INSULET CORP
Form 10-Q
May 15, 2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q

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

For the quarterly period ended March 31, 2008

OR

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

Commission File Number 001-33462
Insulet Corporation
(Exact name of Registrant as specified in its charter)

Delaware	**04-3523891**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
9 Oak Park Drive **Bedford, Massachusetts**	**01730**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(781) 457-5000**

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 þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

o Large accelerated filer	o Accelerated filer	þ Non-accelerated filer	o Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

As of May 12, 2008, the registrant had 27,535,940 shares of common stock outstanding.

INSULET CORPORATION
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2008
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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

INSULET CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of March 31, 2008 (Unaudited)	As of December 31, 2007
	(In thousands, except share data)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 73,035	$ 94,588
Accounts receivable, net	7,223	4,783
Inventories	7,506	7,990
Prepaid expenses and other current assets	2,843	1,391
Total current assets	90,607	108,752
Property and equipment, net	25,225	21,304
Other assets	635	685
Total assets	$ 116,467	$ 130,741
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 7,399	$ 4,544
Accrued expenses	6,538	4,464
Deferred revenue	1,337	1,350
Current portion of long-term debt	10,670	10,671
Preferred stock warrant liability		
Total current liabilities	25,944	21,029
Long-term debt, net of current portion	13,338	16,006
Other long-term liabilities	3,546	1,431
Total liabilities	42,828	38,466
Stockholders equity		
Preferred stock, $.001 par value: Authorized: 5,000,000 shares at March 31, 2008 and December 31, 2007. Issued and outstanding: zero shares at March 31, 2008 and December 31, 2007		
Common stock, $.001 par value: Authorized: 100,000,000 shares at March 31, 2008 and December 31, 2007 Issued and outstanding: 27,535,871 and 27,223,820 shares at March 31, 2008 and December 31, 2007, respectively	28	28
Additional paid-in capital	249,064	247,835
Accumulated deficit	(175,453)	(155,579)

Subscription receivable		(9)
Total stockholders equity	73,639	92,275
Total liabilities and stockholders equity	$ 116,467	$ 130,741

The accompanying notes are an integral part of these condensed consolidated financial statements.

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INSULET CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2008	**2007**
	(In thousands, except share and per share data)	
	(Unaudited)	
Revenue	$ 6,671	$ 2,008
Cost of revenue	9,998	4,572
Gross loss	(3,327)	(2,564)
Operating expenses:		
Research and development	2,923	2,470
General and administrative	5,197	2,660
Sales and marketing	8,565	3,104
Total operating expenses	16,685	8,234
Operating loss	(20,012)	(10,798)
Interest income	713	304
Interest expense	(575)	(982)
Net interest income (expense)	138	(678)
Change in value of preferred stock warrant liability		(84)
Net loss	(19,874)	(11,560)
Net loss per share basic and diluted	$ (0.73)	$ (23.86)
Weighted-average number of shares used in calculating net loss per share	27,394,322	484,431

The accompanying notes are an integral part of these condensed consolidated financial statements.

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INSULET CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended March 31,	
	2008	2007
	(In thousands) (Unaudited)	
Cash flows from operating activities		
Net loss	$ (19,874)	$ (11,560)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	1,358	846
Amortization of debt discount	58	60
Redeemable convertible preferred stock warrant expense		84
Stock compensation expense	674	209
Provision for bad debts	572	120
Non cash interest expense		(57)
Changes in operating assets and liabilities:		
Accounts receivable	(3,012)	(821)
Inventory	484	(866)
Prepaids and other current assets	(1,452)	30
Other assets	50	(1,675)
Accounts payable and accrued expenses	4,929	1,369
Other long term liabilities	2,115	1
Deferred revenue, short term	(13)	395
Net cash used in operating activities	(14,111)	(11,865)
Cash flows from investing activities		
Purchases of property and equipment	(5,279)	(2,331)
Net cash used in investing activities	(5,279)	(2,331)
Cash flows from financing activities		
Principal payments of long term debt	(2,727)	
Proceeds from issuance of common stock, net of offering expenses	555	22
Proceeds from payment of subscription receivable	9	19
Net cash (used in) provided by financing activities	(2,163)	41
Net decrease in cash and cash equivalents	(21,553)	(14,155)
Cash and cash equivalents, beginning of period	94,588	33,231
Cash and cash equivalents, end of period	$ 73,035	$ 19,076
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 708	$ 604

The accompanying notes are an integral part of these condensed consolidated financial statements.

