial dependence on the commercial success of the SEVEN PLUS makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, unless government and other third-party payors provide adequate coverage and reimbursement for the SEVEN PLUS, patients may not use our products.

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

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

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

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

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

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

- our systems may not be deemed by the FDA to be substantially equivalent to appropriate predicate devices;
- our systems may not satisfy the FDA s safety or efficacy requirements;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;

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

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

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

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

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

To support these and any future additional PMA or 510(k) applications we must successfully complete pre-clinical studies, bench-testing, and clinical trials that we believe will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the studies and trials may be inadequate to support approval of a PMA or 510(k) application and the FDA may request additional clinical data in support of those applications, which may result in significant additional clinical expenses and may delay product approvals. While we have in the past obtained, and may in the future obtain, an Investigational Device Exemption, or IDE, prior to commencing clinical trials for our continuous glucose monitoring systems, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial to be sufficient to support approval of a PMA or 510(k) application, even if the trial s intended safety and efficacy endpoints are achieved. Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations, including 510(k) submissions, by hiring new investigators and increasing the frequency and scope of its inspections of manufacturing facilities. In January 2011, the FDA announced that it will, in the course of 2011, endeavor to streamline its 510(k) review process and the FDA s Center for Devices and Radiological Health, or CDRH, issued an implementation plan containing 25 specific actions to be implemented in 2011 relating to the 510(k) review process and associated administrative matters. The CDRH also deferred action on several other initiatives, including the creation of a new class of devices that would be subject to heightened review processes, until the Institute of Medicine issues a related report on the 510(k) regulatory process, which was released in late July 2011. Many of the actions proposed by the CDRH could result in significant changes to the 510(k) process, which could complicate the product approval process, although we cannot predict the effect of such procedural changes and cannot ascertain if such changes will have a substantive impact on the approval of our products. If we fail to adequately respond to the increased scrutiny and new 510(k) submission process and associated matters, our business may be adversely impacted.

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

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

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients do not comply with trial protocols;

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

patients experience adverse side effects;

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

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

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

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

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

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

changes in governmental regulations, policies or administrative actions;

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

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

The results of pre-clinical studies do not necessarily predict future clinical trial results, and prior clinical trial results might not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the approval of our products. If we are unable to demonstrate the safety and efficacy of our products in our clinical trials to the FDA s satisfaction, we will be unable to obtain regulatory approval to market our products in the United States. In addition, the data we collect from our current clinical trials, our pre-clinical studies and other clinical trials may not be sufficient to support FDA approval, even if our endpoints are met.

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

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

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

Comprehensive healthcare legislation, signed into law in March 2010, imposes stringent compliance, recordkeeping, and reporting requirements on companies in various sectors of the life sciences industry, with which we may need to comply, and enhanced penalties for non-compliance with the new healthcare regulations. The impact and durability of this legislation, in its current form, remains unclear, and costs of compliance with this legislation, or any future amendments thereto, could result in certain risks and expenses that we may have to assume. Other political and regulatory influences are also subjecting our industry to significant changes, and we cannot predict whether new regulations will emerge at the federal or state level, or abroad. The U.S. government may in the future consider healthcare policies and proposals intended to curb rising

healthcare costs, including those that could significantly affect reimbursement for healthcare products such as the SEVEN PLUS. These policies have included, and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. Future significant changes in the healthcare systems in the United States or elsewhere could also have a negative impact on the demand for our current and future products. These include changes that may reduce reimbursement rates for our products and changes that may be proposed or implemented by the current U.S. Presidential administration or Congress.

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

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

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

- billing for services;
- financial relationships with physicians and other referral sources;
- inducements and courtesies given to physicians and other health care providers and patients;
- labeling products;
- quality of medical equipment and services;
- confidentiality, maintenance and security issues associated with medical records and individually identifiable health information;
- medical device reporting;
- false claims; and
- professional licensure.

