DEXCOM INC
Form 10-Q
November 10, 2008
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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, 2008

¨ **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 is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of accelerated filer, large 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 November 5, 2008, 29,787,706 shares of the Registrant s common stock were outstanding.

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DexCom, Inc.

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DexCom, Inc.

Consolidated Balance Sheets

(In thousands except par value data)

(Unaudited)

	September 30, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 4,642	$ 23,115
Short-term marketable securities, available-for-sale	20,741	41,208
Accounts receivable, net	429	215
Inventory	2,590	1,139
Prepaid and other current assets	1,382	1,614
Total current assets	29,784	67,291
Property and equipment, net	6,442	6,649
Restricted cash	4,839	914
Other assets	2,010	2,405
Total assets	$ 43,075	$ 77,259
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,663	$ 4,535
Accrued payroll and related expenses	2,722	2,537
Current portion of long-term debt	2,275	1,375
Current portion of deferred revenue	167	
Total current liabilities	7,827	8,447
Long-term portion of deferred revenue	212	
Other liabilities	679	666
Long-term debt, net of current portion	61,650	61,031
Total liabilities	70,368	70,144
Commitments and contingencies (Note 4)		
Stockholders (deficit) equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; no shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively		
Common stock, $0.001 par value, 100,000 authorized; 30,067 and 29,788 issued and outstanding at September 30, 2008; 28,778 and 28,624 shares issued and outstanding at December 31, 2007	30	29
Additional paid-in capital	190,744	183,325
Accumulated other comprehensive income (loss)	(81)	13
Accumulated deficit	(217,986)	(176,252)
Total stockholders (deficit) equity	(27,293)	7,115
Total liabilities and stockholders (deficit) equity	$ 43,075	$ 77,259

See accompanying notes

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DexCom Inc.

Consolidated Statements of Operations

(In thousands except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Product revenue	$ 1,878	$ 1,224	$ 5,643	$ 3,099
Development grant revenue	42		122	
Total revenue	1,920	1,224	5,765	3,099
Product cost of sales	3,577	3,113	9,833	9,081
Development cost of sales	263		643	
Total cost of sales	3,840	3,113	10,476	9,081
Gross margin (deficit)	(1,920)	(1,889)	(4,711)	(5,982)
Operating expenses				
Research and development	5,418	3,671	15,058	11,734
Selling, general and administrative	6,652	5,943	20,320	16,783
Total operating expenses	12,070	9,614	35,378	28,517
Operating loss	(13,990)	(11,503)	(40,089)	(34,499)
Interest income	215	1,014	1,087	2,932
Interest expense	(913)	(895)	(2,732)	(2,082)
Net loss	$ (14,688)	$ (11,384)	$ (41,734)	$ (33,649)
Basic and diluted net loss per share	$ (0.50)	$ (0.40)	$ (1.42)	$ (1.19)
Shares used to compute basic and diluted net loss per share	29,627	28,325	29,415	28,283

See accompanying notes

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DexCom, Inc.

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2008	**2007**
Operating activities		
Net loss	$ (41,734)	$ (33,649)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	2,268	1,908
Share-based compensation	5,707	4,245
Accretion and amortization related to investments, net	(26)	(344)
Amortization of debt issuance costs	412	281
Changes in operating assets and liabilities:		
Accounts receivable	(214)	(51)
Inventory	(1,451)	378
Prepaid and other assets	281	473
Restricted cash	(3,925)	
Accounts payable and accrued liabilities	(1,872)	(676)
Accrued payroll and related expenses	185	1,086
Deferred revenue	379	
Deferred rent and other liabilities	13	306
Net cash used in operating activities	(39,977)	(26,043)
Investing activities		
Purchase of available-for-sale marketable securities	(32,950)	(63,306)
Proceeds from the maturity of available-for-sale marketable securities	53,301	40,403
Purchase of property and equipment	(2,061)	(848)
Net cash provided by/(used in) investing activities	18,290	(23,751)
Financing activities		
Proceeds from issuance of senior convertible notes		60,000
Payment of senior convertible notes issuance costs		(2,661)
Purchase of senior convertible notes call spread options		(10,950)
Net proceeds from issuance of common stock	1,696	690
Proceeds from equipment loan	2,657	412
Repayment of equipment loan	(1,138)	(688)
Net cash provided by financing activities	3,215	46,803
Effect of exchange rate changes on cash and cash equivalents	(1)	
Increase (decrease) in cash and cash equivalents	(18,473)	(2,991)
Cash and cash equivalents, beginning of period	23,115	18,167
Cash and cash equivalents, ending of period	$ 4,642	$ 15,176
Non-cash investing and financing transactions:		
Common shares received as settlement for a call spread option	$ 869	$ 1,420

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. (the Company) is a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems for people with diabetes. On March 24, 2006, the Company received approval from the FDA for its first product, the STS, designed for up to three days of continuous use. On May 31, 2007, the Company received approval from the FDA for its second generation continuous glucose monitoring system, the SEVEN, designed for up to seven days of continuous use, and the Company began commercializing this product in the third quarter of 2007.

Basis of Presentation

The Company has 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 (except for the changes in estimates described below) include only normal recurring adjustments considered necessary for a fair presentation, have been included. Operating results for the three and nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. 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, 2007 included in the Annual Report on Form 10-K filed by the Company with the Securities and Exchange Commission on March 11, 2008.

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

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management 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 2008 bonus plan s authorized target bonus amounts of up to 50%, 35% and 25% of base salary for the Company s Chief Executive Officer, its Senior Vice Presidents, and the remainder of its non-sales management employees, respectively, to be awarded from the bonus pool based on the weighted average achievement of certain objectives. The amount of any bonus under the 2008 plan will be predicated on achieving targeted revenue goals and performance milestones. In general, 70% of any bonus paid under the 2008 Plan is based on achieving certain annual revenue goals and 30% 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

The Company recorded $1.8 million and $1.7 million in share-based compensation expense during the three months ended September 30, 2008 and 2007, respectively, and $5.7 million and $4.2 million during the nine months ended September 30, 2008 and 2007, respectively. At September 30, 2008, unrecognized estimated compensation costs related to non-vested stock options totaled $20.0 million and is expected to be recognized through 2012. The Company utilizes the Black-Scholes option-pricing model as the method of valuation for share-based awards granted.

Revenue Recognition

The Company sells its durable systems and disposable units through a direct sales force in the United States and through distribution arrangements in the United States. Components are individually priced and can be purchased separately or together. The SEVEN durable system includes a reusable transmitter, a receiver, a power cord, a finger-stick meter interface cable, data management software and a USB cable. Disposable sensors for use with the SEVEN durable system are sold separately in packages of four. The initial SEVEN durable system price is not dependent upon the purchase of any amount of disposable SEVEN sensors. The Company discontinued sales of its STS three day durable system in the second quarter of 2007 and discontinued the sale of its three day sensors during the second quarter of 2008.

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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. The company recognizes revenue from contracted insurance payors based on the contracted rate. The company recognizes revenue from non-contracted insurance payors based on the estimated collectible amount and historical experience.

After approval of the Company s second generation continuous glucose monitoring system, the SEVEN, on May 31, 2007, the Company started taking orders for an Upgrade Kit to upgrade existing customers for $150. Before the Upgrade Kit became available for shipment, for systems sold that included an upgrade right, a portion of the sales price was allocated to the undelivered Upgrade Kit and deferred based on the fair value of the Upgrade Kit. This deferred revenue was recognized when the Upgrade Kit was delivered to the customer. In August 2007, the Company adopted a 30-day money back guarantee program whereby customers who purchase the SEVEN durable system and a package of four disposable sensors may return the SEVEN durable system for any reason within thirty days of purchase and receive a full refund of their purchase price. The Company accrues for estimated returns and/or refunds by reducing revenues and establishing a liability account at the time of shipment based on historical experience. During 2008, the Company entered into distribution agreements that allow the distributors to sell the Company s durable systems and disposable units. With respect to one distributor, the Company shipped product directly to the distributor s customers and recognized $416,000 and $610,000 in revenue for the three and nine months ending September 30, 2008.

Revenue from development grants is recognized ratably over the life of the development agreements when all conditions for revenue recognition have been met as outlined in Staff Accounting Bulletin 104 and Emerging Issues Task Force (EITF) 00-21 *Revenue with Multiple Element Arrangements*.

