

DEXCOM INC  
Form 10-Q  
October 23, 2006

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10 - Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the quarterly period ended September 30, 2006**

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

**For the transition period from** \_\_\_\_\_ **to** \_\_\_\_\_  
**Commission file number 000-51222**

**DEXCOM, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or Other Jurisdiction of

Incorporation or Organization)

**33-0857544**

(I.R.S. Employer

Identification No.)

**5555 Oberlin Drive**

**San Diego, California**

(Address of Principal Executive offices)

**92121**

(Zip Code)

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

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

Yes  No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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Yes  No

As of October 10, 2006, 28,103,817 shares of the Registrant's common stock were outstanding.

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## DexCom, Inc.

## BALANCE SHEETS

	September 30, 2006 (unaudited)	December 31, 2005
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 23,202,979	\$ 37,247,064
Short-term marketable securities, available-for-sale	41,474,292	13,277,688
Accounts receivable, net	119,221	
Inventory	1,937,111	
Prepaid and other current assets	1,210,043	488,015
Total current assets	67,943,646	51,012,767
Property and equipment, net	6,678,480	5,463,491
Restricted cash	914,000	250,000
Total assets	\$ 75,536,126	\$ 56,726,258
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 3,064,669	\$ 6,008,194
Accrued payroll and related expenses	2,416,667	889,362
Accrued clinical trials	546,710	176,540
Current portion of long-term debt	540,000	
Total current liabilities	6,568,046	7,074,096
Deferred rent	462,462	240,099
Long-term debt, net of current portion	2,160,000	
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively.		
Common stock, \$0.001 par value, 100,000,000 authorized; 28,102,341 and 25,416,559 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively.		
Additional paid-in capital	28,102	25,417
Deferred stock-based compensation	185,615,369	134,257,379
Accumulated other comprehensive income (loss)	(1,084,214)	(11,928)
Accumulated deficit	2,386	(83,774,591)
Total stockholders' equity	(119,300,239)	(83,774,591)
Total liabilities and stockholders' equity	66,345,618	49,412,063
	\$ 75,536,126	\$ 56,726,258

See accompanying notes to financial statements

## DexCom, Inc.

## STATEMENTS OF OPERATIONS

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2006	2005	September 30, 2006	2005
Revenues	\$ 841,020	\$	\$ 1,334,873	\$
Cost of sales	3,388,675		7,560,439	
Gross margin	(2,547,655 )		(6,225,566 )	
Operating expenses:				
Research and development	4,634,157	5,042,993	15,489,662	15,823,638
Selling, general and administrative	7,073,768	1,818,060	15,847,567	4,001,313
Total operating expenses	11,707,925	6,861,053	31,337,229	19,824,951
Interest and other income	817,809	531,432	2,037,147	1,125,147
Net loss	(13,437,771 )	(6,329,621 )	(35,525,648 )	(18,699,804 )
Accretion to redemption value of Series B, Series C, and Series D redeemable convertible preferred stock				(122,232 )
Net loss attributable to common stockholders	\$ (13,437,771 )	\$ (6,329,621 )	\$ (35,525,648 )	\$ (18,822,036 )
Basic and diluted net loss per share attributable to common stockholders				
	\$ (0.48 )	\$ (0.25 )	\$ (1.32 )	\$ (1.12 )
Shares used to compute basic and diluted net loss per share attributable to common stockholders				
	28,068,427	25,354,432	26,938,509	16,777,470

See accompanying notes to financial statements

## DexCom, Inc.

## STATEMENTS OF CASH FLOW

(unaudited)

	Nine Months Ended	
	September 30, 2006	2005
<b>Operating activities</b>		
Net loss	\$ (35,525,648 )	\$ (18,699,804 )
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,626,121	686,242
Share-based compensation	4,363,537	1,371,077
Accretion and amortization related to investments, net	(269,018 )	(20,874 )
Compensation expense associated with stock options issued to consultants		98,058
Changes in operating assets and liabilities:		
Inventories	(1,937,111 )	
Accounts receivable	(119,221 )	
Prepaid and other assets	(363,420 )	(726,491 )
Restricted cash	(664,000 )	(50,000 )
Accounts payable and accrued liabilities	(2,623,355 )	891,957
Accrued payroll and related expenses	1,527,305	438,433
Deferred rent	222,363	116,767
Net cash used in operating activities	(33,762,447 )	(15,894,635 )
<b>Investing activities</b>		
Purchase of available-for-sale marketable securities	(55,170,880 )	(26,624,534 )
Proceeds from the maturity of available-for-sale marketable securities	26,899,000	9,080,000
Purchase of property and equipment	(2,841,110 )	(2,394,815 )
Net cash used in investing activities	(31,112,990 )	(19,939,349 )
<b>Financing activities</b>		
Net proceeds from issuance of common stock	48,131,352	50,724,069
Proceeds from equipment loan	2,700,000	
Net cash provided by financing activities	50,831,352	50,724,069
Increase (decrease) in cash and cash equivalents	(14,044,085 )	14,890,085
Cash and cash equivalents, beginning of period	37,247,064	27,229,208
Cash and cash equivalents, ending of period	\$ 23,202,979	\$ 42,119,293
<b>Non-cash investing and financing transactions:</b>		
Conversion of Series A, B, C, and D preferred stock	\$	\$ 77,099,572
Accretion to redemption value of Series B, Series C, and Series D redeemable convertible preferred stock	\$	\$ 122,232

See accompanying notes to financial statements

**DexCom, Inc.**

**NOTES TO FINANCIAL STATEMENTS**

**(Unaudited)**

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

***Organization and Basis of Presentation***

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 U.S. Food and Drug Administration, or FDA, for its Short-Term Continuous Glucose Monitoring System, or STS®. The Company commenced initial commercial shipments of its STS throughout the United States on March 28, 2006 and during the quarter ended June 30, 2006 exited the development stage. This approval allows for the use of the STS 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. The Company has also conducted development activities on a long-term continuous glucose monitoring system with a sensor that must be implanted by a physician. The long-term sensor has not received approval from the FDA. Since inception, the Company has devoted substantially all of its resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials, and more recently, to the commercialization of the Company's STS.

The information contained herein has been prepared in accordance with instructions for Form 10-Q and Rule 10-01 of Regulation S-X. The information as of September 30, 2006, and for the three and nine months ended September 30, 2006 and 2005, is unaudited. In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting only of normal and recurring accruals) necessary to present fairly the financial position of the Company as of September 30, 2006, and the results of its operations and cash flows for the three and nine months ended September 30, 2006 and 2005. These results have been determined on the basis of accounting principles generally accepted in the United States of America (GAAP) and applied consistently with those used in the preparation of the audited financial statements for the year ended December 31, 2005 included in the Company's annual report on Form 10-K.

