

INSULET CORP  
Form 10-Q  
November 13, 2008

Table of Contents

**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, 2008**

**OR**

☐ **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**

(State or other jurisdiction of incorporation or  
organization)

**04-3523891**

(I.R.S. Employer Identification Number)

**9 Oak Park Drive**

**Bedford, Massachusetts**

(Address of principal executive offices)

**01730**

(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 ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ 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 ☐ No ☒

As of November 7, 2008, the registrant had 27,762,578 shares of common stock outstanding.

**INSULET CORPORATION  
TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>1</b>
<u>Item 1. Condensed Consolidated Financial Statements (unaudited)</u>	1
<u>Condensed Consolidated Balance Sheets at September 30, 2008 and December 31, 2007</u>	1
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2008 and 2007</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2008 and 2007</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	23
<u>Item 4T. Controls and Procedures</u>	24
<b><u>PART II. OTHER INFORMATION</u></b>	<b>25</b>
<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	25
<u>Item 3. Defaults Upon Senior Securities</u>	26
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	26
<u>Item 5. Other Information</u>	26
<u>Item 6. Exhibits</u>	26
<u>Signatures</u>	27
<u>Ex-10.1 Amended and Restated 2007 Stock Option and Incentive Plan</u>	
<u>Ex-31.1 Certification of Duane DeSisto, President and Chief Executive Officer</u>	
<u>Ex-31.2 Certification of Carsten Boess, Chief Financial Officer</u>	
<u>Ex-32.1 Certification of Duane DeSisto, President and Chief Executive Officer, and Carsten Boess, Chief Financial Officer pursuant to Section 906</u>	

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements**

**INSULET CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEET**

	<b>As of September 30, 2008 (Unaudited) (In thousands, except share data)</b>	<b>As of December 31, 2007</b>
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 74,134	\$ 94,588
Accounts receivable, net	11,842	4,783
Inventories	16,467	7,990
Prepaid expenses and other current assets	3,521	1,391
Total current assets	105,964	108,752
Property and equipment, net	26,080	21,304
Other assets	3,288	685
Total assets	\$ 135,332	\$ 130,741
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 5,965	\$ 4,544
Accrued expenses	7,587	4,464
Deferred revenue	2,271	1,350
Current portion of long-term debt		10,671
Total current liabilities	15,823	21,029
Long-term debt, net of current portion	85,000	16,006
Other long-term liabilities	2,861	1,431
Total liabilities	103,684	38,466
<b>Stockholders' equity</b>		
Preferred stock, \$.001 par value:		
Authorized: 5,000,000 shares at September 30, 2008 and December 31, 2007.		
Issued and outstanding: zero shares at September 30, 2008 and December 31, 2007		
Common stock, \$.001 par value:		
Authorized: 100,000,000 shares at September 30, 2008 and December 31, 2007. Issued and outstanding: 27,748,162 and 27,223,820 shares at September 30, 2008 and December 31, 2007, respectively		
Additional paid-in capital	29	28
Accumulated deficit	251,706	247,835
	(220,087)	(155,579)

Subscription receivable		(9)
Total stockholders' equity	31,648	92,275
Total liabilities and stockholders' equity	\$ 135,332	\$ 130,741

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

Table of Contents

**INSULET CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>(In thousands, except share and per share data)</b>			
	<b>(Unaudited)</b>			
Revenue	\$ 10,110	\$ 3,791	\$ 24,198	\$ 9,011
Cost of revenue	10,197	7,583	29,980	19,054
Gross loss	(87)	(3,792)	(5,782)	(10,043)
Operating expenses:				
Research and development	3,263	2,231	9,569	7,221
General and administrative	6,308	3,388	16,900	8,845
Sales and marketing	10,176	4,144	29,735	10,652
Impairment of assets		1,027		1,027
Total operating expenses	19,747	10,790	56,204	27,745
Operating loss	(19,834)	(14,582)	(61,986)	(37,788)
Interest income	481	1,418	1,554	2,435
Interest expense	(1,399)	(475)	(4,076)	(2,444)
Net interest income (expense)	(918)	943	(2,522)	(9)
Change in value of preferred stock warrant liability				(74)
Net loss	(20,752)	(13,639)	(64,508)	(37,871)
Net loss per share basic and diluted	\$ (0.75)	\$ (0.52)	\$ (2.34)	\$ (2.85)
Weighted average number of shares used in calculating basic and diluted net loss per share	27,716,473	26,322,763	27,560,258	13,294,107