Warranty Accrual

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

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments and foreign currency translation adjustments, shall be reported, net of their related tax effect, to arrive at comprehensive income (loss). The Company s comprehensive loss is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss	$ (14,688)	$ (11,384)	$ (41,734)	$ (33,649)
Unrealized gain (loss) on short-term available-for-sale marketable securities	(35)	67	(93)	22
Foreign currency translation gain (loss)	(1)		(1)	
Comprehensive gain (loss)	$ (14,724)	$ (11,317)	$ (41,828)	$ (33,627)

Inventory

Inventory is valued at the lower of cost or market value. The Company makes 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. The Company utilizes 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 the standard costs are based on full utilization of the Company s manufacturing capacity.

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Income Taxes

At December 31, 2007, the Company had federal and state tax net operating loss carryforwards of approximately $159.0 million and $119.8 million, respectively. The federal and state tax loss carryforwards will begin to expire in 2019 and 2012, respectively, unless previously utilized. The Company also has federal and state research and development tax credit carryforwards of approximately $3.2 million and $3.3 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. The tax benefits related to future utilization of federal and state net operating losses and tax credit carryforwards may be limited or lost if cumulative changes in ownership exceed 50% within any three-year period.

Recent Accounting Guidance

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. In February 2008, the FASB deferred the effective date of SFAS 157 by one year for certain non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). On January 1, 2008, the Company adopted the provisions of SFAS 157, except as it applies to those nonfinancial assets and nonfinancial liabilities for which the effective date has been delayed by one year.

The fair value hierarchy described by the standard 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.

In accordance with SFAS 157, the following table represents the Company s fair value hierarchy for its financial assets (cash equivalents and investments) measured at fair value on a recurring basis as of September 30, 2008 (in thousands):

	Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash and cash equivalents	$ 4,642			$ 4,642
Marketable securities, available for sale	$ 20,741			$ 20,741
Restricted cash	$ 4,839			$ 4,839

The Company has maintained only Level 1 financial assets during the three and nine months ended September 30, 2008.

The adoption of SFAS 157 did not have a material effect on the Company s financial position or results of operations. 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.

Effective January 1, 2008 the Company adopted Statement of Financial Accounting Standard No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115*. This Standard permits the Company to choose to measure many financial instruments and certain other items at fair value and established presentation and disclosure requirements. In adopting this Standard, the Company did not elect to measure any new assets or liabilities at their respective fair values.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force Issue 07-1, *Accounting for Collaborative Arrangements*. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*. EITF 07-1 will be effective for the Company beginning on January 1, 2009. The adoption of EITF 07-1 is not expected to have a material effect on the Company s financial statements.

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In May 2008, the FASB issued FASB Staff Position (FSP) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. The FSP requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability and equity components of the instrument. The debt would be recognized at the present value of its cash flows discounted using the Company s nonconvertible debt borrowing rate. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The FSP also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The effective date of the FSP is for financial statements issued for fiscal years beginning after December 15, 2008. The Company believes the convertible debt issued in March 2007 falls under the FSP and the Company will be required to retroactively apply the guidance. Although the Company has not completed its analysis of the impact of this guidance, it believes the application would cause a reduction to the carrying value of the debt on its balance sheet and a corresponding increase in non-cash interest expense to be recognized over the initial five year redemption period, which could be significant.

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, warrants, 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,	
	2008	2007	2008	2007
Options outstanding to purchase common stock	6,141	5,764	6,141	5,764
Restricted stock	105	45	105	45
Convertible senior notes	7,692	7,692	7,692	7,692
Total	13,938	13,501	13,938	13,501

3. Financial Statement Details (in thousands)

Inventory

	September 30, 2008	December 31, 2007
Raw materials	$ 1,552	$ 649
Work-in-process	148	130
Finished goods	890	360
Total	$ 2,590	$ 1,139

Accounts Payable and Accrued Liabilities

	September 30, 2008	December 31, 2007
Accounts payable trade	$ 1,229	$ 1,532

Accrued tax, audit, and legal fees	552	442
Clinical trials	89	76
Accrued other including warranty	793	2,485
Total	$ 2,663	$ 4,535

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Accrued Warranty

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Beginning balance	$ 85	$ 28	$ 52	$ 49
Charges to costs and expenses	127	85	454	128
Costs incurred	(135)	(67)	(429)	(131)
Ending balance	$ 77	$ 46	$ 77	$ 46

4. Commitments and Contingencies

Convertible Senior Notes

In March 2007, the Company issued $60 million aggregate principal amount of Convertible Senior Notes due 2027 in a private offering. The notes are convertible into shares of common stock based on an initial conversion rate of 128.2051 shares of common stock per $1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately $7.80 per share. Interest on the notes is due semiannually on March 15 and September 15 of each year at a rate of 4.75% per year. The notes are redeemable by the Company beginning March 20, 2010 at a price equal to 100% of the principal amount to be redeemed plus accrued and unpaid interest. Holders of the notes may require the Company to repurchase the notes for cash equal to 100% of the principal amount to be repurchased plus accrued and unpaid interest upon the occurrence of certain designated events, including a change of control. In addition, the Company will have the right to automatically convert the notes if the closing price of its common stock exceeds 150% of the conversion price, or $11.70 per share, for at least 20 trading days during any 30-day period. If such an automatic conversion occurs before March 15, 2010, the Company is required to pay additional interest in cash or, at its option, in shares of its common stock, equal to three full years of interest on the converted notes, less any interest actually paid or provided for on the notes prior to automatic conversion. The holders of the notes may require the Company to repurchase the notes for cash on March 15, 2012, March 15, 2017 and March 15, 2022 at a repurchase price equal to 100% of the principal amount, plus accrued and unpaid interest.

Call Spread Option

In March 2007, the Company entered into hedge transactions to minimize the potential dilution of the Company s common stock upon conversion of the Convertible Senior Notes if the Company s stock price exceeds $7.80 per share through March 2009. The Company has the right to purchase a number of shares of common stock equal to the number of shares underlying the $60 million principal amount of the notes, at a strike price equal to the conversion price of the notes, or $7.80 per share. The call spread options are structured in four tranches with one tranche expiring in each six-month interval for two years from the date of March 6, 2007. Each of the four options caps the potential benefit to the Company at market prices ranging from $9.00 for the option which expired in September 2007 to $18.50 for the option expiring in March 2009, which represents the single remaining tranche. The call spread options are separate transactions entered into by the Company and are not part of the terms of the Convertible Senior Notes.

In accordance with Emerging Issues Task Force Issue, or EITF, No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock*, the Company recorded the $10,950,000 cost of the call spread transactions as a net reduction in additional paid in capital in the Balance Sheet for the quarter ended March 31, 2007, and will not recognize subsequent changes in fair value. During March 2008, the Company received approximately 118,000 shares of its common stock with a value of $869,000 on the date the shares were returned to the Company as settlement for the second tranche.

Line of Credit

In March 2006, the Company entered into a loan and security agreement (the Loan Agreement) that provided for up to $5,000,000 to finance various equipment purchases through March 2007. In January 2008, the Company entered into an amendment to the Loan Agreement to finance additional equipment purchases. The amendment allows the Company to draw an additional amount of up to $3,000,000 under a new and additional Facility B Equipment Line.

At September 30, 2008, the Company had total borrowings of $3,925,000 under the Loan Agreement pursuant to the Facility A Equipment Line and Facility B Equipment Line and none was available for future borrowings. The loan bears an interest rate equal to the lender s prime rate plus 0.25% and at September 30, 2008, the interest rate was 5.25%. Beginning April 2008, terms of the Facility B Equipment Line began to require

monthly amortized payments through the maturity date of July 2011. Under the amended Loan Agreement, the Company continues to grant a security interest in substantially all of its personal property as collateral for the loan and is required to maintain cash balances equal to total outstanding loan balances with the lender.

Lease

In January 2007, the Company entered into a sublease agreement to sublet an existing facility near its corporate headquarters to a third party. Under the terms of the agreement, the Company sublet approximately 7,000 square feet of facilities space at terms and conditions, including real estate taxes and operating costs, which mirror the original lease agreement. The Company retains

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obligations per the original lease. Rental obligations, excluding real estate taxes and operating costs, owed by the Company, but subject to reimbursement by the subtenant in accordance with the terms of the sublease agreement, as of September 30, 2008, were as follows (in thousands):

Fiscal Year Ending	
2008	$ 27
2009	111
2010	114
2011	48
Total	$ 300

Total rent expense for the nine months ended September 30, 2008 was $1.4 million.