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INSULET CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of Business

Insulet Corporation (the Company) is principally engaged in the development, manufacture, marketing and selling of an insulin infusion system for people with insulin-dependent diabetes. The Company was incorporated in Delaware in 2000 and has its corporate headquarters in Bedford, Massachusetts. Since inception, the Company has devoted substantially all of its efforts to developing, manufacturing, marketing and selling the OmniPod Insulin Management System, which consists of the OmniPod disposable insulin infusion device and the handheld, wireless Personal Diabetes Manager. The Company commercially launched the OmniPod Insulin Management System in August 2005 after receiving FDA 510(k) approval in January 2005. The first commercial product was shipped in October 2005. In May 2007, the Company completed an initial public offering of its common stock.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals, considered necessary for a fair presentation have been included. Operating results for the three month period ended March 31, 2008 is not necessarily indicative of the results that may be expected for the full fiscal year ending December 31, 2008, or for any other subsequent interim period.

The condensed consolidated financial statements should be read in conjunction with the Company s consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2007.

Use of Estimates in Preparation of Financial Statements

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expense during the reporting periods. The most significant estimates used in these financial statements include the valuation of inventories and equity instruments, the lives of property and equipment, and warranty and doubtful account allowance calculations. Actual results may differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Sub-Q Solutions, Inc. All material intercompany balances and transactions have been eliminated in consolidation. To date there has been no activity in Sub-Q Solutions, Inc.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of amounts due from third-party payors and patients. In estimating whether accounts receivable can be collected, the Company performs evaluations of customers and continuously monitors collections and payments and estimates an allowance for doubtful accounts based on the aging of the underlying invoices, experience to date and any specific collection issues that have been identified.

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Inventories

Inventories are stated at the lower of cost or market, determined under the first-in, first-out (FIFO) method. Inventory has been recorded at market value for all periods presented as the Company currently sells the OmniPod at a loss. Work in process is calculated based upon a build up in the stage of completion using estimated labor inputs for each stage in production. Costs for Personal Diabetes Managers (PDMs) and OmniPods include raw materials, labor and manufacturing overhead. The Company evaluates inventory valuation on a quarterly basis for obsolete or slow-moving items.

Property & Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. Assets capitalized under capital leases are amortized in accordance with the respective class of owned assets and the amortization is included with depreciation expense. Maintenance and repair costs are expensed as incurred.

Impairment of Property & Equipment

The Company reviews the carrying value of its property and equipment to assess the recoverability of these assets whenever events indicate that impairment may have occurred. As part of this assessment, the Company reviews the future undiscounted operating cash flows expected to be generated by those assets. If impairment is indicated through this review, the carrying amount of the asset would be reduced to its estimated fair value.

Revenue Recognition

The Company generates revenue from sales of its OmniPod Insulin Management System to diabetes patients. The initial sale to a new customer typically includes OmniPods and a Starter Kit, which include the PDM, two OmniPods, the OmniPod System User Guide and the OmniPod System Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

Revenue is recognized in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements* (SAB 104), which requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval.

Transfer of title and risk and rewards of ownership are passed to the patient upon receipt the patient s receipt of the products.

The selling prices for all sales are fixed and agreed with the patient, and if applicable, the patient s third-party insurance provider(s) prior to shipment and are based on established list prices or, in the case of certain third-party insurers, contractually agreed upon prices. Provisions for discounts and rebates to customers are established as a reduction to revenue in the same period the related sales are recorded.

The Company has considered the requirements of Emerging Issues Task Force (EITF) No. 00-21, *Revenue Arrangements with Multiple Deliverables*, when accounting for the OmniPods and Starter Kits. EITF 00-21 requires the Company to assess whether the different elements qualify for separate accounting. The Company recognizes revenue for the initial shipment to a patient or other third party once all elements have been delivered.

The Company offers a 45-day right of return for its Starter Kits sales, and, in accordance with SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, the Company defers revenue and related costs of revenue

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to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through comparison of historical return data to their related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. Historically, sales returns have amounted to approximately 4% of gross product sales.

When doubt exists about reasonable assuredness of collectibility from specific customers, the Company defers revenue from sales of products to those customers until payment is received.