Certain information and footnote disclosures normally included in financial statements presented in accordance with GAAP have been omitted in accordance with the applicable rules to Form 10-Q. The accompanying financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2005 included in the Company's annual report on Form 10-K.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from these estimates. Significant estimates include estimated excess or obsolete inventories, warranty accruals, employee bonus, clinical study expenses and allowances for returned product. Excess and obsolete inventories are estimated by identifying the amount of on hand and on order materials and comparing those to expected future sales, taking into account clinical trial and development usage along with new product introductions. Warranty accruals are estimated by analyzing the timing, cost and amount of returned product. The 2006 bonus pool authorized an amount of up to 25% of salary and wages for non sales employees to be awarded from the pool based on the weighted average achievement measured against certain objectives. The actual current employee bonus accrual is approximately 10% of wages and assumes the achievement of certain targets by the end of 2006. Actual costs may differ from estimated costs based on the achievement of certain objectives. 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 is determined by analyzing the timing and amounts of past refund activity.

***Share-Based Compensation***

The Company's share-based employee compensation plans are described in Note 4. On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (SFAS 123(R)) which

requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants including grants of employee stock options and stock purchases by employees under the Employee Stock Purchase Plan ( ESPP ) based on estimated fair values. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ) and SFAS 123, *Accounting for Stock-Based Compensation* ( SFAS 123 ), for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ( SAB 107 ) relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

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The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's Statement of Operations as of and for the three and nine months ended September 30, 2006 reflects the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's Statements of Operations for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Share-based compensation expense recognized under SFAS 123(R) for the three and nine months ended September 30, 2006 was \$1,439,901 and \$4,363,537, respectively. Share-based compensation expense recorded in the Company's Statements of Operations of \$402,841 and \$1,469,135 for the three and nine months, respectively, ended September 30, 2005 was related to the grant of certain options to employees during 2004 and represented the difference between the fair value of the common stock and the option exercise price at the date of grant accounted for in accordance with APB 25.

Prior to January 1, 2006, the Company had adopted the disclosure-only provision of SFAS 123. Accordingly, the Company had not previously recognized compensation expense, except for stock-based compensation expense accounted for in accordance with APB 25. The table below reflects net income and diluted net income per share for the three and nine months ended September 30, 2005 recognized under APB 25 compared with net income and diluted net income per share assuming the Company determined compensation expense consistent with SFAS 123 for the three and nine months ended September 30, 2005:

	<b>Three Months</b>	<b>Nine Months</b>
	<b>Ended</b>	<b>Ended</b>
	<b>September 30,</b>	<b>September 30,</b>
	<b>2005</b>	<b>2005</b>
Net loss attributable to common stockholders, as reported	\$ (6,329,621 )	\$ (18,822,036 )
Add: Stock-based employee compensation expense included in net loss	402,841	1,469,135
Deduct: Stock-based employee compensation expense determined under fair-value method	(1,084,428 )	(3,072,174 )
Pro forma net loss attributable to common stockholders	\$ (7,011,208 )	\$ (20,425,075 )
Basic and diluted net loss per share attributable to common stockholders	\$ (0.25 )	\$ (1.12 )
Pro forma basic and diluted net loss per share attributable to common stockholders	\$ (0.28 )	\$ (1.22 )

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods as stock-based compensation expense in the Company's Statement of Operations. For the three and nine months ended September 30, 2006, the Company's Statement of Operations included compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). In conjunction with the adoption of SFAS 123(R), the Company changed its method of attributing the value of share-based compensation to expense from the accelerated multiple-option approach to the straight-line single option method. Compensation expense for all share-based payment awards granted on or prior to December 31, 2005 will continue to be recognized using the accelerated multiple-option approach while compensation expense for all share-based payment awards granted subsequent to December 31, 2005 is recognized using the straight-line single-option method. As share-based compensation expense recognized in the Statement of Operations for the first nine months of fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

As permitted by SFAS 123(R), the Company utilizes the Black-Scholes option-pricing model ( Black-Scholes model ) as its method of valuation for share-based awards granted. The Black-Scholes model was previously utilized for the Company's pro forma disclosure required under SFAS 123. The Company's determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors.

Prior to the adoption of SFAS 123(R), the Company presented deferred compensation as a separate component of stockholders' equity. In accordance with the provisions of SFAS 123(R), on January 1, 2006 the Company reclassified the balance in deferred compensation to

additional paid-in capital on the balance sheet.

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**Revenue Recognition**

Revenue on product sales is recognized upon shipment of our STS systems and disposable units. The Company accrues for estimated refunds and warranty costs at the time of shipment based on historical experience.

**Inventory**

Inventories are 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.

**Reclassifications**

Certain prior period amounts have been reclassified to conform to current period presentation. The separate display of stock-based compensation expenses associated with research and development and selling, general, and administrative totaling \$267,681 and \$135,160, respectively, for the three months ended September, 2005 and \$1,065,331 and 403,804, respectively, for the nine months ended September 30, 2005 have been reclassified as components of research and development and selling, general, and administrative expenses.

**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 is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, including foreign currency translation adjustments, and unrealized gains and losses on investments, shall be reported, net of their related tax effect, to arrive at comprehensive income. The Company's comprehensive loss is as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2006	2005	September 30, 2006	2005
Net loss attributable to common stockholders	\$ (13,437,771 )	\$ (6,329,621 )	\$ (35,525,648 )	\$ (18,822,036 )
Unrealized gain (loss) on available-for-sale marketable securities	65,126	453	14,314	(21,003 )
Comprehensive loss	\$ (13,372,645 )	\$ (6,329,168 )	\$ (35,511,334 )	\$ (18,843,039 )

**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, redeemable convertible preferred stock, convertible preferred stock, stock options and the outstanding warrant 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:

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	For the Three Months Ended		For the Nine Months Ended	
	September 30, 2006	2005	September 30, 2006	2005
Warrant	43,729	43,729	43,729	43,729
Options to purchase common stock	3,913,151	3,212,980	3,913,151	3,212,980
Restricted stock	14,813	19,750	14,813	19,750
	3,971,693	3,276,459	3,971,693	3,276,459

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### 3. Stockholder s Equity

#### *Follow-on Offering*

On May 2, 2006, the Company and selling stockholders closed a follow-on offering in which they sold an aggregate of 5,499,875 shares of its common stock. Of the 5,499,875 shares, 2,117,375 were sold by the Company for net proceeds of approximately \$47.0 million, after deducting underwriting discounts, commissions and estimated offering expenses, and 3,382,500 shares were sold by selling stockholders. The Company did not receive any proceeds from the sale of shares by the selling stockholders.