Litigation

On August 11, 2005, Abbott Diabetes Care, Inc., or Abbott, filed a patent infringement lawsuit against the Company in the United States District Court for the District of Delaware, seeking a declaratory judgment that the Company s continuous glucose monitor infringes certain patents held by Abbott. In August 2005, the Company moved to dismiss these claims and filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office (the Patent Office) and by March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against the Company 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 the Company s continuous glucose monitor. On August 18, 2006, the court granted the Company s 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 the Company s motion to strike, or disallow, Abbott s amended complaint in which Abbott had sought to add three additional patents to the litigation. In late 2006, the Patent Office issued a non-final rejection of all claims the Company submitted for reexamination in two of the Abbott patents cited in the original lawsuit. In both cases, Abbott has filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented by the Company, seeking to amend certain claims to overcome the prior art presented by the Company, and seeking to add new claims. In response, the Company filed a second reexamination request with the Patent Office challenging each of Abbott s proposed amendments and in October 2007, the Patent Office ordered reexamination of each of the second reexamination requests. In early 2008, the Patent Office issued a non-final rejection of all claims the Company submitted for reexamination in the other two patents cited in the original complaint. In both cases, Abbott filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented by the Company, seeking to amend certain claims to overcome the prior art presented by the Company, and seeking to add new claims. The Patent Office subsequently issued final rejections of all claims the Company submitted for reexamination for both patents. In October 2008, Abbott filed a response to the final rejections in one of the two reexaminations and the Company submitted second reexamination requests for these two patents.

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 infringement of the additional patents it had sought to include in the litigation discussed above. The Company believes this complaint, like the first, is without merit and the Company intends to vigorously contest the action. To that end, the Company filed requests with the Patent Office to reexamine each of the three additional patents cited by Abbott and on September 7, 2006, the Company 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, the Company 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. On September 30, 2007, the court granted the Company s 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 the Company. In February 2007, the Patent Office ordered reexamination of each of the three patents cited in this new lawsuit and in June 2007, the Patent Office issued a non-final rejection of all claims the Company submitted for reexamination in two of the Abbott patents cited in the new lawsuit. In each of these cases, Abbott filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented by the Company, seeking to amend certain claims to overcome the prior art presented by the Company, and seeking to add new claims. In response, the Company filed a second reexamination request with the Patent Office challenging each of Abbott s proposed amendments and by February 2008, the Patent Office had ordered reexamination of each of the second reexamination requests, one of which is under final rejection as of October 2008. Abbott has responded to the final rejection by filing an after final amendment. In March 2008, the Patent Office issued a Notice of Intent to Issue a Reexamination Certificate, confirming the claims of the third of the additional three patents asserted by Abbott. In response, the Company filed another

reexamination request on this patent, which was ordered in June of 2008. In October of 2008 the Patent Office issued a non-final Office Action, rejecting claims 1-3 but confirming patentability of claim 4.

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In 2008, Abbott copied claims from certain of the Company s applications, and stated that it may seek to provoke an interference with certain of the Company s pending applications in the Patent Office. If the interference is declared and Abbott prevails in the interference, the Company would lose certain patent rights to the subject matter defined in the interference. Also in 2008, Abbott has filed reexamination requests seeking to invalidate two of the Company s patents in the Patent Office. In both reexamination requests, the Patent Office has ordered the reexamination and issued non-final office actions and the Company has responded to those non-final office actions by seeking claim construction to differentiate certain claims from the prior art, seeking to amend certain claims to overcome the prior art, and canceling certain claims.

Purchase Commitments

The Company is party to various purchase arrangements related to its development activities including materials used in its glucose monitoring systems. As of September 30, 2008, the Company had purchase commitments with vendors of $3.7 million due within one year. There are no purchase commitments due beyond one year.

5. Development Agreements

Insulet Corporation

On January 7, 2008, the Company entered into a development agreement with Insulet Corporation to integrate DexCom s 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, the Company entered into a joint development agreement with Animas Corporation to integrate DexCom s continuous glucose monitoring technology into Animas insulin pumps. Under the terms of the agreement, Animas will contribute up to $750,000 to DexCom to offset certain development, clinical and regulatory expenses. The agreement is non-exclusive and does not impact either party s existing third party development agreements. In January of 2008 the Company received $500,000 and recorded $42,000 and $122,000 in revenue for the three and nine-month period ended September 30, 2008.

6. Subsequent Event

On November 10, 2008, the Company entered into a Collaboration Agreement (the Agreement) with Edwards Lifesciences LLC (Edwards). Pursuant to the Agreement, the Company and Edwards have agreed to develop jointly and to market continuous blood glucose sensing devices for application within the hospital market. Under the terms of the Agreement, Edwards is obligated to pay the Company an upfront fee of $13,000,000. In addition, the Company is entitled to receive up to $23,500,000 over the next three years for product development costs and milestones related to regulatory approvals and manufacturing readiness. The Company will also receive either a profit-sharing payment of up to 10% of commercial sales of the device, or a royalty of up to 6% of commercial sales of the device. The Agreement provides Edwards with an exclusive license under the Company s intellectual property in the hospital market. Edwards will be responsible for global sales and marketing, and the Company will initially be responsible for manufacturing.

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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 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 people with diabetes. On March 24, 2006, we received approval from the FDA for our first product, the STS, designed for up to three days of continuous use. On May 31, 2007, we received approval from the FDA for our second generation continuous glucose monitoring system, the SEVEN, designed for up to seven days of continuous use, and we began commercializing this product in the third quarter of 2007. As part of our commercialization of the SEVEN, we discontinued sales of our STS three day durable system in the second quarter of 2007 and discontinued the sale of our three day sensors during the second quarter of 2008. Our approval allows for the use of the SEVEN by adults with diabetes to detect trends and track glucose patterns, to aid in the detection of hypoglycemia and hyperglycemia and to facilitate acute and long-term therapy adjustments. Our products must be prescribed by a physician and include a disposable sensor, a transmitter and a small handheld receiver. Our products are indicated for use as adjunctive devices to complement, not replace, information obtained from standard home blood glucose monitoring devices and our products must be calibrated periodically using a standard home blood glucose monitor. On November 15, 2007, we received FDA approval to calibrate the SEVEN using any FDA cleared blood glucose meter and we began shipping receivers with this feature in the first quarter of 2008. Previously, patients were required to calibrate the SEVEN using a LifeScan® Ultra® blood glucose meter connected to the receiver via an upload cable. The SEVEN sensor is inserted by the patient and is intended to be used continuously for up to seven days after which it is removed by the patient and may be replaced by a new sensor. Our transmitter and receiver are reusable. Since inception, we have devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. More recently, we have devoted considerable resources to the commercialization of the SEVEN as well as the continued research and clinical development of our technology platform.

According to the World Health Organization, in 2006 there were approximately 180 million people who suffered from diabetes worldwide. In 2007, there were an estimated 23.6 million people in the United States with diabetes, of which 17.9 million have been diagnosed, an increase of 2.8 million and 3.3 million, respectively, from 2005. The Centers for Disease Control and Prevention (CDC) estimates that approximately 4.8 million of these patients were treated with insulin. 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 the ADA, the direct medical costs and indirect expenditures attributable to diabetes in the United States were an estimated $174 billion in 2007, an increase of $42 billion since 2002. Of the $174 billion in overall expenses, the ADA estimates that approximately $116 billion were direct medical costs. According to industry sources, the worldwide market for personal glucose monitoring systems and related disposables, which include test strips and lancets, was approximately $6.2 billion in 2005, and is expected to grow to $8.9 billion during 2008.

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. We currently sell the SEVEN only in the United States, but plan to expand our sales into Europe and elsewhere in the future. In September 2008, we established a wholly owned subsidiary in Sweden and hired a Vice President of International Business Development to begin our expansion. To complement our direct sales efforts, we also employ clinical specialists who educate and provide clinical support in the field. We believe our direct, highly-specialized and focused sales organization is sufficient for us to support our sales efforts and have no immediate plans to increase the size of the sales organization.

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We are leveraging our technology platform to enhance the capabilities of our current products and to develop additional continuous glucose monitoring products. We are continuing clinical development of a third generation product which we expect will further improve sensor reliability, stability and accuracy over the useful life of the sensor, and will be more comfortable for patients to wear. We also intend to seek approval for pediatric indication (patients under 18 years of age) and pregnancy indication (patients with gestational diabetes) for our product platform in the future. In addition, we are developing a product platform specifically for the in-hospital glucose monitoring market, with an initial focus on the development of an intravenous sensor specifically for the critical care market. Despite our continued efforts in these areas, our development timelines are highly dependent on our clinical trials, which may be delayed due to scheduling issues with patients and investigators, institutional review boards, sensor performance and manufacturing supply constraints, among other factors. In addition, support of these clinical trials requires significant resources from employees involved in the production of our SEVEN, 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.