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

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

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

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

We currently have limited resources, facilities and experience in commercially manufacturing sufficient quantities of product to meet expected demand. In the past, we have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support our commercialization efforts. From time to time, we have also experienced brief periods of backorder and, at times, have had to limit the efforts of our sales force to introduce our products to new customers. We have focused significant effort on continual improvement programs in our manufacturing operations intended to improve quality, yields and throughput. We have made progress in manufacturing to enable us to supply adequate amounts of product to support our commercialization efforts, however, there can be no assurances that supply will not be constrained in the future. In order to produce our products in the quantities we anticipate will be necessary to meet market demand, we will need to increase our manufacturing capacity by a significant factor over the current level. In addition, we will have to modify our manufacturing design and process if and when our next generation

sensor technologies are approved and commercialized. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, materials procurement, manufacturing site expansion, problems with production yields and quality control and assurance. Developing commercial-scale manufacturing facilities will require the investment of substantial additional funds and the hiring and retention of additional management, quality assurance, quality control and technical personnel who have the necessary manufacturing experience. Also, the scaling of manufacturing capacity is subject to numerous risks and uncertainties, and may lead to variability in product quality or reliability, increased construction timelines, as well as resources required to design, install and maintain manufacturing equipment, among others, all of which can lead to unexpected delays in manufacturing output. In addition, any changes to our manufacturing processes may require FDA submission and approval and our facilities may have to undergo additional inspections by the FDA and corresponding state agencies. We cannot assure you that we will be able to develop and expand our manufacturing process and operations or obtain FDA and state agency approval of our facilities in a timely manner or at all. If we are unable to manufacture a sufficient supply of our current products or any future products for which we may receive approval, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand and our business will suffer.

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

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

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

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

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

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our products are technologically complex and it is difficult to develop alternative supply sources;
- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;

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

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

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

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

our suppliers may make obsolete components that are critical to our products; and

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

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

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

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

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

Any product for which we obtain marketing approval will be subject to continual review and periodic inspections by the FDA and other regulatory bodies, which may include inspection of our manufacturing processes, post-approval clinical data and promotional activities for such product. The FDA s medical device reporting, or MDR, regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned and, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury. We and our suppliers are also required to comply with the FDA s Quality System Regulation, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, selection and oversight of suppliers or contractors, quality assurance, labeling, packaging, storage, complaint handling, shipping and servicing of our products. The FDA enforces the QSR through unannounced inspections. We currently manufacture our devices at our headquarters facilities in San Diego, California. In these facilities we have more than 8,000 square feet of laboratory space and approximately 12,000 square feet of controlled environment rooms. In February 2010, our facility was subject to a post-approval inspection by the FDA. After the close of the inspection, the FDA investigator issued a Form 483 identifying several inspectional observations. Subsequent to the inspection, we also received a warning letter from the FDA requiring us to file MDRs in accordance with the MDR regulations for complaints involving sensor wire fractures underneath a patient s skin. The warning letter also recommended that we add certain warnings and precautions statements to the labeling, patient education brochures, and our company website regarding the appropriate use of the SEVEN PLUS system, including that they are not approved for use in children under age 18, pregnant women, or persons on dialysis. In response to the warning letter and the Form 483 inspectional observations, we have taken corrective action to address the observations to achieve substantial compliance with the FDA regulatory requirements applicable to a commercial medical device manufacturer. In October 2010, we were subject to a follow-up site inspection by the FDA, and upon completion of that inspection, we were notified by the inspector that there were no 483 inspectional observations. We also received written notification dated November 1, 2010 from the FDA that we adequately addressed all issues cited in the warning letter.

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

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

warning letters or untitled letters that require corrective action;

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

fines and civil penalties;

unanticipated expenditures;

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

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

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

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

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

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

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

In connection with this litigation, five of Abbott s seven patents that are the subject of the litigation 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, canceling claims and/or seeking to add new claims. Regarding the remaining two patents, Abbott has appealed the decisions of final rejection to the Federal Circuit, the cases have been consolidated and their brief has recently been filed. Since 2008, Abbott has copied claims from certain of our applications, and stated that it may seek to provoke an interference with certain of our pending applications in the Patent Office. If an interference is declared and Abbott prevails in the interference, we would lose certain patent rights to the subject matter defined in the interference. Also since 2008, Abbott has filed 30 reexamination requests seeking to invalidate 29 of our patents in the Patent Office. Fifteen of the 30 reexamination requests are in various stages at the Patent Office and 15 have been issued a Certificate of Reexamination. We have filed responses with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented in the reexaminations,

seeking to amend certain claims to overcome the prior art presented in the reexaminations, canceling claims and/or seeking to add new claims. It is possible that the Patent Office may determine that some or all of the claims of our patents subject to the reexamination are invalid, which could have a significant impact on our ability to protect aspects of our technology.