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

Table of Contents

**INSULET CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Nine Months Ended  September 30,  2008                      2007  (In thousands)  (Unaudited)</b>	
<b>Cash flows from operating activities</b>		
Net loss	\$ (64,508)	\$ (37,871)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	4,665	3,352
Amortization of debt discount	596	179
Redeemable convertible preferred stock warrant expense		74
Stock compensation expense	2,618	939
Provision for bad debts	2,012	682
Loss on impairment and disposal of assets		1,027
Non cash interest expense	856	(57)
Changes in operating assets and liabilities:		
Accounts receivable	(9,071)	(2,608)
Inventory	(8,477)	(1,182)
Prepays and other current assets	(2,130)	64
Other assets	9	(478)
Accounts payable and accrued expenses	4,544	276
Other long term liabilities	2,330	1,012
Deferred revenue, short term	921	427
Net cash used in operating activities	(65,635)	(34,164)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(9,441)	(8,340)
Net cash used in investing activities	(9,441)	(8,340)
<b>Cash flows from financing activities</b>		
Principal payments of long term loan	(5,454)	
Net proceeds from convertible note offering	81,532	
Redemption of long term loan	(22,719)	
Proceeds from issuance of common stock, net of offering expenses	1,254	113,486
Proceeds from payment of subscription receivable	9	
Net cash provided by financing activities	54,622	113,486
Net increase (decrease) in cash and cash equivalents	(20,454)	70,982
Cash and cash equivalents, beginning of period	94,588	33,231
Cash and cash equivalents, end of period	\$ 74,134	\$ 104,213

**Supplemental disclosure of cash flow information**

Cash paid for interest	\$ 1,746	\$ 2,368
------------------------	----------	----------

**Non-cash financing activities**

Conversion of preferred stock to common stock upon initial public offering	\$	\$ 119,509
--	----	------------

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



**Table of Contents**

**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 (OmniPod), which consists of the OmniPod disposable insulin infusion device and the handheld, wireless Personal Diabetes Manager (PDM). 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 unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2008 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2008, or for any other subsequent interim period.

The condensed consolidated financial statements in this Quarterly Report on Form 10-Q 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 GAAP 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 stock options, 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 in this Quarterly Report on Form 10-Q include the accounts of the Company and its wholly-owned subsidiary, Sub-Q Solutions, Inc. All material inter-company 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, patients and third-party distributors. 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 payor-specific collection issues that have been identified.

## **Table of Contents**

### ***Inventories***

Inventories are stated at the lower of cost or market, determined under the first-in, first-out ( FIFO ) method. Prior to June 30, 2008, inventory was recorded at market value as the Company was selling the OmniPods and PDMs at a loss. Since June 30, 2008, the Company's inventory of finished OmniPods has been presented at cost, as the costs to produce OmniPods are lower than the Company's selling price. The Company's inventory of PDMs continue to be stated at the market value as the costs to produce PDMs continue to be greater than the Company's selling price. Work in process is calculated based upon the stage of completion using estimated labor inputs for each stage in production. Costs for PDMs and OmniPods include raw materials, labor and manufacturing overhead. The Company evaluates inventory valuation on a quarterly basis for excess, obsolete or slow-moving items.

### ***Property and 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 and 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 nearly all of its revenue from sales of its OmniPod Insulin Management System to diabetes patients and third-party distributors who resell the product to diabetes patients. The initial sale to a new customer typically includes OmniPods and a Starter Kit, which is comprised of 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 for sales directly to patients or a purchase order for sales to a third-party distributor.

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

The selling prices for all sales are fixed and agreed with the patient or third-party distributor, 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.

## **Table of Contents**

The Company has considered the requirements of Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables* ( EITF 00-21 ), 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 to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of the Company's 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 3% 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 related costs of revenue for 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 concluded that it had sufficient historical data on which to base its estimated returns from January 1, 2008. If the Company had continued to defer all initial shipments until the 45-day right of return had expired, deferred revenue as of September 30, 2008 would have been larger by \$1.2 million.

In March 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 initial 5-year term of the agreement, and the non-current portion of the agreement fee is included in other long-term liabilities. Under the amended Abbott agreement, beginning July 1, 2008, Abbott agreed to pay an amount to the Company for services performed by Insulet in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to a new customer. The Company recognizes the revenue related to this portion of the Abbott agreement at the time the revenue is recognized on the sale of the PDM to the patient. In the three and nine months ended September 30, 2008, the Company recognized \$1.2 million and \$1.4 million of revenue, respectively, related to the amended Abbott agreement. There was no impact to cost of revenue related to this agreement.

The Company had deferred revenue of \$2.3 million and \$1.4 million as of September 30, 2008 and December 31, 2007, respectively. The deferred revenue recorded as of September 30, 2008 was comprised of product-related revenue as well as the current portion of the agreement fee related to the Abbott agreement.

### ***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 or third-party distributors, the majority of shipments are billed to third-party insurance payors. As of September 30, 2008, the two largest third-party payors accounted for 6% and 5% of gross accounts receivable balances, respectively. As of December 31, 2007, the two largest third-party payors accounted for 8% and 4% of gross accounts receivable balances, respectively.

### ***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.

**Table of Contents**

As of September 30, 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.

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 Company adopted SFAS 159 in the first quarter of fiscal year 2008. The adoption of SFAS 159 did not have a material effect on the Company's financial position, results of operations or cash flows.