Since our first commercial launch in 2006, we have experienced periodic field failures. We do not believe these failures created any patient safety concerns and we are not aware of any reports of adverse events or incidents related to these failures. Although we believe we have taken appropriate actions aimed at reducing or eliminating field failures, there can be no assurances that we will not experience additional failures going forward.

As a medical device company, reimbursement from Medicare and private third-party healthcare payors is an important element of our success. Our SEVEN does not yet qualify for reimbursement by Medicare. Several private third-party payors have issued coverage policies for continuous glucose monitoring devices. In addition, we have negotiated contracted rates with three of the seven largest private insurance providers for the purchase of our products by their members. However, patients without insurance that covers our devices will have to bear the financial cost of our SEVEN. In order to establish widespread reimbursement or insurance coverage for our SEVEN, we believe that we need to develop an established base of users, gain the support of advocacy groups and show the benefits of our system through clinical data generated by clinical trials. On November 2, 2007, The Centers for Medicare and Medicaid, or CMS, released its 2008 Alpha-Numeric HCPCS File, which included three separate codes applicable to each of the three components of our continuous glucose monitoring systems, and HCPCS codes for continuous glucose monitoring became effective on January 1, 2008. HCPCS codes are billing codes used by Medicare and private third-party payors, but do not represent a reimbursement coverage decision by CMS. We currently employ in-house reimbursement expertise to assist physicians and patients in obtaining reimbursement from private third-party payors. We also maintain a field-based reimbursement team charged with calling on third-party private payors to obtain coverage decisions and contracts. We have had formal meetings and have increased our efforts to create coverage policies with third-party payors during 2008. However, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them.

We currently manufacture our devices at our headquarters in San Diego, California, and at another facility located nearby. In these facilities we have more than 5,000 square feet of laboratory space and approximately 5,000 square feet of controlled environment rooms. In January 2007, our facilities were subject to a post-approval PMA and QSR audit by the FDA. Based on the results of this inspection, we believe we are in substantial compliance with the regulatory requirements for a commercial medical device manufacturer and there were no major observations from the FDA resulting from this audit. At the close of the inspection, the FDA issued a Form 483 identifying several inspectional observations and, although we have no formal requirements or obligations to provide anything further to the FDA regarding these observations, we voluntarily provided formal written evidence to the FDA of our actions taken to address these minor observations. We manufacture our SEVEN with components supplied by outside vendors and with parts manufactured internally. Key components that we manufacture internally include the wire-based sensor for our SEVEN. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished product, which includes a reusable transmitter, a receiver and a disposable sensor. We are expanding our manufacturing capacity in our facilities in San Diego, California. Our capacity expansion could be constrained by the lack of material availability, equipment design, production and validation, regulatory approval of any required additional facilities, personnel staffing and other factors.

Revenues are generated from sales of our SEVEN transmitter and receiver and from the recurring sales of disposable sensors. The SEVEN s sensor is inserted by the patient and intended to be used continuously for up to seven days, after which it may be replaced with a new disposable sensor. Our SEVEN transmitter and receiver are reusable. In the event we establish an installed base of patients using our SEVEN, we expect to generate an increasing portion of our revenues through recurring sales of our disposable sensors. We recognize revenue on our products upon shipment and our sales terms provide for customer payment at the time of order.

From inception through September 30, 2008, we had generated $12.6 million of revenue, and we have incurred net losses in each year since our inception in May 1999. From inception through September 30, 2008, we had an accumulated deficit of $218 million. We expect our losses to continue and increase as we expand our clinical trial activities and continue commercialization activities. We have financed our operations primarily through offerings of equity securities and convertible debt. In April 2005, we completed our initial public offering in which we sold

4,700,000 shares of common stock for net proceeds of $50.5 million. In March 2006, we entered into a Loan Agreement, which was subsequently amended in January 2008. As of September 30, 2008, we had an outstanding balance of $3.9 million under the Loan Agreement. In May 2006, we completed a follow-on offering of 2,117,375 shares of our common stock for net proceeds of $47.0 million. In March 2007, we issued an aggregate principal amount of $60,000,000 in 4.75% Convertible Senior Notes due in 2027.

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Financial Operations

Revenue

From inception through September 30, 2008, we generated $12.4 million in 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 Corporation and recognize development grant revenue ratably over the term of the agreement. From inception through September 30, 2008, we recognized $122,000 in development grant revenue.

Cost of Sales

Product cost of sales includes direct labor and material costs related to each product sold or produced, including assembly and 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, stock based compensation, facility expense, supplies and purchased services. The majority of our costs are currently fixed due to the relatively low production volumes compared to our potential capacity. All of our manufacturing costs are included in cost of sales. Development cost of sales consists primarily of salaries, fringe, facilities, and supplies directly attributable to a contract.

Research and Development

Our research and development expenses primarily consist of engineering and research expenses related to our continuous glucose monitoring technology, clinical trials, regulatory expenses, materials and products for clinical trials. Until December 31, 2005 our manufacturing costs were included in research and development expense. Research and development expenses are primarily related to employee compensation, including salary, fringe benefits, stock based compensation, and temporary employee expenses. We also incur significant expenses to operate our clinical trials including trial design, clinical site reimbursement, data management, 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 stock 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 expenses for board meetings.

Results of Operations

Quarter Ended September 30, 2008 Compared to September 30, 2007

Revenue, Cost of Sales and Gross Margin

Product revenues increased $654,000 to $1.9 million for the third quarter of 2008 compared to $1.2 million for the third quarter of 2007 based primarily on increased sales volume. Product cost of sales increased $464,000 to $3.6 million for the third quarter of 2008 compared to $3.1 million for the third quarter of 2007. The increased product cost of sales associated with additional product sales was offset primarily by increased manufacturing absorption during the third quarter of 2008 as compared to the same period in 2007. The product gross margin loss of $1.7 million for the third quarter of 2008 decreased $191,000 compared to $1.9 million for the same period in 2007, primarily due to increased revenue and better direct labor utilization.

Development grant revenues totaled $42,000 for the third quarter of 2008 and development cost of sales totaled $263,000. There were no development grant revenues or development cost of sales generated during 2007. The increase in both revenues and costs associated with development was primarily due to our entry into a joint development agreement with Animas Corporation in the first quarter of 2008.

Research and Development. Research and development expense increased $1.7 million to $5.4 million for the third quarter of 2008, compared to $3.7 million for the third quarter of 2007. Changes in research and development expense include $1.1 million in higher development costs and $685,000 in higher clinical and regulatory and quality assurance costs. Major elements of increased research and development costs include $531,000 in additional consulting fees, $243,000 in increased facilities costs, and $216,000 in additional supplies.

Selling, General and Administrative. Selling, general and administrative expense increased $709,000 to $6.7 million for the third quarter of 2008, compared to $5.9 million for the third quarter of 2007. The increase was primarily due to higher general and administrative and marketing costs offset by lower sales costs. Major elements of increased selling, general, and administrative expenses include $498,000 in higher salaries and $196,000 in increased facilities costs, offset by $352,000 in lower sales commissions.

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Interest Income. Interest income decreased $799,000 to $215,000 for the third quarter of 2008, compared to $1.0 million for the third quarter of 2007. The decrease in interest income was primarily due to lower interest earning cash and marketable securities balances and lower yields during the third quarter of 2008 as compared to the third quarter of 2007.

Interest Expense. Interest expense totaled $913,000 for the third quarter of 2008, compared to $895,000 for the third quarter of 2007.

Nine Months Ended September 30, 2008 Compared to September 30, 2007

Revenue, Cost of Sales and Gross Margin

Product revenues increased $2.5 million to $5.6 million for the nine months ending September 30, 2008 compared to $3.1 million for the nine months ended September 30, 2007 based primarily on increased sales volume. Product cost of sales increased $752,000 to $9.8 million for the nine months ending September 30, 2008 compared to $9.1 million for the same period in 2007. The increased product cost of sales associated with additional product sales was offset by lower direct labor costs and increased manufacturing absorption during the nine months ending September 30, 2008 as compared to the same period in 2007. The product gross margin loss of $4.2 million for the nine months ending September 30, 2008 decreased $1.8 million compared to $6.0 million for the same period in 2007, primarily due to increased revenue and better direct labor utilization.