### 4. Benefit Plans

#### *2006 Bonus Pool*

In December 2005, the Compensation Committee of the Company approved the 2006 bonus pool. Under the 2006 bonus pool, the Company s employees, including its executive officers, are eligible for cash bonus awards ( Awards ) for their 2006 performance. The 2006 bonus pool authorized an amount of up to 25% of salary and wages for non sales employees to be awarded from the pool based on the weighted average achievement measured against certain objectives. The actual current employee bonus accrual is approximately 10% of wages and assumes the achievement of certain targets by the end 2006.

#### *Employee Stock Purchase Plan*

The ESPP permits eligible employees of the Company to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 10% of the participant s cash compensation subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair market value of the stock at either the beginning of the applicable Offering Period or the Purchase Date. Except for the First Offering Period, each Offering Period is 12 months, with new Offering Periods commencing every six months on the dates of February 1 and August 1 of each year. Each Offering Period consists of two (2) six month purchase periods (each a Purchase Period ) during which payroll deductions of the participants are accumulated under the ESPP. The last business day of each Purchase Period is referred to as the Purchase Date. The First Offering Period ran from April 13, 2005 to July 31, 2006 and included the Purchase Dates of January 31 and July 31 of 2006. Thereafter, Purchase Dates shall be every six months on the dates of January 31 and July 31. Annually in January of each year, subject to Board discretion and certain limitations, shares reserved for the ESPP will automatically be increased by a number of shares equal to 1% of the total number of issued and outstanding shares of the Company s common stock at the preceding year end. On January 31 and July 31, 2006, the Company issued 35,556 and 23,817, respectively, shares of common stock under the ESPP.

#### *Equity Incentive Plans*

In 2005, the Company adopted the 2005 Equity Incentive Plan ( 2005 Plan ) which replaced the 1999 Incentive Stock Plan and provides for the grant of incentive and nonstatutory stock options, restricted stock, stock bonuses, stock appreciation rights, and restricted stock units to employees, directors or consultants of the Company. Shares reserved include all shares that were available under the 1999 plan on the day it was terminated. Options generally vest over four years and expire ten years from the date of grant. In addition, incentive stock options may not be granted at a price less than the 100% of the fair market value on the date of grant. The term of the 2005 Plan is scheduled to end in March 2015. Annually in January of each year, subject to Board discretion and certain limitations, shares reserved for the 2005 Plan will automatically be increased by a number of shares equal to 3% of the total number of issued and outstanding shares of the Company s common stock during the preceding year end.

#### **Valuation and expense information under SFAS 123(R) and SFAS 123**

The following table summarizes share-based compensation expense related to employee stock options and employee stock purchases under SFAS 123(R) for the three and nine months ended September 30, 2006 and under APB 25 for employee stock options for the three and nine months ended September 30, 2005 allocated as follows:

**For the Three Months Ended**

**For the Nine Months Ended**

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	September 30, 2006	2005	September 30, 2006	2005
Cost of sales	\$ 28,663	\$	\$ 241,203	\$
Research and development	546,267	267,681	1,755,675	1,065,331
Selling, general and administrative	864,971	135,160	2,366,659	403,804
Share-based compensation expense included in operating expenses	\$ 1,439,901	\$ 402,841	\$ 4,363,537	\$ 1,469,135

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The Company estimated the fair value of each option grant and ESPP purchase rights on the date of grant using the Black-Scholes option pricing model with the below assumptions.

Options:

	For the Three Months Ended		For the Nine Months Ended					
	September 30, 2006	2005	September 30, 2006	2005	September 30, 2006	2005		
Risk-free interest rate (range)	4.6 - 5.2	%	4.1	%	4.6 - 5.2	%	3.8 - 4.2	%
Dividend yield								
Expected volatility	0.51		0.60		0.51		0.60	
Expected life (in years)	6.1		5.0		6.1		5.0	

ESPP:

	For the Three Months Ended		For the Nine Months Ended					
	September 30, 2006	2005	September 30, 2006	2005	September 30, 2006	2005		
Risk-free interest rate (range)	5.1 - 5.2	%	3.7 - 3.8	%	4.6	%	3.3 - 3.8	%
Dividend yield								
Expected volatility	0.50		0.43 - 0.49		0.43 - 0.50		0.40 - 0.49	
Expected life (in years)	0.5 - 1.0		0.5 - 1.0		0.5 - 1.0		0.5 - 1.0	

### Stock Option Activity

A summary of stock option activity under all share-based compensation plans during the nine months ended September 30, 2006 is as follows:

	Number of	Weighted-Average
	Shares	Exercise Price
Outstanding at December 31, 2005	3,557,395	\$ 4.33
Granted	1,035,300	18.33
Exercised	(502,912)	0.98
Cancelled	(176,632)	14.11
Outstanding at September 30, 2006	3,913,151	8.02

The weighted average fair values of options granted was \$10.03 for the nine months ended September 30, 2006.

The Company received proceeds of \$22,608 and \$1,972 for the three months ended September 30, 2006 and 2005, respectively, and \$1,750,206 and \$245,120 for the nine months ended September 30, 2006 and 2005, respectively, from the exercise of stock options.

The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected life of the Company's employee stock options. The dividend yield assumption is based on the Company's history and expectation of dividend payouts.

Due to the Company's limited history as a publicly traded company that began in April 2005, the Company's expected volatility beginning January 1, 2006 is based on both its historical stock prices and the historical prices of similar companies, as determined by the Company. Due to limited history as a publicly traded company, the Company used the simplified method allowed under SAB 107 to determine the expected life.

As share-based compensation expense recognized in the Statement of Operations for the first nine months of fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant

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and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

The following table summarizes information about stock options outstanding at September 30, 2006:

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Range of Exercise Price	Options Outstanding Weighted				Options Exercisable		
	Number	Average	Weighted	Aggregate Intrinsic Value	Number of Shares	Weighted	Aggregate Intrinsic Value
		Remaining	Average			Average	
		Contractual	Exercise			Exercise	
\$0.30 - \$2.40	2,037,845	7.0	\$ 1.13	\$ 20,384,270	1,451,589	\$ 0.84	\$ 14,941,768
\$10.00 - \$12.28	673,779	9.0	11.60	138,263	185,868	11.65	43,237
\$12.84 - \$14.30	530,000	9.2	13.88		28,107	14.00	
\$17.64 - \$19.75	92,750	9.4	18.22				
\$20.05 - \$22.30	518,777	9.5	20.65		18,188	20.98	
\$25.02 - \$25.80	60,000	9.6	25.43				
	3,913,151			\$ 20,522,533	1,683,752		\$ 14,985,005

The Company defines in-the-money options at September 30, 2006 as options that had exercise prices that were lower than the \$11.13 closing market price of the Company's common stock at that date. The aggregate intrinsic value of options outstanding at September 30, 2006 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 2,170,024 shares that were in-the-money at that date. There were 1,489,852 in-the-money options exercisable at September 30, 2006. The total intrinsic value of options exercised during the nine months ended September 30, 2006 was \$9,192,142, determined as of the date of exercise.