Prior to January 1, 2008, the Company deferred the revenue and, to the extent allowed, all related costs of all initial shipments until the 45-day right of return had lapsed. With the accumulation of approximately 2 years of data for sales and return rates, the Company now bases its estimated returns on historical return data. If the Company had continued to defer all initial shipments until the 45-day right of return had expired, deferred revenue as of March 31, 2008 would have been larger by $1,211,000 compared to the amount recorded as of March 31, 2008.

During the three months ended March 31, 2008, the Company received a cash payment from Abbott Diabetes Care, Inc. (Abbott) for an agreement fee in connection with execution of the first amendment to the development and license agreement between the Company and Abbott. The Company recognizes the agreement fee from Abbott over the 5-year term of the agreement.

The Company had deferred revenue of $1,337,000 and $1,350,000 as of March 31, 2008 and December 31, 2007, respectively. The deferred revenue recorded as of March 31, 2008 is comprised of product related revenue as well as the current portion of the agreement fee related to the Abbott agreement. The Company recognizes the agreement fee received from Abbott over the 5-year term of the agreement, and the non-current portion of the agreement fee is included in other long-term liabilities.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents. The Company maintains the majority of its cash with one accredited financial institution.

Although revenue is recognized from shipments directly to patients, the majority of shipments are billed to third party insurance payors. As of March 31, 2008, the two largest third party payors accounted for 8% and 7% of gross accounts receivable balances. As of December 31, 2007, the two largest third party payors accounted for 8% and 4% of gross accounts receivable balances.

Income Taxes

The Company files federal and state tax returns. The Company has accumulated significant losses since its inception in 2000. Since the net operating losses may potentially be utilized in future years to reduce taxable income, all of the Company s tax years remain open to examination by the major taxing jurisdictions to which the Company is subject.

The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense. Upon adoption and as of March 31, 2008, the Company had no interest and penalty accrual or expense.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company adopted SFAS 157 in the first quarter of fiscal year 2008. The adoption of SFAS-157 did not have a material effect on the Company s financial position, results of operations, or cash flows.

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In February 2008, the FASB issued FASB Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2). FSP FAS 157-2 delays the effective date of SFAS 157 to fiscal years beginning after November 15, 2008 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, at least annually. FSP FAS 157-2 is effective for fiscal years beginning after September 1, 2009. The adoption of FSP FAS 157-2 is not expected to have a material impact on the Company s financial position, results of operations, or cash flows.

In February 2007, the FASB issued SFAS No. 159, *Fair Value Option for Financial Assets and Financial Liabilities* - Including an amendment of FASB Statement 115 (SFAS 159), which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective as of the beginning of an entity s first fiscal year that begins after November 15, 2007. The adoption of SFAS-159 did not have a material effect on the Company s financial position, results of operations, or cash flows.

3. Net Loss Per Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options and warrants (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method). Because the Company reported a net loss for the three months ended March 31, 2008 and 2007, respectively, all potential common shares have been excluded from the computation of the dilutive net loss per share for all periods presented, as the effect would have been anti-dilutive. Such potentially dilutive common share equivalents consist of the following:

	Three Months Ended March 31,	
	2008	2007
Series A redeemable convertible preferred stock		380,705
Series B redeemable convertible preferred stock		2,263,651
Series C redeemable convertible preferred stock		3,988,337
Series D redeemable convertible preferred stock		5,584,722
Series E redeemable convertible preferred stock		5,230,376
Outstanding options and ESPP	2,975,098	2,511,691
Outstanding warrants	62,752	219,981
Total	3,037,850	20,179,463

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4. Accounts Receivable

The components of accounts receivable are as follows:

	As of	
	March 31, 2008	December 31, 2007
	(In thousands)	
Trade receivables	$ 8,759	$ 5,992
Allowance for doubtful accounts	(1,536)	(1,209)
	$ 7,223	$ 4,783

5. Inventories

Inventories consist of the following:

	As of	
	March 31, 2008	December 31, 2007
	(In thousands)	
Raw materials	$ 2,948	$ 2,994
Work-in-process	1,057	1,583
Finished goods	3,501	3,413
	$ 7,506	$ 7,990

Inventories of finished goods were adjusted by $21,000 and $625,000 as of March 31, 2008 and December 31, 2007, respectively, to reflect values at the lower of cost or market. As of March 31, 2008 and December 31, 2007, 3% and 43%, respectively, of the reported finished goods inventory was valued below the Company s cost. The Company s production process has a high degree of fixed costs due to the early stage of capacity build-up and market penetration of its products. Consequently, sales and production volumes have not been adequate to result in per-unit costs that are lower than the current market price for the Company s products.