Development grant revenues totaled $122,000 for the nine months ending September 30, 2008 and development cost of sales totaled $643,000. There were no development grant revenues or development cost of sales generated during 2007. The increase in both revenues and costs associated with development was due to our entry into a joint development agreement with Animas Corporation in the first quarter of 2008.

Research and Development. Research and development expense increased $3.3 million to $15.1 million for the nine months ending September 30, 2008, compared to $11.7 million for the nine months ending September 30, 2007. Changes in research and development expense include $1.9 million in higher development costs and $1.4 million in higher clinical and regulatory and quality assurance costs. Major elements of increased research and development costs include $785,000 in additional consulting fees, $746,000 in additional facilities costs, and $361,000 in increased supplies.

Selling, General and Administrative. Selling, general and administrative expense increased $3.5 million to $20.3 million for the nine months ending September 30, 2008, compared to $16.8 million for the nine months ending September 30, 2007. The increase was primarily due to additional sales and general and administrative costs. Major elements of increased selling, general, and administrative expenses include $1.3 million in higher share-based compensation, $567,000 in additional facilities costs, and $502,000 in additional salaries.

Interest Income. Interest income decreased $1.8 million to $1.1 million for the nine months ending September 30, 2008, compared to $2.9 million for the nine months ending September 30, 2007. The decrease in interest income was primarily due to lower interest earning cash and marketable securities balances and lower yields during the nine months ending September 30, 2008 as compared to the same period in 2007.

Interest Expense. Interest expense increased $650,000 to $2.7 million for the nine months ending September 30, 2008, compared to $2.1 million for the nine months ending September 30, 2007. The increase in expense was primarily due to our $60 million in convertible notes that was outstanding for the entire nine months ending September 30, 2008 compared to being outstanding during a shorter period of time in the nine months ending September 30, 2007 following the issuance in March of 2007.

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, 2008, we had an accumulated deficit of $218.0 million and had working capital of $22.0 million. Our cash, cash equivalents and short-term marketable securities totaled $25.4 million, excluding $4.8 million in restricted cash. We have funded our operations primarily from the sale of equity and debt securities and our bank line, raising aggregate net proceeds of $169 million from equity sales and $46.3 million from debt sales through September 30, 2008. As of September 30, 2008 we had a total of $3.9 million outstanding under our amended bank equipment loan that we are required to repay through July 2011.

***Net Cash Used in Operating Activities*.** Net cash used in operating activities increased $14.0. million to $40.0 million for the nine months ending September 30, 2008, compared to $26.0 million net cash used for the same period in 2007. The increase in cash used in operations was primarily due to $8.1 million in changes in operating assets and liabilities and $8.1 million in additional net loss, offset by $2.3 million in additional non-cash charges primarily comprised of share-based compensation. Of the $8.1 million in changes in operating assets and liabilities, $3.9 million was due to additional restricted cash requirements and $1.8 million was due to additional on hand inventory in anticipation of

moving manufacturing operations to our new production facility and to meet forecasted sales.

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Net Cash Provided By Investing Activities. Net cash provided by investing activities was $18.3 million for the nine months ending September 30, 2008, compared to $23.8 million used for the same period of 2007. The increase in cash provided by investing activities was primarily due to $30.4 million decrease in cash used to purchase available-for-sale marketable securities offset by $12.9 million in additional proceeds from the maturities of short-term marketable securities for the nine months ending September 30, 2008 as compared to the same period in 2007. For the nine months ending September 30, 2008, we invested $2.1 million in equipment to support manufacturing improvements compared to $848,000 during the same period in 2007.

***Net Cash Provided by Financing Activities*.** Net cash provided by financing activities decreased $43.6 million to $3.2 million for the nine months ending September 30, 2008, compared to $46.8 million for the same period of 2007. The decrease was primarily due to the $46.4 million in net convertible debt proceeds generated for the nine months ending September 30, 2007 compared to none in the same period of 2008.

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 commercialize 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, projected cash contributions from future partnership arrangements, and cost reduction actions will be sufficient to meet our anticipated cash requirements with respect to the scale-up of our commercialization, clinical trials, research and development activities, PMA applications and to meet our other anticipated cash needs through at least September 2009. There can be no assurance that we will be successful in obtaining additional cash contributions from future partnership arrangements. 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. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

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

- the revenue generated by sales of our approved products and other future products;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- the quality levels of our products and services;
- the third party reimbursement of our products for our customers;
- our ability to efficiently scale our manufacturing operations to meet demand for our current and any future products;
- the costs and timing 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 production and research and development activities. As of September 30, 2008, we had purchase commitments with certain vendors totaling approximately $3.7 million due within one year. There are no purchase commitments due beyond one year.

Off-Balance Sheet Arrangements

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

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Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our 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. Components are individually priced and can be purchased separately or together. The SEVEN durable system includes a transmitter, a receiver, a power cord, a finger-stick meter interface cable, data management software and a USB cable. Disposable sensors for use with the SEVEN are sold separately in packages of four. The initial SEVEN durable system price is not dependent upon the purchase of any amount of disposable SEVEN sensors. We discontinued sales of our STS three day durable system in the second quarter of 2007 and we discontinued the sale of our three day sensors during the second quarter of 2008.

Revenue on product sales is recognized upon shipment, which is when title and the risk of loss have been transferred to the customer and there are no other post-shipment obligations. With respect to customers who directly pay for the products, the products are generally paid for at the time of shipment using a customer s credit card and do not include customer acceptance provisions. We recognize revenue from contracted insurance payors based on the contracted rate. We recognize revenue from non-contracted insurance payors based on the estimated collectible amount and historical experience. After approval of our second generation continuous glucose monitoring system, the SEVEN, on May 31, 2007, we started taking orders for an Upgrade Kit to upgrade existing customers for $150. Before the Upgrade Kit became available for shipment, for systems sold that included an upgrade right, a portion of the sales price was allocated to the undelivered Upgrade Kit and deferred based on the fair value of the Upgrade Kit. This deferred revenue was recognized when the Upgrade Kit was delivered to the customer. Deferred product revenue as of September 30, 2008 totaled approximately $1,000. In August 2007, we adopted a 30-day money back guarantee program whereby customers who purchase the SEVEN durable system and a package of four disposable sensors may return the SEVEN durable system for any reason within thirty days of purchase and receive a full refund of their purchase price. We accrue for estimated returns and/or refunds by reducing revenues and establishing a liability account at the time of shipment based on historical experience. During 2008, we entered into distribution agreements that allow the distributors to sell our durable systems and disposable units. With respect to one distributor, we shipped product directly to the distributor s customers and recognized $416,000 and $610,000 in revenue for the three and nine months ending September 30, 2008.

During the first quarter of 2008, we entered into a development agreement which provided us with a development grant. Revenue from development grants is recognized ratably over the life of the development agreements when all conditions for revenue recognition have been met as outlined in Staff Accounting Bulletin 104 and Emerging Issues Task Force (EITF) 00-21 *Revenue with Multiple Element Arrangements*. As of September 30, 2008, we had $378,000 in deferred revenue relating to our development agreement.

Share-Based Compensation

On January 1, 2006, we adopted SFAS 123(R), using the modified prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants including employee stock options and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values. As permitted by SFAS 123(R), we utilize the Black-Scholes option-pricing model as the method of valuation for share-based awards granted. Share-based compensation expense recognized under SFAS 123(R) for the three and nine months ending September 30, 2008 was $1.8 million and $5.7 million, respectively, compared to $1.7 million and $4.2 million, respectively, for the three and nine months ending September 30, 2007. As of September 30, 2008, there was $20.0 million of unrecognized compensation cost related to outstanding options that is expected to be recognized as a component of our operating expenses through 2012. Compensation costs will be adjusted for future changes in estimated forfeitures. Prior to January 1, 2006, we had adopted the disclosure-only provision of SFAS 123 as discussed further in our annual report on Form 10-K. Accordingly, we had not previously recognized compensation expense, except for share-based compensation expense accounted for in

accordance with APB 25.

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Foreign Currency

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

Income Taxes

In July 2006, the FASB issued FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes*, or FIN 48, 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, FIN 48 provides guidance 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 FIN 48.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. In February 2008, the FASB deferred the effective date of SFAS 157 by one year for certain non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). On January 1, 2008, we adopted the provisions of SFAS 157, except as it applies to those nonfinancial assets and nonfinancial liabilities for which the effective date has been delayed by one year.