*Restricted Stock Awards*

During 2005, the Company issued 19,750 shares of unvested restricted common stock awards to certain employees. The grant awards vest 25% annually and are fully vested following the fourth anniversary of the vesting start date which ranges between January 3 and February 14, 2009. Vesting is subject to employment and the Company has the right to repurchase unvested shares at the original issuance price of \$0.001 per share subject to certain terms and conditions. As of September 30, 2006, there were 14,813 shares subject to repurchase with an intrinsic value of \$164,854.

*Reserved Shares*

The Company has reserved shares of common stock for future issuance as follow:

	September 30, 2006	December 31, 2005
Warrant	43,729	43,729
Stock options under the Company's plans:		
Granted and outstanding	3,913,151	3,557,395
Reserved for future grant	2,173,581	2,269,753
Employee Stock Purchase Plan	340,627	150,000
Total	6,471,088	6,020,877

**5. Related Party Transactions**

The Company's Chairman is a director of Oracle Corporation. For expenditures relating to the Company's ERP system, the company paid Oracle Corporation \$109,569 during the nine months ended September 30, 2006 and recorded expenses of \$62,150.

**6. Commitments and Contingencies**

*Lease*

In April 2006, the Company entered into a lease agreement for approximately 66,400 square feet of additional facilities located near the Company's headquarters in San Diego, CA. Rental obligations, excluding real estate taxes, operating costs, and tenant improvement allowances of up to \$673,000, under the lease agreement as of September 30, 2006 were as follows:

Fiscal Year Ending	
2006	\$ 207,257
2007	708,740
2008	1,133,622
2009	1,178,967
2010	1,226,126
Thereafter	4,452,416
Total	\$ 8,907,128

### *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 short-term glucose monitor infringes certain patents held by Abbott. The Company moved to dismiss these claims on August 31, 2005 on the grounds that Abbott's complaint was premature. In addition to the Company's motion to dismiss, the Company also filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office on January 25, 2006 and February 1, 2006. On February 22, 2006, the Company filed a motion to stay the entirety of the Delaware case pending decision from the Patent Office on those requests for reexamination, and in March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against the Company in the litigation. On February 23, 2006, the Court held a scheduling conference, during which it set a trial date of October 9, 2007. 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 short-term 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. However, subsequent to the court's ruling, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of those same three additional patents. The Company believes this complaint, like the first, is without merit and 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 decision from the Patent Office on our requests for reexamination of the three additional patents. Subject to the stay, the Company intends to vigorously contest the action. Although it is the Company's position that Abbott's assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees can be assessed. No assurances can be given that the Company will prevail in the lawsuit or that the Company can successfully defend itself against the claims made by Abbott, and the Company expects to incur significant costs in defending the action, which could have a material adverse effect on the Company's financial condition and results of operations regardless of the final outcome of such litigation.

### *Purchase Commitments*

The Company is party to various purchase arrangements related to components used in production and research and development activities. As of September 30, 2006, the Company had purchase commitments with certain vendors totaling approximately \$2,755,043 due within one year. There are no purchase commitments due beyond one year.

### *Loan*

In March 2006, the Company entered into a loan and security agreement that provides for up to \$5,000,000 to finance various equipment purchases through March 2007. The loan bears an interest rate equal to the lender's prime rate plus 0.25% and matures in September 2009. At September 30, 2006, the interest rate was 8.50%. The agreement requires monthly interest payments. The outstanding principal balance is amortized and payable over the term of the agreement beginning the earlier of March 2007 or when funds are fully drawn. The Company has granted a security interest in substantially all of its tangible assets as collateral for the loans under the loan and security agreement. The agreement imposes certain limitations on the Company's ability to engage in certain transactions. At September 30, 2006, the Company had borrowings of \$2,700,000 under the loan and security agreement and \$2,300,000 was available for future borrowings.

## 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 the company's research and development programs, the inability of patients to receive reimbursements from third-party payors, inadequate financial and other resources and the other risks those 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 U.S. Food and Drug Administration, or FDA, for our Short-Term Continuous Glucose Monitoring System, or STS®. We commenced initial commercial shipments of our STS throughout the United States on March 28, 2006 and during the quarter ended June 30, 2006 exited the development stage. Our approval allows for the use of our STS 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 STS is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices. Our STS must be prescribed by a physician and includes a disposable sensor, a transmitter and a small cell phone-sized receiver. The sensor is inserted by the patient and is intended to be used continuously for three days after which it is removed and may be replaced by a new sensor. Our STS 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 for the commercialization of our STS as well as the continued clinical development of our technology platform.

To support our national product launch, 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. To complement our direct sales efforts, we also employ clinical specialists who educate and provide clinical support in the field. We expect to continue to grow our sales and marketing organization to support the commercial launch of our STS. We believe a direct, highly-specialized and focused sales organization of approximately 40 to 50 people will be sufficient for us to continue to support our commercial launch.

We are leveraging our technology platform to enhance the capabilities for our STS and develop additional continuous glucose monitoring products. During our second fiscal quarter of 2006, we filed a PMA supplement with the FDA seeking approval for a second generation STS product intended to be worn by the patient continuously for up to seven days. We are continuing clinical development to seek replacement claim labeling from the FDA, which would allow patients to use our STS as the sole basis for making therapeutic adjustments, to obtain a pediatric indication for our STS, and are developing a product for the in-hospital monitoring market. Finally, we are continuing development of a long-term continuous glucose monitoring system with a sensor that can be implanted by a physician in a short outpatient procedure requiring only local anesthesia. Our clinical trials may be delayed due to scheduling issues with patients and investigators, institutional review boards, sensor performance and manufacturing supply constraints, among other factors. Support of these clinical trials requires significant resources in 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.

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We manufacture our STS at our facility in San Diego, California. This facility was inspected for medical device manufacturing by the FDA in August 2005. We manufacture our STS with components supplied by outside vendors and with parts manufactured by us internally. Key components that we manufacture internally include our wire-based sensor for our STS. The remaining components and assemblies are purchased from outside vendors. We then assemble, test, package and ship the finished product, which includes a transmitter, a receiver and a disposable sensor. We are expanding our manufacturing capacity in our current facility in San Diego, California and have leased an additional 66,400 square foot manufacturing facility in San Diego, California to enable us to produce greater quantities of our devices. Our capacity expansion could be constrained by the lack of material availability, equipment design, production and validation, regulatory approval of our new facility, personnel staffing and other factors.