Although it is our position that Abbott s assertions of infringement have no merit, and that the potential interference and reexamination requests have no merit, the outcome of the litigation and interference or reexamination requests cannot be assessed

currently with any certainty. We may not successfully defend ourselves against the claims made by Abbott or prevail in the litigation. Subject to the stay of litigation, if Abbott were to seek and obtain a preliminary or permanent injunction, it could force us to stop making, using, selling or offering to sell our products. The technology at issue in our litigation with Abbott is currently used in our products, including SEVEN PLUS, our only current ambulatory product that is approved for commercial sale, and our GlucoClear system for in-hospital use. If we were forced to stop selling these products, our business and prospects would suffer. In addition, defending against this action could have a number of harmful effects on our business, including those discussed in the following risk factor, regardless of the final outcome of such litigation. For example, we have incurred, and expect to continue to incur, significant costs in defending the action.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On November 10, 2008, we entered into a Collaboration Agreement with Edwards pursuant to which we have agreed to develop jointly and to market the GlucoClear, a blood-based in-vivo automated glucose monitoring system for use by healthcare providers in the hospital. Under the Collaboration Agreement, we expect to receive payments for various milestones related to regulatory approvals and commercial readiness of the

product. In addition, we also expect to receive either a profit-sharing payment of 10% of the products gross profits, or a royalty of 6% of commercial sales of the product. The Collaboration Agreement provides Edwards with an exclusive license to our intellectual property that relates to blood-based glucose sensors in the critical care sector of the hospital market. However, this collaboration may not result in the development of products that achieve regulatory approval in the United States or commercial success, which would result in various penalties to us under the Collaboration Agreement, up to and including delay or loss of some or all of our milestone payments and rights to any profit-sharing or royalties. On October 30, 2009, we received CE Mark approval for the first generation GlucoClear that we developed in collaboration with Edwards. Although Edwards commenced market evaluations during 2009, this product did not generate significant revenue during 2010 and we do not expect this product to generate significant revenue during 2011. We will seek 510(k) clearance from the FDA for future GlucoClear

products, and are working with Edwards to formulate the next steps for these submissions. We cannot predict whether the FDA will classify the GlucoClear as a 510(k) or PMA product, nor can we predict when, if ever, the GlucoClear will obtain FDA clearance or approval.

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

In the ordinary course of our business, we enter into collaborative arrangements to develop new products and to pursue new markets, such as our agreements with Animas, Insulet and Roche, to integrate our continuous glucose monitoring technology into their respective insulin delivery systems. We have also entered into an OUS Commercialization Agreement, as amended, with Animas pursuant to which Animas retains the exclusive right to develop and market outside the United States an ambulatory insulin pump that is combined with our continuous glucose monitoring technology which has been branded the Vibe. In May 2011, we, together with Animas, received CE Mark certification for the Vibe, allowing it to be marketed in the countries that recognize CE Mark approval. These collaborations may not result in the development of products that achieve commercial success and could be terminated prior to developing any products. Accordingly, we cannot assure you that any of our collaborations will result in the successful development of a commercially viable product or result in significant additional future revenues. In addition, our development timelines are highly dependent on our ability to achieve clinical endpoints and regulatory requirements and to overcome technology challenges, and may be delayed due to scheduling issues with patients and investigators, requests from institutional review boards, product performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our products, including research and development, manufacturing, quality assurance, and clinical and regulatory personnel. Even if our development and clinical trial efforts are successful, the FDA may not approve the combined products or may require additional product testing and clinical trials before approving the combined products, which would result in product launch delays and additional expense. If approved by the FDA, the combined products may not achieve acceptance in the marketplace by physicians and patients.

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

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

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

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

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

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

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

We may be subject to claims against us even if the apparent injury is due to the actions of others or misuse of the device. Our customers, either on their own or following the advice of their physicians, may use our products in a manner not described in the

products labeling and that differs from the manner in which it was used in clinical studies and approved by the FDA. For example, our SEVEN PLUS is designed to be used by a patient continuously for up to seven days, but the patient might be able to circumvent the safeguards designed into the SEVEN PLUS and use the product for longer than seven days. Off-label use of products by patients is common, and any such off-label use of our products could subject us to additional liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

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

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

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

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

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

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

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

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

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

We are highly dependent on our senior management, especially Terrance H. Gregg, our Chief Executive Officer, Kevin Sayer, our President, Steven R. Pacelli, our Chief Operating Officer, Jorge Valdes, our Chief Technical Officer, and Andrew K. Balo, our Senior Vice President of Clinical and Regulatory Affairs. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including sales persons, scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as sales persons, scientists, clinicians and engineers, is intense and we may not be able to retain our personnel.