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

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

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

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

The adoption of SFAS 157 did not have a material effect on our financial position or results of operations. 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.

Effective January 1, 2008 the we adopted Statement of Financial Accounting Standard No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, Including an Amendment of FASB Statement No. 115*. This Standard permits us to choose to measure many financial instruments and certain other items at fair value and established presentation and disclosure requirements. In adopting this Standard, we did not elect to measure any new assets or liabilities at their respective fair values.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force Issue 07-1, *Accounting for Collaborative Arrangements*. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*. EITF 07-1 will be effective for the Company beginning on January 1, 2009. The adoption of EITF 07-1 is not expected to have a material effect on our financial statements.

In May 2008, the FASB issued FASB Staff Position (FSP) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. The FSP requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability and equity components of the instrument. The debt would be recognized at the present value of its cash flows discounted using the Company s nonconvertible debt borrowing rate. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The FSP also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The effective date of the FSP is for financial statements issued for fiscal years beginning after December 15, 2008. We believe the convertible debt issued in March 2007 falls under the FSP and we will be required to retroactively apply the guidance. Although we have not completed our analysis of the impact of this guidance, we believe the application would cause a reduction to the carrying value of the debt on our balance sheet and a corresponding increase in non-cash interest expense to be recognized over the initial five year redemption period which could be significant.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

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

Foreign Currency Risk

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Regulations under the Securities Exchange Act of 1934 require public companies to maintain disclosure controls and procedures, which are defined to mean a company s controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is 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 the 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 (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 the 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. In late 2006, the Patent Office issued a non-final rejection of all claims we submitted for reexamination in two of the Abbott patents cited in the original lawsuit. In both cases, Abbott has filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art presented by us, seeking to amend certain claims to

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overcome the prior art presented by us, and seeking to add new claims. In response, we filed a second reexamination request with the Patent Office challenging each of Abbott s proposed amendments and in October 2007 the Patent Office ordered reexamination of each of the second reexamination requests. In early 2008, the Patent Office issued a non-final rejection of all claims we submitted for reexamination in the other two patents cited in the original complaint. In both cases, Abbott filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art we have presented, seeking to amend certain claims to overcome the prior art we have presented, and seeking to add new claims. The Patent Office subsequently issued final rejections of all claims we submitted for reexamination for both patents. In October 2008, Abbott filed a response to the final rejections in one of the two reexaminations and we submitted second reexamination requests for these two patents.

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. We believe this complaint, like the first, is without merit and we intend to vigorously contest the action. To that end, we filed requests with the Patent Office to reexamine each of the three additional patents cited by Abbott and 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. 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 February 2007, the Patent Office ordered reexamination of each of the three patents cited in this new lawsuit and in June 2007, the Patent Office issued a non-final rejection of all claims we submitted for reexamination in two of the Abbott patents cited in the new lawsuit. In each of these cases, Abbott filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art we have presented, seeking to amend certain claims to overcome the prior art we have presented, and seeking to add new claims. In response, we filed a second reexamination request with the Patent Office challenging each of Abbott s proposed amendments and by February 2008, the Patent Office had ordered reexamination of each of the second reexamination requests, one of which is under final rejection as of October 2008. Abbott has responded to the final rejection by filing an after final amendment. In March 2008, the Patent Office issued a Notice of Intent to Issue a Reexamination Certificate, confirming the claims of the third of the additional three patents asserted by Abbott. In response, we filed another reexamination request on this patent, which was ordered in June of 2008. In October of 2008 the Patent Office issued a non-final Office Action, rejecting claims 1-3 but confirming patentability of claim 4. In response, we are preparing to file a subsequent reexamination request with the Patent Office.

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

ITEM 1A. RISK FACTORS

Factors that May Affect our Financial Condition and Results of Operations

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

We are a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems for people with diabetes. On March 24, 2006, we received approval from the FDA for our first product, the STS, designed for up to three days of continuous use. On May 31, 2007, we received approval from the FDA for our second generation continuous glucose monitoring system, the SEVEN, designed for up to seven days of continuous use, and we began commercializing this product in the third quarter of 2007. As part of our commercialization of the SEVEN, we discontinued sales of our STS three-day durable system in the second quarter of 2007 and discontinued the sale of our three day sensors during the second quarter of 2008. Since inception, we have devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. More recently, we have devoted considerable resources to the commercialization of the SEVEN as well as the continued clinical development of our technology platform. We expect that sales of our SEVEN, which consists of a handheld receiver, reusable transmitter and disposable sensor, will account for substantially all of our revenue for the foreseeable future. From inception through September 30, 2008, revenues from sales of our continuous glucose monitoring products total approximately $12.4 million. However, we have limited experience in selling our products and we might be unable to successfully commercialize our products for a number of reasons, including:

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

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

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- patients do not generally receive reimbursement from third-party payors for their purchase of our products, which may reduce widespread use of our products;
- our inexperience in marketing, selling and distributing our products;
- we may not have adequate financial or other resources to successfully commercialize our products;
- the uncertainties associated with establishing and qualifying new manufacturing facilities;
- our products are 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 products in addition to single-point finger stick devices;
- the introduction and market acceptance of competing products and technologies;
- our inability to obtain sufficient quantities of supplies at appropriate quality levels from our sole source and other key suppliers; and
- rapid technological change may make our technology and our products obsolete.

Our products are 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 long-term clinical evidence to convince them to alter their existing treatment methods, (ii) there are recommendations from prominent physicians that our products are effective in monitoring glucose levels and (iii) reimbursement or insurance coverage is widely available. We cannot predict when, if ever, physicians and patients may adopt the use of our products. If our products do 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.

Since our first commercial launch in 2006, we have experienced periodic field failures. We do not believe these failures created any patient safety concerns and we are not aware of any reports of adverse events or incidents related to these failures. Although we believe we have taken appropriate actions aimed at reducing or eliminating field failures, there can be no assurances that we will not experience additional failures going forward.

Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.

In March 2007, we issued an aggregate principal amount of $60,000,000 in 4.75% Convertible Senior Notes due in 2027. The level of our indebtedness, among other things, could:

- require us to dedicate a portion of our expected cash flow or our existing cash to service our indebtedness, which would reduce the amount of our cash available for other purposes, including working capital, capital expenditures and research and development expenditures;

make it difficult for us to incur additional debt or obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;

limit our flexibility in planning for or reacting to changes in our business;

limit our ability to sell ourselves or engage in other strategic transactions;

make us more vulnerable in the event of a downturn in our business; or

place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have greater access to capital resources.

If we fail to generate sufficient revenue due to any of the factors described in this section entitled Risk Factors, or otherwise, we could have difficulty paying amounts due on our indebtedness. Although the convertible senior notes mature in 2027, the holders of the convertible senior notes may require us to repurchase their notes prior to maturity under certain circumstances, including specified fundamental changes such as the sale of a majority of the voting power of the company. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of the convertible senior notes, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any other indebtedness that we may have outstanding at such time. Any default under our indebtedness could have a material adverse effect on our business, operating results and financial condition.

Conversion of the convertible senior notes will dilute the ownership interests of existing stockholders.

The terms of the convertible senior notes permit the holders to convert the notes into shares of our common stock. The convertible senior notes are convertible into our common stock initially at a conversion price of $7.80 per share, which would result in an aggregate of approximately 7.7 million shares of our common stock being issued upon conversion, subject to adjustment upon the occurrence of specified events, provided that the total number of shares of common stock issuable upon conversion, as may

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be adjusted for fundamental changes or otherwise, may not exceed approximately 9.2 million shares. The conversion of some or all of the convertible senior notes will dilute the ownership interest of our existing stockholders. Any sales in the public market of the common stock issuable upon conversion could adversely affect prevailing market prices of our common stock.

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 $41.7 million for the nine months ended September 30, 2008. As of September 30, 2008, we had an accumulated deficit of $218.0 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, and more recently, we have incurred significant sales and marketing and manufacturing expenses associated with the commercialization of our products. 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. We also expect that our general and administrative expenses will continue to increase due to the additional operational and regulatory burdens applicable to public 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 and may adversely affect our ability to pay interest on, and principal of, the convertible senior notes.