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

As of September 30, 2006, we had generated \$1.3 million of revenue, and we have incurred net losses in each year since our inception in May 1999. Through September 30, 2006, we had an accumulated deficit of \$119.3 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. 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 and security agreement that provides for a loan of up to \$5.0 million to finance various equipment expenses. As of September 30, 2006, we had \$2.7 million in borrowings under this agreement. On May 2, 2006 we completed a follow-on offering of 2,117,375 shares of our common stock at \$24 per share for gross proceeds of \$50.8 million. After deduction of underwriting discounts and expenses of the offering we received net proceeds of \$47.0 million.

## **Financial Operations**

### ***Revenue***

As of September 30, 2006, we generated \$1.3 million in revenue from the sale of our continuous glucose monitoring systems after launching our system on March 28, 2006. We expect that revenues we generate from the sales of our STS will fluctuate from quarter to quarter.

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

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. This 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. From our inception until December 31, 2005, all of our manufacturing costs were included in research and development expense due to our development stage. From January 1, 2006 and forward these costs are included in cost of sales.

### ***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. Up 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, recruitment, stock based compensation, relocation 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. We expect our research and development expenses to increase as we continue to support the development and clinical trials of additional products.

### ***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. We expect our selling, general and administrative expenses to continue to increase to support the commercialization of our STS.

## **Results of Operations**

### ***Quarter Ended September 30, 2005 Compared to September 30, 2006.***

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

We recorded revenues of \$841,000 for the third quarter of 2006 after launching our first product on March 28, 2006. Cost of sales increased to \$3.4 million for the third quarter of 2006 compared to zero for the third quarter in 2005. During 2005 these costs were



included in research and development expense. Cost of sales includes both the direct costs of each product sold and the indirect and fixed costs associated with maintaining our manufacturing operations.

The increase in cost of sales was primarily related to the direct costs associated with our quarterly revenue, and \$1.7 million in factory overhead as well as direct material and direct labor costs associated with the production of our products. Changes in cost of sales includes \$610,000 in higher compensation expense, \$486,000 in increased facility and equipment depreciation costs and \$293,000 in higher production supplies.

**Research and Development.** Research and development expense, including stock-based compensation, decreased \$409,000 to \$4.6 million for the third quarter of 2006, compared to \$5.0 million for the third quarter of 2005. Changes in research and development expense include \$1.1 million in lower manufacturing costs that are now included in cost of sales and \$495,000 in lower outside design services, partially offset by \$312,000 in increased clinical trial expense and \$279,000 in higher stock based compensation expenses.

**Selling, General and Administrative.** Selling, general and administrative expense, including stock-based compensation, increased \$5.3 million to \$7.1 million for the third quarter of 2006, compared to \$1.8 million for the third quarter of 2005. The increase was primarily due to \$4.2 million in higher sales and marketing costs as we continued to launch our STS system in the United States. Changes in selling, general and administrative expense include \$2.0 million in higher compensation costs, \$1.6 million for increased promotions and advertising and \$729,000 in higher stock based compensation.

**Interest Income and Expense, Net.** Net interest income and interest expense increased \$287,000 to \$818,000 for the third quarter of 2006, compared to \$531,000 for the third quarter of 2005. The increase was due to higher combined average cash, cash equivalents, and short-term marketable securities balances due to our April 2006 follow-on public offering, partially offset by interest expense on our capital equipment bank line.

***Nine Months Ended September 30, 2005 Compared to September 30, 2006.***

**Revenue, Cost of Sales and Gross Margin.** We recorded revenues of \$1.3 million for the nine months ending September 30, 2006 after launching our first product on March 28, 2006. No revenues were recorded in 2005. Cost of sales increased \$7.6 million to \$7.6 million for the nine months ending September 30, 2006 compared to zero for the nine months ending September 30, 2005. During 2005, \$3.4 million of these costs were included in research and development expense. The \$4.5 million of fixed manufacturing costs included in cost of sales for the nine months ending September 30, 2006 reflects a \$1.1 million increase for the nine months compared to the \$3.4 million of these expenses that were included in research and development expense for the same period of 2005. The increase in year to date cost of sales was primarily related costs to produce our commercial products including a \$1.7 million increase in compensation expense, \$1.2 million in increased facility and equipment costs and \$544,000 in higher supplies, primarily offset by a credit of \$1.1 million for materials purchased and expensed in 2005.

**Research and Development.** Research and development expense, including stock-based compensation, decreased \$334,000 to \$15.5 million for the nine months ending September 30, 2006, compared to \$15.8 million for the same period in 2005. Development expenses increased \$2.1 million and clinical and regulatory costs increased \$1.0 million and these increases were offset by a \$3.4 million decrease in manufacturing expenses that are now classified in cost of sales for 2006. Changes in research and development expenses were driven by \$1.7 million in increased compensation expenses, \$690,000 in greater stock based compensation costs, partially offset by \$1.1 million in lower design costs.

**Selling, General and Administrative.** Selling, general and administrative expense, including stock-based compensation, increased \$11.8 million to \$15.8 million for the nine months ending September 30, 2006, compared to \$4.0 million for the same period in 2005. The increase was primarily due to \$7.7 million in higher sales and marketing costs and \$4.1 million in higher administrative costs. Changes in selling, general and administrative expense were driven by \$4.5 million in higher compensation costs, primarily in sales and marketing, \$1.6 million in higher promotions, \$2.0



million in higher stock based compensation and \$1.2 million in increased legal expenses.

***Interest Income and Expense, Net.*** Net interest income and expense increased \$912,000 to \$2.0 million for the nine months ending September 30, 2006, compared to \$1.1 million for the same period in 2005. The increase was due to higher combined average cash, cash equivalents, and short-term marketable securities balances due to our April 2006 follow-on public offering partially offset by \$36,000 in interest expense on our bank equipment line.

#### **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, 2006, we had an accumulated deficit of \$119.3 million and had working capital of \$61.4 million, which included \$64.7 million in cash, cash equivalents and short-term marketable securities. We have funded our operations primarily from the sale of equity securities and our bank line, raising aggregate net proceeds of \$168.7 million from equity sales through September 30, 2006. In April 2005, we

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completed our initial public offering in which we sold 4,700,000 shares of common stock for net proceeds of \$50.5 million. Concurrent with the closing of our initial public offering, all of our outstanding preferred stock converted into common stock. On March 20, 2006, we entered into a loan and security agreement that provides for a loan of up to \$5.0 million to finance various equipment purchases. As of September 30, 2006 we had drawn \$2.7 million under our bank equipment loan. On May 2, 2006 we completed the sale of 2,117,375 shares of common stock at \$24 per share for net proceeds of \$47.0 million.