The loss of the services of members of our senior management, scientists, clinicians or

engineers could prevent the implementation and completion of our objectives, including the commercialization of our current products and the development and introduction of additional products. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement. Each of our officers may terminate their employment at any time without notice and without cause or good reason. Additionally, volatility or a lack of positive performance in our stock price may adversely affect our ability to retain key employees.

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

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

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the SEC will result in increased costs to us as we evaluate the implications of any new rules and regulations and respond to new requirements under such rules and regulations. We are required to comply with many of these rules and regulations, and will be required to comply with additional rules and regulations in the future. Furthermore, on July 21, 2010, President Obama signed into law the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. This new law makes significant changes to corporate governance and executive compensation rules for public companies across all industries. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards, may adversely impact our reported financial results and business, and may further require us to incur greater accounting fees. The effects of new laws and regulations remain unclear and will likely require us to incur significant additional accounting and legal costs and divert management s time and attention away from our business in order to ensure compliance with these regulatory requirements.

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

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

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

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

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

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

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting

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pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. The method in which we market and sell our products may have an impact on the manner in which we recognize revenue. In addition, changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, as a result of changes approved by the FASB on January 1, 2006 we began recording compensation expense in our statements of operations for equity compensation instruments, including employee stock options, using the fair value method. Our reported financial results beginning for the first quarter of 2006 and for all foreseeable future periods will be negatively and materially impacted by this accounting change. Other potential changes in existing taxation rules related to stock options and other forms of equity compensation could also have a significant negative effect on our reported results. Additionally, changes to existing accounting rules or standards, such as the potential requirement that U.S. registrants prepare financial statements in accordance with International Financial Reporting Standards, may adversely impact our reported financial results and business, and may further require us to incur greater accounting fees.

Risks Related to Our Common Stock

Our stock price is highly volatile and investing in our stock involves a high degree of risk, which could result in substantial losses for investors.

Historically, the market price of our common stock, like the securities of many other medical products companies, fluctuates and could continue to be volatile in the future. Since January 1, 2011, the closing price of our common stock on the NASDAQ Global Market has been as high as $16.72 per share and as low as $10.30 per share.

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

- securities analyst coverage or lack of coverage of our common stock or changes in their estimates of our financial performance;
- variations in quarterly operating results;
- future sales of our common stock by our stockholders;
- investor perception of us and our industry;
- announcements by us or our competitors of significant agreements, acquisitions or capital commitments;
- changes in market valuation or earnings of our competitors;
- general economic conditions;
- regulatory actions;
- legislation and political conditions; and
- terrorist acts.

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

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

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

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

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

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

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

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

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

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

inadequate financial and other resources; and

global economic conditions.

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

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

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

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

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

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

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

our Board of Directors may, without stockholder approval, issue shares of preferred stock with special voting or economic rights;

our stockholders do not have cumulative voting rights and, therefore, each of our directors can only be elected by holders of a majority of our outstanding common stock;

a special meeting of stockholders may only be called by a majority of our Board of Directors, the Chairman of our Board of Directors, or our Chief Executive Officer;

our stockholders may not take action by written consent;

our Board of Directors is divided into three classes, only one of which is elected each year; and

we require advance notice for nominations for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES
Not applicable.

ITEM 4. REMOVED AND RESERVED

ITEM 5. OTHER INFORMATION
Not applicable.

ITEM 6. EXHIBITS
The following exhibits are filed as a part of this report.

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*					X
32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*					X
101	101.INS XBRL Instance Document 101.SCH XBRL Taxonomy Extension Schema Document 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document 101.LAB XBRL Taxonomy Extension Label Linkbase Document 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document					

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

SIGNATURES

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

DEXCOM, INC.
(Registrant)

Dated: November 2, 2011 By: /s/ TERRANCE H. GREGG

Terrance H. Gregg,
Chief Executive Officer

Dated: November 2, 2011 By: /s/ JESS ROPER

Jess Roper,
Chief Financial Officer