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 recently deteriorated significantly in the United States and other countries, and may remain depressed for the foreseeable future. These conditions may make it difficult for our customers and potential customers to afford our products, and could cause our customers to stop using our products or to use them less frequently. If that were to occur, we would experience a decrease in revenue and our performance would be negatively impacted. We cannot predict the timing, strength or duration of any economic slowdown or subsequent economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect our financial condition and operating results.

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 continuous glucose monitoring products, our business may be harmed.

To achieve commercial success for our products, we must continue to develop and grow our sales and marketing organization and enter into arrangements with others to market and sell our products. We currently employ a small direct sales force to market our products in the United States. Our sales organization competes with the experienced and well-funded marketing and sales operations of our competitors. We have also entered into distribution arrangements to leverage existing distributors already engaged in the diabetes marketplace. Because of the competition for their services, we may be unable to recruit or retain additional qualified distributors. Further, we may not be able to enter into agreements with distributors on commercially reasonable terms, if at all.

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 sales personnel;
- effectively train our sales personnel in the benefits of our products;
- establish and maintain successful sales and marketing and education programs that encourage endocrinologists, physicians and diabetes educators to recommend our products to their patients; and
- manage geographically disbursed sales and marketing operations.

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

We have contracted with third parties to market and sell our products in the United States to access the existing bases of diabetes patients of certain distributors. To the extent that we enter into additional arrangements with third parties to perform sales, marketing, distribution and billing services in the United States, 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 do not know whether these efforts will be successful. 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 product revenue and may not become profitable.

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing capabilities are insufficient to produce an adequate supply of products 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 for our products. We have had difficulty scaling our manufacturing operations to provide a sufficient supply of product to support our commercialization efforts. We have also experienced periods of backorder and, at times, have had to limit the

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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 going forward. In order to produce our products in the quantities we anticipate will be necessary to meet market demand, we will need to increase our manufacturing capacity by a significant factor over the current level. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, materials procurement, 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, such as construction timelines, design, installation and maintenance of manufacturing equipment, among others, which can lead to unexpected delays. In addition, 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 in a lot. 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.

Our products do not have broad reimbursement and receive only limited insurance coverage by third party payors. If we are unable to obtain adequate reimbursement at acceptable prices for our 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. Our SEVEN does not yet qualify for reimbursement by Medicare. Several private third-party payors have issued coverage policies for continuous glucose monitoring devices. In addition, we have negotiated contracted rates with three of the seven largest private insurance providers for the purchase of our products by their members. However, patients without insurance that covers our devices will have to bear the financial cost of the SEVEN. On November 2, 2007, the Centers for Medicare and Medicaid (CMS) released its 2008 Alpha-Numeric HCPCS File which included three separate codes applicable to each of the three components of our continuous glucose monitoring system and HCPCS codes for continuous glucose monitoring became effective on January 1, 2008. HCPCS codes are billing codes used by Medicare and private third-party payors, but do not represent a reimbursement coverage decision by CMS. 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 coverage and reimbursement is widely available for patients that use our products. 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 reimbursement arrangements, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Our initial dependence on the commercial success of our products 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 our products, patients may not use it.

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.

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 the receiver included as part of our continuous glucose monitoring systems and the circuit boards for our short-term sensors; we rely on AMI Semiconductor, Inc. to manufacture and supply the application specific integrated circuit, or ASIC, that is incorporated into the transmitter for our continuous glucose monitoring systems; we rely on The Polymer Technology Group 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 sole-source supplier. In some cases, our agreements with these and our other suppliers can be terminated by either party upon short

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notice. Our contract manufacturers also rely on sole-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing due to 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. 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 sole-source supplies;
- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, including those related to changes in global economic conditions, which could inhibit their ability to fulfill our orders and meet our requirements.

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

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

On August 11, 2005, Abbott Diabetes Care, Inc., or Abbott, filed a patent infringement lawsuit against us in the United States District Court for the District of Delaware, seeking a declaratory judgment that our continuous glucose monitor infringes certain patents held by Abbott. In August 2005, we moved to dismiss these claims and filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office (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. In late 2006, the Patent Office issued a non-final rejection of all claims we submitted for reexamination in two of the Abbott patents cited in the original lawsuit. In both cases, Abbott has filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art that we have presented, seeking to amend certain claims to overcome the

prior art that we have presented, and seeking to add new claims. In response, we filed a second reexamination request with the Patent Office challenging each of Abbott s proposed amendments and in October 2007, the Patent Office ordered reexamination of each of the second reexamination requests. In early 2008, the Patent Office issued a non-final rejection of all claims we have submitted for reexamination in the other two patents cited in the original complaint. In both cases, Abbott filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art we have presented, seeking to amend certain claims to overcome the prior art we have presented, and seeking to add new claims. The Patent Office subsequently issued final rejections of all claims we submitted for reexamination for both patents. In October 2008, Abbott filed a response to the final rejections in one of the two reexaminations and we submitted second reexamination requests for these two patents.

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. We believe this complaint, like the first, is without merit and we intend to vigorously contest the action. To that end, we filed requests with the Patent Office to reexamine each of the three additional patents cited by Abbott and 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. On September 30, 2007, the court granted our motion to consolidate the cases and stay the entirety of the case pending

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conclusion of the reexamination proceedings in the Patent Office relating to all seven patents asserted against us. In February 2007, the Patent Office ordered reexamination of each of the three patents cited in this new lawsuit and in June 2007, the Patent Office issued a non-final rejection of all claims we submitted for reexamination in two of the Abbott patents cited in the new lawsuit. In each of these cases, Abbott filed a response with the Patent Office seeking claim construction to differentiate certain claims from the prior art we have presented, seeking to amend certain claims to overcome the prior art we have presented, and seeking to add new claims. In response, we filed a second reexamination request with the Patent Office challenging each of Abbott s proposed amendments and by February 2008, the Patent Office had ordered reexamination of each of the second reexamination requests, one of which is under final rejection as of October 2008. Abbott has responded to the final rejection by filing an after final amendment. In March 2008, the Patent Office issued a Notice of Intent to Issue a Reexamination Certificate, confirming the claims of the third of the additional three patents asserted by Abbott. In response, we filed another reexamination request on this patent, which was ordered in June of 2008. In October of 2008 the Patent Office issued a non-final Office Action, rejecting claims 1-3 but confirming patentability of claim 4. In response, we are preparing to file a subsequent reexamination request with the Patent Office.

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

Although it is our position that Abbott s assertions of infringement have no merit, and that the potential interference and reexamination requests have no merit, neither the outcome of the litigation nor the amount and range of potential fees associated with the litigation, potential interference or reexamination requests can be assessed. No assurances can be given that we will prevail in the lawsuit or that we can successfully defend ourselves against the claims made by Abbott, and we expect to incur significant costs in defending the action, which could have a material adverse effect on our business and our results of operations regardless of the final outcome of such litigation. Subject to the stay, Abbott could immediately seek a preliminary injunction that, if granted, would force us to stop making, using, selling or offering to sell our products. Our SEVEN is our only current product that is approved for commercial sale, and if we were forced to stop selling it, our business and prospects would suffer. We cannot assure you that Abbott will not file for a preliminary injunction, that we would be successful in defending against such an action if filed or that we can successfully defend ourselves against the claim. In addition, defending against this action could have a number of harmful effects on our business, including those discussed in the following risk factor, regardless of the final outcome of such litigation.

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.

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.

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

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

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

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

The federal trademark application for the DEXCOM mark has been opposed, and we continue to vigorously defend against the opposition. The opposition proceeding only determines the right to federally register a trademark and cannot result in the award of any damages. We believe that we are entitled to a registration for our DEXCOM mark, but cannot assure you that we will succeed in these efforts. If we are unsuccessful, we could be forced to change our company name or market our products under a different name, which could result in a loss of brand recognition, could require us to retrieve product and interrupt supply and could require us to devote substantial resources to advertising and marketing our products under the new brand.

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 our products, 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 DexCom, three other companies, Cygnus, Medtronic and Abbott, have received approval from the FDA for continuous glucose monitors. We believe that one of the products, originally developed and marketed by Cygnus, is no longer actively marketed. In addition, we believe that Johnson & Johnson, Roche Diagnostics and others are developing invasive and non-invasive continuous glucose monitoring systems. Most of the companies developing or marketing competing devices are publicly traded or divisions of publicly-traded companies, and these companies enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;

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

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

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

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

We enter into collaborations with third parties 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 Corporation and Insulet Corporation, to integrate our receiver technology into their respective insulin delivery systems. 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.