**Net Cash Used in Operating Activities.** Net cash used in operating activities increased \$17.9 million to \$33.8 million for the nine months ending September 30, 2006, compared to \$15.9 million for the same period in 2005. The increase in cash used in operations was primarily due to our increased net loss, as well as higher inventories and lower accounts payable and accrued liabilities, partially offset by a \$3.0 million increase in stock based compensation that is a non cash expense.

**Net Cash Used in Investing Activities.** Net cash used in investing activities increased \$11.2 million to \$31.1 million for the nine months ending September 30, 2006, compared to \$19.9 million for the same period of 2005. The increase was primarily due to \$10.7 million in net purchases and sales of short-term marketable securities as we invested the proceeds from our follow-on offering. For the nine months ending September 30, 2006, we invested \$2.8 million in equipment and facilities to support manufacturing capacity increases and sales and marketing expansion.

**Net Cash Provided by Financing Activities.** Net cash provided by financing activities increased \$107,000 to \$50.8 million for the nine months ending September 30, 2006, compared to \$50.7 million for the same period of 2005. The proceeds from our 2006 follow on offering, stock option exercises and our bank line were approximately the same as our 2005 IPO proceeds.

#### ***Operating Capital and Capital Expenditure Requirements***

We recently commercialized our first product. However, we anticipate that we will continue to incur net losses for the next several years as we incur expenses to commercialize our STS, develop additional continuous glucose monitoring products, expand our sales, marketing, manufacturing and corporate infrastructure.

We believe that our cash, cash equivalents and short-term marketable securities balances, and the interest we earn on these balances, will be sufficient to meet our anticipated cash requirements with respect to the commercial launch of our STS, clinical trials, PMA applications and to meet our other anticipated cash needs for at least the next twelve months. If our available cash, cash equivalents and short-term marketable securities and the funds available under our loan and security agreement 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 STS and other future products;
- the expenses we incur in manufacturing, developing, selling and marketing our products;
- the quality levels of our products and services
- our ability to efficiently scale our manufacturing operations to meet demand for our current and any future products;

- the costs to produce our monitoring systems;
- 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;

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- the emergence of competing or complementary technological developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish; and
- the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

#### ***Contractual Obligations***

In March 2006, the Company entered into a loan and security agreement that provides for a loan of up to \$5.0 million to finance various equipment expenses through March 2007. As of September 30, 2006, there was a balance of \$2.7 million and \$2.3 million available for future borrowings. We are required to repay the outstanding balance beginning March 2007 until September 2009 on a pro rata basis plus interest.

In April 2006, we entered into an office lease agreement for approximately 66,400 square feet of additional facilities located near our headquarters in San Diego, CA. We also have a five-year option to renew the lease upon the expiration of the initial term. In connection with the lease, we entered into a \$664,000 letter of credit to secure future payments under the lease and paid a security deposit in the amount of \$89,640 in April 2006. Excluding real estate taxes and operating costs, we are required to make monthly payments through April 2014 totaling \$8.9 million.

We are party to various purchase arrangements related to components used in production and research and development activities. As of September 30, 2006, the Company had purchase commitments with certain vendors totaling approximately \$2.8 million due within one year. There are no purchase commitments due beyond one year.

#### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with generally accepted accounting principles. The preparation of these 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 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.

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

Our share-based employee compensation plans are described in Note 4. On January 1, 2006, we adopted SFAS 123(R) 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. SFAS 123(R) supersedes our previous accounting under APB 25 and SFAS 123, for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued SAB 107 relating to SFAS 123(R). We have applied the provisions of SAB 107 in its adoption of SFAS 123(R).

We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our Statement of Operations as of and for the three and nine months ended September 30, 2006 reflects the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's Statements of Operations for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Share-based compensation expense recognized under SFAS 123(R) for the three and nine months ended September 30, 2006 was \$1,440,000 and \$4,364,000, respectively. Share-based compensation expense of \$403,000 and \$1,469,000 for the three and nine months ended September 30, 2005 was related to the grant of certain options to employees during the 2004 which represented the difference between the fair value of the common stock and the option exercise price at the date of grant accounted for in accordance with APB 25. As of September 30, 2006, there was \$12.2 million of

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unrecognized compensation cost related to outstanding options that is expected to be recognized as a component of our operating expenses through 2010. Compensation costs will be adjusted for future changes in estimated forfeitures.

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Prior to January 1, 2006, we had adopted the disclosure-only provision of SFAS 123. Accordingly, we had not previously recognized compensation expense, except for share-based compensation expense accounted for in accordance with APB 25.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods as share-based compensation expense in the Company's Statement of Operations. For the three and nine months ended September 30, 2006, the Statement of Operations included compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). In conjunction with the adoption of SFAS 123(R), we changed our method of attributing the value of share-based compensation to expense from the accelerated multiple-option approach to the straight-line single option method. Compensation expense for all share-based payment awards granted on or prior to December 31, 2005 will continue to be recognized using the accelerated multiple-option approach while compensation expense for all share-based payment awards granted subsequent to December 31, 2005 is recognized using the straight-line single-option method. As share-based compensation expense recognized in the Statement of Operations in fiscal 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

As permitted by SFAS 123(R), we utilize the Black-Scholes option-pricing model as its method of valuation for share-based awards granted. The Black-Scholes model was previously utilized for our pro forma information required under SFAS 123. Our determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. Option-pricing models were developed for use in estimating the value of traded options that have no vesting or hedging restrictions and are fully transferable. Because our employee stock options have certain characteristics that are significantly different from traded options, and because changes in the subjective assumptions can materially affect the estimated value, the existing valuation models may not provide an accurate measure of the fair value of the our employee stock options. Although the fair value of employee stock options is determined in accordance with SFAS 123(R) using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

**Prior to the adoption of SFAS 123(R), we presented deferred compensation as a separate component of stockholders' equity. In accordance with the provisions of SFAS 123(R), on January 1, 2006 we reclassified the balance in deferred compensation to additional paid-in capital on our balance sheet.**

### *Inventory*

Inventories are valued at the lower of cost or market value. We make adjustments to reduce the cost of inventory to its net realizable value, if required, for estimated excess, obsolete and potential scrapped inventories. We estimate excess and obsolete inventories by identifying the amount of on hand and on order materials and comparing those to expected future sales, taking into account clinical trial and development usage along with new product introductions. We utilize a standard cost system to track inventories on a part-by-part basis that approximates first in, first out. If necessary, adjustments are made to the standard materials, standard labor and standard overhead costs to approximate actual labor and actual overhead costs. The labor and overhead elements of our standard costs are based on full utilization of our manufacturing capacity.