6. Product Warranty Costs

The Company provides a four-year warranty on its PDMs and replaces any OmniPods that do not function in accordance with product specifications. Warranty expense is recorded in the period that shipment occurs. The expense is based on the Company s historical experience and the estimated cost to service the claims. A reconciliation of the changes in the Company s product warranty liability follows:

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	Three Months Ended March 31,	
	2008	2007
	(In thousands)	
Balance at the beginning of period	$ 865	$ 193
Warranty expense	717	177
Warranty claims settled	(486)	(91)
Balance at the end of the period	$ 1,096	$ 279
Composition of balance:		
Short-term	494	161
Long-term	602	117
Total warranty balance	$ 1,096	$ 279

7. Indebtedness and Warrants to Purchase Shares Subject to Redemption

Loan and Security Agreements

On December 27, 2006, the Company entered into a credit and security agreement with a group of lenders led by Merrill Lynch Capital pursuant to which the Company borrowed $30.0 million in a term loan. The Company used $9.5 million of the proceeds from this term loan to repay all amounts owed under a term loan with Lighthouse Capital Partners V, L.P. This term loan is secured by all the assets of the Company other than its intellectual property. The borrowings under the term loan bear interest at a floating rate equal to the LIBOR rate plus 6% per annum. Interest is payable on a monthly basis during the term of the loan and from October 1, 2007, the Company began to repay the principal in 33 equal monthly installments of $909,091. This term loan is also subject to a loan origination fee amounting to $900,000. The Company capitalized these costs as deferred financing costs as of December 31, 2006. The deferred cost asset will be amortized to interest expense over the 42-month life of this term loan. This term loan is subject to acceleration upon the occurrence of any fact, event or circumstance that has resulted or could reasonably be expected to result in a material adverse effect.

In connection with this term loan, the Company issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock at a purchase price of $3.64 per share. The warrants automatically converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share at the closing of the Company s initial public offering. The Company recorded the $835,000 fair value of the warrants as a discount to the term loan. The costs of the warrants are being amortized to interest expense over the 42-month life of this term loan.

8. Commitments and Contingencies

Operating Leases

The Company leases its facilities, which are accounted for as operating leases. The leases generally provide for a base rent plus real estate taxes and certain operating expenses related to the leases.

In March 2008, the Company extended the lease of its Bedford, Massachusetts headquarters facility containing office, research and development and manufacturing space. Following the extension, the lease expires in September 2014. The lease is non-cancellable and contains a five-year renewal option and escalating payments over the life of the lease.

In February 2008, the Company entered into a non-cancellable lease for additional office space in Bedford, Massachusetts. The lease expires in February 2013, and provides a renewal option of five years and escalating payments over the life of the lease.

The Company also leases warehouse facilities in Billerica, Massachusetts. This lease expires in December 2012.

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The aggregate future minimum payments of all operating leases as of March 31, 2008, are as follows:

Year	Minimum lease payments (In thousands)
2008	$ 589
2009	783
2010	755
2011	755
2012	755
2013	657
2014	493
Total	$ 4,787

The Company s operating lease agreements contain scheduled rent increases, which are being amortized over the terms of the agreement using the straight-line method, and are included in other long-term liabilities in the accompanying balance sheet. The Company has considered FASB Technical Bulletin 88-1, *Issues Relating to Accounting for Leases*, and FASB Technical Bulletin 85-3, *Accounting for Operating Leases with Scheduled Rent Increases*, in accounting for these lease provisions.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company s exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company s request in such capacity. There have been no claims to date and the Company has a director and officer insurance policy that enables it to recover a portion of any amounts paid for future claims.

9. Equity

On April 12, 2007, the Company s Board of Directors approved a 1-for-2.6267 reverse stock split of the Company s common stock, which was executed on May 10, 2007. All share and per share amounts of common and preferred stock in the accompanying condensed consolidated financial statements have been restated for all periods to give retroactive effect to the stock split.