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No continuous glucose monitoring system, including our products, has yet received FDA clearance as a replacement for single-point finger stick devices, and our products may never be approved for that indication.

Our products do 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 replacement claim labeling and we cannot assure you that we will not experience delays if we do file. If any of our competitors were to obtain replacement claim labeling for a continuous glucose monitoring system, our products may not be able to compete effectively against that system and our business would suffer.

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

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

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

Before submitting any additional PMA applications, we must successfully complete pre-clinical studies and clinical trials that we believe will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the studies and trial may be inadequate to support approval of a PMA application. 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 application, even if the trial s intended safety and efficacy endpoints are achieved.

The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA 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;

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;

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 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.

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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, we will be unable to obtain regulatory approval to market our products. 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.

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

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

We have not received, and may never receive, FDA approval to market our continuous glucose monitoring systems that are under development.

We are continuing to invest in the development of our technology platform and will seek to obtain FDA approvals for continuous glucose monitoring systems under development, including an intravenous continuous glucose monitoring system for the in-hospital market. The regulatory approval process for these continuous glucose monitoring systems that are under development involves, among other things, successfully completing clinical trials and obtaining either prior 510(k) clearance or prior approval from the FDA through the PMA process. The PMA process requires us to prove the safety and efficacy of our continuous glucose monitoring systems to the FDA s satisfaction. This process can be expensive and uncertain, requires detailed and comprehensive scientific and human clinical data, generally takes one to three years after a PMA application is filed and may never result in the FDA granting a PMA. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- 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, our continuous glucose monitoring systems under development may not be approved for the indications that are necessary or desirable for successful commercialization. We may not obtain the necessary regulatory approvals to market these continuous glucose monitoring systems in the United States or anywhere else. Any delay in, or failure to receive or maintain, approval for our continuous glucose monitoring systems under development could prevent us from generating revenue from these products or achieving profitability.

We may be unable to continue the commercialization of our products or the development and commercialization of our other continuous glucose monitoring systems without additional funding.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on commercializing our products, including further development of our direct sales force and expansion of our manufacturing capacity, and on

research and development, including conducting clinical trials for our next generation continuous glucose monitoring systems. For the nine months ended September 30, 2008, our net cash used in operating activities was $40.0 million, compared to $26.0 million for the same period in 2007, and as of September 30, 2008, we had working capital of $22.0 million, including $25.4 million in cash, cash equivalents and short-term marketable securities. We expect that our cash used by operations will increase significantly in each of the next several years, and we may need additional funds to continue the commercialization of our products and for the development and commercialization of other continuous glucose monitoring 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 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;

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- the costs and timing of additional regulatory approvals;
- 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 marketing, customer support or other resources devoted to our products. Any of these factors could harm our financial condition.

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

If unanticipated long-term side-effects result from the use of our current products or other glucose monitoring systems under development, we could be subject to liability and our systems would not be widely adopted. Our clinical trials have been limited to seven days of continuous use with our products. 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 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, quality assurance, labeling, packaging, storage, shipping and servicing of our products. The FDA enforces the QSR through unannounced inspections. We currently manufacture our devices at our headquarters facility in San Diego, California and at another facility nearby. In these facilities we have more than 5,000 square feet of laboratory space and approximately 5,000 square feet of controlled environment rooms. In January 2007, our facilities were subject to a post-approval PMA and QSR audit by the FDA. Based on the results of this inspection, we believe we are in substantial compliance with the regulatory requirements for a commercial medical device manufacturer and there were no major observations from the FDA resulting from this audit. At the close of the inspection, the FDA issued a Form 483 identifying several inspectional observations and, although we had no formal requirements or obligations to provide anything further to the FDA regarding these observations, in April 2007 we voluntarily provided formal written evidence to the FDA of our actions taken to address these minor observations. In addition, our method of wireless communication from the transmitter to the receiver may be affected by regulatory amendments. Medtronic has filed a petition with the FCC requesting the FCC establish a bifurcated MICS band which would require 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 does not comply with existing MICS band listen-before-transmit requirements, the FCC determined that the likelihood of our device causing interference is low, which was the basis for the FCC s issuance of a waiver from these requirements. Our waiver includes a one year grace period to conform with any new rules adopted by the FCC with respect to the use of the MICS band. If the FCC does create a separate spectrum and does not extend our waiver to allow us to continue to operate in the main MICS band, we may be required to re-engineer our product to transmit over a different frequency which may require changes to our regulatory approvals and may have an adverse impact on the operation of our products. 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;

fines and civil penalties;

unanticipated expenditures;

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- delays in approving or refusal to approve our continuous glucose monitoring systems;
- 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 MDRs are generally underreported and any underlying problems could be of a larger magnitude than suggested by the number or types of MDRs we receive. 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 of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and 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, 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.

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 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 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.

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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 relating to:

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

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

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

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 plan to begin marketing our products in Europe 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

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approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States on a timely basis, or at all.

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

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

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

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

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission, or SEC, will result in increased costs to us as we evaluate the implications of any new rules and regulations and respond to new requirements under such rules and regulations. We are required to comply with many of these rules and regulations, and will be required to comply with additional rules and regulations in the future. As an early commercialization stage company with limited capital and human resources, we will need to divert management s time and attention away from our business in order to ensure compliance with these regulatory requirements. This diversion of management s time and attention may have a material adverse effect on our business, financial condition and results of operations.

Valuation of share-based payments, which we are required to perform for purposes of recording compensation expense under SFAS 123(R), involves significant assumptions that are subject to change and difficult to predict.

On January 1, 2006, we adopted SFAS 123(R), which requires that we record compensation expense in the statement of income for share-based payments, such as employee stock options, using the fair value method. The requirements of SFAS 123(R) 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.

SFAS 123(R) 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.

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For those reasons, among others, SFAS 123(R) 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.

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

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

In May 2008, the FASB issued FASB Staff Position (FSP) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. The FSP requires the issuer of certain convertible debt instruments that may be settled in cash (or other assets) on conversion to separately account for the liability and equity components of the instrument. The debt would be recognized at the present value of its cash flows discounted using the Company s nonconvertible debt borrowing rate. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The FSP also requires an accretion of the resultant debt discount over the expected life of the debt. The transition guidance requires retrospective application to all periods presented, and does not grandfather existing instruments. The effective date of the FSP is for financial statements issued for fiscal years beginning after December 15, 2008. We believe the convertible debt issued in March 2007 falls under the FSP and we will be required to retroactively apply the guidance. Although we have not completed our analysis of the impact of this guidance, we believe the application would cause a reduction to the carrying value of the debt on our balance sheet and a corresponding increase in non-cash interest expense to be recognized over the initial five year redemption period which could be significant.

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

In March of 2006, we entered into our Loan Agreement that provided for a loan to finance various equipment and leasehold improvement expenses. In January of 2008, we amended our Loan Agreement to enable us to draw an additional $3.0 million. We are required to repay this additional amount between April 2008 and July 2011. As of September 30, 2008, we had a total outstanding loan balance under the Loan Agreement of $3.9 million. The Loan Agreement requires us to maintain a minimum cash balance with Square 1 Bank, and also imposes certain limitations on us, including limitations on our ability to:

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

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

relocate our chief executive offices or state of incorporation;

change our legal name or fiscal year;

replace our chief executive officer or chief financial officer;

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

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

incur additional indebtedness, with certain exceptions;

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

pay dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock, other than repurchases of the stock of former employees;

directly or indirectly acquire or own, or make any investment in, any persons, with certain exceptions;

directly or indirectly enter into or permit to exist any material transaction with any affiliates except such transactions that are in the ordinary course of business that are done upon fair and reasonable terms that are no less favorable to us than would be obtained in an arm s length transaction with a non-affiliated company;

make any payment in respect of any subordinated debt, or permit any of our U.S. domestic subsidiaries to make any such payment, except in compliance with the terms of such subordinated debt; or

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store any equipment or inventory in which the lender has any interest with any bailee, warehousemen or similar third party unless the third party has been notified of the lender s security interest, or

become or be controlled by an investment company.

Complying with these covenants may make it more difficult for us to successfully execute our business strategy and compete against companies who are not subject to such restrictions.

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Date of First Filing**	**Exhibit Number**	**Provided Herewith**
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).					X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*					X

32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*	X

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

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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 10, 2008

By: /s/ Terrance H. Gregg
Terrance H. Gregg,
President and Chief Executive Officer

Dated: November 10, 2008

By: /s/ Jess Roper
Jess Roper,
Chief Financial Officer