### *Bonus Accrual*

The 2006 bonus pool authorized an amount of up to 25% of salary and wages for non sales employees to be awarded from the pool based on the weighted average achievement measured against certain objectives. The actual current employee bonus accrual is approximately 10% of wages and is based on our assumption of achieving certain targets by the end of 2006. Actual costs may differ from estimated costs based on the achievement of certain objectives.

### *Revenue Recognition*

We recognize revenue on product sales upon shipment. We accrue for estimated warranty costs and returns at the time of shipment.



### ***Clinical Trial Accounting***

We record accruals for estimated clinical study expenses, comprising payments for work performed by contract research organizations, physicians and participating hospitals. These expenses are a significant component of research and development expenses. We accrue expenses for clinical studies performed by contract research organizations based on estimates of work performed under the contracts. Expenses for setting up clinical trial sites are accrued immediately. Clinical expenses related to patient enrollment are accrued as patients are enrolled in the trial.

### ***Warranty Accrual***

We accrue for estimated warranty costs and returns at the time of shipment. We estimate warranty accruals by analyzing the timing, cost and amount of returned product.

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

To date we have recorded no product sales and have not entered into any agreements denominated in other than U.S. dollars. Accordingly we believe we have no material exposure to risk from changes in foreign currency exchange rates.

## **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. DexCom's 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 short-term glucose monitor infringes certain patents held by Abbott. We moved to dismiss these claims on August 31, 2005 on the grounds that Abbott's complaint was premature. In addition to our motion to dismiss, we also filed requests for reexamination of the Abbott patents with the United States Patent and Trademark Office on January 25, 2006 and February 1, 2006. On February 22, 2006, we filed a motion to stay the entirety of the Delaware case pending decision from the Patent Office on those requests for reexamination, and in March 2006, the Patent Office ordered reexamination of each of the four patents originally asserted against us in the litigation. On February 23, 2006, the Court held a scheduling conference, during which it set a trial date of October 9, 2007. 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 short term 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. However, subsequent to the court's ruling, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of those same three additional patents. 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 decision from the Patent Office on our requests for reexamination of the three additional patents. Subject to the stay, we intend to vigorously contest the action. Although it is our position that Abbott's assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees 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.

**ITEM 1A. RISK FACTORS**

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

**We have a limited operating history and our STS® may never achieve market acceptance.**

We are a medical device company with a limited operating history. We received approval from the FDA for our STS on March 24, 2006 and have recently launched this product throughout the United States. We expect that sales of our STS, which consists of a cell phone-sized receiver, transmitter and disposable sensor, will account for substantially all of our revenue for the foreseeable future. However, we have limited experience in selling our products and we might be unable to successfully commercialize our STS for a number of reasons, including:

- market acceptance of our STS by physicians and patients will largely depend on our ability to demonstrate its relative safety, efficacy, cost-effectiveness and ease of use;
- our inexperience in marketing, selling and distributing our products;
- we may not have adequate financial or other resources to successfully commercialize our STS;
- we may not be able to manufacture our STS in commercial quantities or at an acceptable cost;
- the uncertainties associated with establishing and qualifying our new manufacturing facility;
- our STS is not labeled as a replacement for the information that is obtained from single-point finger stick devices;
- patients will need to incur the costs of the STS in addition to single-point finger stick devices;

- patients do not generally receive reimbursement from third-party payors for their purchase of our STS, which may reduce widespread use of our STS;

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- the introduction and market acceptance of competing products and technologies;
- our inability to obtain sufficient quantities of supplies from our sole source and other key suppliers; and
- rapid technological change may make our technology and our STS obsolete.

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

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

We have incurred net losses in each year since our inception in May 1999, including a net loss attributable to common stockholders of \$35.5 million for the nine months ended September 30, 2006. As of September 30, 2006, we had an accumulated deficit of \$119.3 million. We have financed our operations primarily through private placements of our equity securities and our public offerings, and have devoted substantially all 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 STS product. 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.

**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 STS, our business may be harmed.**

To achieve commercial success for our STS, we must either continue to develop and grow our sales and marketing organization or enter into arrangements with others to market and sell our products. We currently employ a small direct sales force to market our STS in the United States. Our sales organization competes with the experienced and well-funded marketing and sales operations of our competitors. We have limited experience developing and managing a direct sales organization and marketing and distributing our products, and we may be unsuccessful in our attempt to do so. 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 dispersed 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 may contract with third parties to market and sell our STS in the United States if we are unable to develop an adequate direct sales organization. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States, our product margins could be lower than if we directly marketed and sold our STS. 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.

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**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 STS. In order to produce our STS 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 the availability and suitability of facility space, construction timelines, design, installation and maintenance of manufacturing equipment, among others, which can lead to unexpected delays. In addition, before we can produce our STS for commercial use at the new facility we have recently leased, the facility will have to undergo a pre-approval inspection 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 new facility in a timely manner or at all. If we are unable to manufacture a sufficient supply of our STS 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 STS 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 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 and long-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 Vita Needle to manufacture and supply the insertion needle in our STS applicator; 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 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 are not a major customer of many of our suppliers, and these suppliers may therefore give other customers needs higher priority than ours;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- 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, which could inhibit their ability to fulfill our orders and meet our requirements.

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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

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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 short-term glucose monitor infringes certain patents held by Abbott. Abbott filed an amended complaint on June 27, 2006 alleging infringement of several additional patents. 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. However, subsequent to the court's ruling, Abbott filed a separate action in the U.S. District Court for the District of Delaware alleging patent infringement of those same three additional patents. 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 decision from the Patent Office on our requests for reexamination of the three additional patents.

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 STS. Our STS is our only 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 material and adverse 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 and 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 and implantable sensors 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, 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.

**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 is 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.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties to protect our intellectual property. 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. 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.

The federal trademark application for the DEXCOM mark has been opposed, and we intend 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.

**Our STS does not have reimbursement and is not approved for insurance coverage. 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.**

Our STS does not have reimbursement and is not approved for insurance coverage. The availability of insurance coverage and reimbursement for newly approved medical devices is uncertain. 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 STS in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our STS. Third-party coverage will be difficult to obtain if our STS is not approved by the FDA as a replacement for existing single-point finger stick devices. 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 STS. 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 STS 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 STS, 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 STS or the exclusion of our products from reimbursement programs.