In the three months ended March 31, 2008, 308,978 common shares were issued related to exercises of employee stock options.

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Stock-Based Compensation Plans

Activity under the Company s Stock Option Plans:

	Number of Options(#)	Weighted Average Exercise Price($)	Aggregate Intrinsic Value($)
Balance, December 31, 2007	2,691,973	6.94	
Granted	627,239	17.11	
Exercised	(308,978)	1.80	4,958,392(1)
Canceled	(38,209)	17.66	
Balance, March 31, 2008	2,972,025	9.48	
Vested, March 31, 2008	1,263,827	3.53	13,736,410(2)
Vested and expected to vest, March 31, 2008 (3)	2,615,382		

(1) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company s common stock as of the date of exercise and the exercise price of the underlying options.

(2) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company s common stock as of March 31, 2008, and the exercise price of

the underlying options.

(3) Represents the number of vested options as of March 31, 2008, plus the number of unvested options expected to vest as of March 31, 2008, based on the unvested options outstanding at March 31, 2008, adjusted for an estimated forfeiture rate of 12%.

In the three months ended March 31, 2008 and 2007, 3,073 and zero shares, respectively, were contingently issued under the employee stock purchase plan (ESPP). In the three months ended March 31, 2008 and 2007, the Company recorded compensation charges of approximately $6,900 and $0, respectively, of stock compensation charges related to the ESPP.

Employee stock-based compensation expense under SFAS 123R recognized in the three month periods ended March 31, 2008 and 2007, was $674,000 and $209,000, respectively.

10. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company provided a valuation allowance for the full amount of its net deferred tax asset for all periods because realization of any future tax benefit cannot be determined as more likely than not, as the Company does not expect income in the near-term.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion of our financial condition and results of operations in conjunction with our selected financial data, our financial statements and the accompanying notes to those financial statements included in this Quarterly Report on Form 10-Q. These forward-looking statements are based on our current expectations and beliefs concerning future developments and their potential effects on it. There can be no assurance that future developments affecting it will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with our dependence on the OmniPod System; our ability to achieve and maintain market acceptance of the OmniPod System; potential manufacturing problems, including damage, destruction or loss of any of our automated assembly units or difficulties in implementing our automated manufacturing strategy; our ability to anticipate and effectively manage risks associated with doing business internationally, particularly in China; potential problems with sole source or other third-party suppliers on which we are dependent; our ability to obtain favorable reimbursement from third-party payors for the OmniPod System and potential adverse changes in reimbursement rates or policies relating to the OmniPod; potential adverse effects resulting from competition with competitors; technological innovations adversely affecting our business; potential termination of our license to incorporate a blood glucose meter into the OmniPod System; our ability to protect our intellectual property and other proprietary rights; conflicts with the intellectual property of third parties; adverse regulatory or legal actions relating to the OmniPod System; the potential violation of federal or state laws prohibiting kickbacks and false and fraudulent claims or adverse affects of challenges to or investigations into our practices under these laws; product liability lawsuits that may be brought against us; unfavorable results of clinical studies relating to the OmniPod System or the products of our competitors; potential future publication of articles or announcement of positions by physician associations or other organizations that are unfavorable to our products; our ability to attract and retain key personnel; our ability to manage our growth; risks associated with potential future acquisitions; our ability to maintain compliance with the restrictions and covenants contained in our existing credit and security agreement; our ability to successfully maintain effective internal controls; and other risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2007, which was filed with the Securities and Exchange Commission on March 20, 2008 as updated by Part II, Item 1A., Risk Factors of this Quarterly Report on Form 10-Q. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements.

Overview

We are a medical device company that develops, manufactures, markets and sells an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. Our proprietary OmniPod Insulin Management System, which consists of our OmniPod disposable insulin infusion device and our handheld, wireless Personal Diabetes Manager, is the only commercially-available insulin infusion system of its kind.

The U.S. Food and Drug Administration, or FDA, approved the OmniPod System in January 2005 and we began commercial sale of the OmniPod System in the United States in October 2005. We have progressively expanded our marketing and sales efforts from an initial focus in the Eastern United States, as well as some key diabetes practitioners, academic centers and clinics elsewhere in the United States, then to the Midwest and most recently to parts of the Western United States. As of March 31, 2008, the OmniPod System was available throughout the United States.

We believe a key contributing factor to the overall attractiveness of the OmniPod System is the disposable OmniPod insulin infusion device. Each OmniPod is worn for up to three days before it is replaced, so in order to manufacture sufficient volumes of the OmniPod and achieve a low per unit production cost, we have designed the OmniPod to be manufactured through a highly automated process.

Currently, the sale price of the OmniPod System is not sufficient to cover our direct manufacturing costs. We are currently producing the OmniPod on a partially automated manufacturing line at our facility in Bedford,

Massachusetts. During 2008, we intend to complete the planned automation of this manufacturing line. In addition to the existing manufacturing line in Bedford, we expect to complete construction of a partially automated manufacturing line at a facility in China, operated by a subsidiary of Flextronics International Ltd. The additional manufacturing line in China is expected to be completed during 2008. Pending construction and installation of the remaining automated manufacturing equipment that we plan to use, we are manually performing these steps in the manufacturing process, and this limits our ability to increase our manufacturing capacity and decrease our per unit cost of goods sold, thereby causing us to continue to incur gross losses.

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We currently purchase a sub-assembly of some of the OmniPod s components from Flextronics, pursuant to an agreement entered into on January 3, 2007. On October 4, 2007, we expanded the scope of this agreement to cover the manufacture and supply of complete OmniPods. We expect to purchase complete OmniPods from Flextronics toward the end of 2008. Under the agreement, Flextronics has agreed to supply us, as a non-exclusive supplier, with OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast that we provide to Flextronics. The initial term of the agreement is three years from January 3, 2007, with automatic one-year renewals. The agreement may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date of termination. The notice period is intended to provide the parties with sufficient time to make alternative arrangements in the event of termination.

Our OmniPod manufacturing capacity as of March 31, 2008 was approximately 75,000 OmniPods per month. By completing the planned automation of our existing manufacturing line in Bedford, Massachusetts and by purchasing complete OmniPods from Flextronics, we expect to increase the production capacity of OmniPods to in excess of 200,000 OmniPods per month toward the end of 2008. By increasing production volumes of the OmniPod, we will be able to reduce our raw material costs and improve absorption of manufacturing overhead costs. This is important to allow us to achieve profitability.

Our sales and marketing effort is focused on generating demand and acceptance of the OmniPod System among healthcare professionals, people with insulin-dependent diabetes and third-party payors. Our marketing strategy is to build awareness for the benefits of the OmniPod System through a wide range of education programs, patient demonstration programs, support materials and events at the national, regional and local levels.

During the three months ended March 31, 2008, we increased our salesforce from 17 to 45 territory managers, and as of March 31, 2008, the OmniPod System was available in all 50 states, the District of Columbia and Puerto Rico. We also increased the number of Certified Diabetes Educators from 17 to 23 during the three months ended March 31, 2008.

As a medical device company, reimbursement from third-party payors is an important element of our success. If patients are not adequately reimbursed for the costs of using the OmniPod System, it will be much more difficult for us to penetrate the market. We continue to negotiate contracts establishing reimbursement for the OmniPod System with national and regional third-party payors, and we believe that substantially all of the units sold have been reimbursed by third-party payors, subject to applicable deductible and co-payment amounts. As we expand our sales and marketing coverage area and increase our manufacturing capacity, we will need to maintain and expand available reimbursement for the OmniPod System.

Since our inception in 2000, we have incurred losses every quarter. In the three months ended March 31, 2008, we incurred a net loss of $19.9 million. As of March 31, 2008, we had an accumulated deficit of $175.5 million. We have financed our operations through the private placement of equity securities, secured indebtedness and public offerings of our common stock. As of March 31, 2008, we had $24.0 million of secured debt outstanding. Since inception, we have received net proceeds of $244.6 million from the issuance of redeemable convertible preferred stock and common stock.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts for the remainder of 2008 will be focused primarily on expanding our production capacity, reducing our per-unit production costs and expanding our sales and marketing efforts for the OmniPod System. The expansion of our manufacturing capacity will allow us to increase production volumes which will help us to achieve lower material costs due to volume purchase discounts and improve the absorption of manufacturing overhead costs. Achieving these objectives is expected to require additional investments in manufacturing and additional hiring of sales and administrative personnel with the goal of increasing our market penetration. We believe that we will continue to incur net losse