**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 STS, we compete directly with Roche Diagnostics, 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



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developing or marketing short-term continuous glucose monitoring products that will compete directly with our STS. To date, in addition to our STS, the FDA has approved three continuous monitors or sensors, including the CGMS System Gold and Guardian RT by Medtronic, and the GlucoWatch, currently owned by Johnson &

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Johnson. Medtronic's CGMS System Gold and Guardian RT are currently in commercial use. Progress of others developing continuous glucose monitors is difficult to assess, but we are aware that Abbott has submitted applications for real-time continuous monitors or sensors to the FDA but is not yet approved and Johnson & Johnson recently announced that it would commence clinical trials in support of a continuous glucose monitoring system in 2007. 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.

**No continuous glucose monitoring system, including our STS, 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 STS does not eliminate the need for single-point finger stick devices and our future products may not be approved for that indication. No precedent for FDA approval of continuous glucose monitoring systems as a replacement for single-point finger stick devices has been established. Accordingly, there is no established study design or agreement regarding performance requirements or measurements in clinical trials for continuous glucose monitoring systems. We have not yet filed for FDA approval for 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 STS 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 three 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.

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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:

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- 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 is not 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.

The results of pre-clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. We believe the data and performance from each of our clinical trials relating to our long-term system were likely insufficient to support a PMA application. While these previous trials were not designed or intended to be used to support a PMA application, our ongoing and future clinical trials that are designed to support a PMA application may not be sufficient to do so. 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. 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. If we are unsuccessful in either filing or receiving FDA approval for additional PMA applications related to our glucose monitoring systems, our business strategy may have to be altered to rely solely on our STS.

**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.

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**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 additional FDA approvals for continuous glucose monitoring systems in addition to our STS, including our seven-day STS for which we have filed a PMA supplement during the second quarter of 2006 and long-term continuous glucose monitoring systems. The regulatory approval process for these continuous glucose monitoring systems that are under development involves, among other things, successfully completing clinical trials and obtaining a PMA from the FDA. 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 be safe or effective to the FDA's satisfaction;
- 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 complete the commercialization of our STS 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 STS, including further development of a 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, 2006, our net cash used in operating activities was \$33.8 million, compared to \$15.9 million for the same period in 2005, and as of September 30, 2006, we had working capital of \$61.4 million, including \$64.7 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 complete the commercialization of our STS 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 STS 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;
- 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.

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If adequate funds are not available, we may not be able to commercialize our STS 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 STS 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 STS 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 STS, seven months of continuous use with our first generation long-term sensor and six months of continuous use with our second generation long-term sensor. Additionally, we have limited clinical experience with repeated use of our STS in the same patient and have not clinically tested repeated use of our long-term sensor 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 STS or long-term systems, or implantation of our long-term sensor for more than seven months, will 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, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. 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. Our existing manufacturing facilities are located in and around our headquarters in San Diego, California, where we have more than 7,000 square feet of laboratory space and approximately 3,000 square feet of class 100K clean rooms. This facility was inspected for medical device manufacturing in August 2005 by the FDA. We have also recently entered into a lease for a 66,400 square foot manufacturing facility in San Diego, California. We cannot assure you that we will be able to obtain FDA and other regulatory approval of this new facility in a timely manner or at all. 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;
- 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.



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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.

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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 coverages 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. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedure and related processes to implant our long-term sensor into patients. If these medical personnel are not properly trained or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, 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 STS is designed to be used by a patient continuously for three days, but the patient might be able to circumvent the safeguards designed into the STS and use the product for longer than three days. Off-label use of products by patients is common, and any such off-label use of our STS 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.

**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;

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- 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 prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our products may not be successful and our business would be harmed.**

We rely on a license from SM Technologies, LLC to use various technologies that are material to our long-term sensors. We do not own the patents that underlie this license. This license grants us exclusive rights under specific patents related to our biointerface membranes and our sensor membranes and allows us to use those rights only in the field of diabetes treatment and management. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our abiding by the terms of the license. In addition, we do not control the prosecution of the patents subject to this license or the strategy for determining when such patents should be enforced. As a result, we are largely dependent upon our licensor to determine the appropriate strategy for prosecuting and enforcing those patents.

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

Historically, the majority of our operations have been conducted at a single location in San Diego, California. We recently entered into a lease for additional manufacturing facilities also located in San Diego, California. 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.**

Following commercial launch of our products in the United States, we may seek to market our products internationally. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We have not taken any actions to obtain foreign regulatory approvals. 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 Andrew P. Rasdal, our President and Chief Executive Officer, Andrew K. Balo, our Vice President of Clinical and Regulatory Affairs, and Mark Brister, our Vice President of Advanced Development Teams. 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 STS and the development and introduction of our other 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.

We expect to rapidly expand our operations and grow our research and development, manufacturing, sales, 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 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. For example, we are evaluating our internal controls systems in order to allow us to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since there is no precedent available by which to measure compliance adequacy. 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 FAS 12(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 our future financial results.

For instance, estimating the fair value of share-based payments is highly dependent on assumptions regarding the future exercise behavior of our employees and changes in our stock price. Our share-based payments have characteristics significantly different from those of freely traded options, and changes to the subjective input assumptions of our share-based payment valuation models can materially change our estimates of the fair values of our share-based payments. In addition, the actual values realized upon the exercise, expiration, early termination or forfeiture of share-based payments might be significantly different than our estimates.



of the fair values of those awards as determined at the date of grant. Moreover, we rely on third parties that supply us with information or help us perform certain calculations that we employ to estimate the fair value of share-based payments. If any of these parties do not perform as expected or make errors, we may inaccurately calculate actual or estimated compensation expense for share-based payments.

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.

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, potentially negatively impacting our ability to provide accurate financial guidance. This variability and uncertainty could further 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. 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 income for equity compensation instruments, including employee stock options, using the fair value method. Our reported financial results beginning for the first quarter of 2006 and for all foreseeable future periods will be negatively and materially impacted by this accounting change. Other potential changes in existing taxation rules related to stock options and other forms of equity compensation could also have a significant negative effect on our reported results.

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

On March 20, 2006, we entered into a loan and security agreement that provides for a loan of up to \$5.0 million to finance various equipment expenses. The agreement 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 or change our legal name;
- merge or consolidate with or into any other business organization;
- 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 person;
- 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;



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- 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
- 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.

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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:

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

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

SIGNATURES

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

DEXCOM, INC.  
(Registrant)

Dated: October 23, 2006

By: /s/ Andrew P. Rasdal  
**Andrew P. Rasdal,**  
**President and Chief Executive Officer**

Dated: October 23, 2006

By: /s/ Steven J. Kemper  
**Steven J. Kemper,**  
**Chief Financial Officer**

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