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 May 2008, the FASB issued Staff Position Accounting Principles Board 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ), which is effective for fiscal years beginning after December 15, 2008. FSP APB 14-1 clarifies that convertible debt instruments that may be settled in cash upon conversion should be separated between the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. The Company is currently evaluating the effect of FSP APB 14-1 and it has not yet determined the impact of the standard on its financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 ). This standard identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company is currently evaluating the potential effect of implementing this standard.

**3. Convertible Notes and Repayment and Termination of Term Loan**

In June 2008, the Company sold \$85 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the 5.375% Notes ) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year, beginning December 15, 2008. The 5.375% Notes are convertible into the Company's common stock at an initial conversion rate of 46.8467 shares of common stock per \$1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately \$21.35 per share, representing a conversion premium of 34% to the last reported sale price of the Company's common stock on the NASDAQ Global Market on June 10, 2008, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of

**Table of Contents**

the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of the Company's common stock for the remainder of the conversion value in excess of the principal amount. The Company does not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require the Company to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest, to, but excluding, the date of repurchase.

If a holder elects to convert its 5.375% Notes upon the occurrence of a make-whole fundamental change, as defined in the Indenture for the 5.375% Notes, the holder may be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option and are set forth in the Indenture to the 5.375% Notes. In no event will the number of shares issuable upon conversion of a note exceed 62.7746 per \$1,000 principal amount (subject to adjustment as described in the Indenture for the 5.375% Notes).

The Company incurred interest expense of approximately \$1.1 million and \$1.3 million for the three and nine months ended September 30, 2008, respectively, related to the 5.375% Notes. The Company incurred deferred financing costs related to this offering of approximately \$3.5 million, which are recorded in the condensed consolidated balance sheet and are being amortized as a component of interest expense over the five year term of the notes.

The Company received net proceeds of approximately \$81.5 million from this offering. Approximately \$23.2 million of the proceeds from this offering were used to repay and terminate the Company's outstanding term loan and the Company intends to use the remainder for general corporate purposes. On June 16, 2008, the Company repaid the entire outstanding principal balance, plus accrued and unpaid interest, under its existing term loan in the aggregate of approximately \$21.8 million. Additionally, the Company paid a prepayment fee related to the term loan of approximately \$0.4 million, a termination fee related to the term loan of \$0.9 million, and incurred certain other expenses related to the repayment and termination of the term loan. The Company incurred interest expense of approximately \$0 and \$1.5 million for the three and nine months ended September 30, 2008, respectively, and approximately \$0.9 million and \$2.6 million for the three and nine months ended September 30, 2007 respectively, related to the term loan. The term loan was subject to a loan origination fee of \$0.9 million, which was recorded in the condensed consolidated balance sheet and was amortized as a component of interest expense over the term of the loan. The remaining balance of deferred financing costs of approximately \$0.6 million was written off at the repayment and termination date. 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 in May 2007. The Company recorded the \$0.8 million fair value of the warrants as a discount to the term loan. Upon repayment and termination of the term loan, the Company recognized approximately \$0.5 million as interest expense for the unamortized balance of the warrants' fair value. The difference between the amount paid, including the prepayment fee, and the carrying value of the term loan, including the remaining deferred financing costs and unamortized warrants to purchase common stock, was recognized as a \$1.5 million loss from early extinguishment of the term loan.

**4. 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 and nine months ended September 30, 2008 and 2007, 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:



**Table of Contents**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Convertible notes	3,981,970		3,981,970	
Outstanding options	2,887,178	2,866,928	2,887,178	2,866,928
Outstanding warrants	62,752	78,440	62,752	78,440
Total	6,931,900	2,945,368	6,931,900	2,945,368

**5. Accounts Receivable**

The components of accounts receivable are as follows:

	<b>September 30, 2008</b>	<b>As of December 31, 2007</b>
	<b>(In thousands)</b>	
Trade receivables	\$ 14,217	\$ 5,992
Allowance for doubtful accounts	(2,375)	(1,209)
	\$ 11,842	\$ 4,783

**6. Inventories**

Inventories consist of the following:

	<b>September 30, 2008</b>	<b>As of December 31, 2007</b>
	<b>(In thousands)</b>	
Raw materials	\$ 5,137	\$ 2,994
Work-in-process	192	1,583
Finished goods	11,138	3,413
	\$ 16,467	\$ 7,990

The Company is currently producing the OmniPod on a partially automated manufacturing line at a facility in China, operated by a subsidiary of Flextronics International Ltd. The Company also produces certain sub-assemblies for the OmniPod as well as maintains packaging operations in its facility in Bedford, Massachusetts. The Company purchases complete OmniPods from Flextronics, pursuant to its agreement with Flextronics entered into on January 3, 2007 and revised on October 4, 2007. The initial term of the agreement is three years from January 3, 2007, with automatic one-year renewals.

Inventories of finished goods were adjusted by \$12,000 and \$625,000 as of September 30, 2008 and December 31, 2007, respectively, to reflect values at the lower of cost or market. As of September 30, 2008 and December 31, 2007, 1% 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. Prior to June 30, 2008, sales and production volumes were not adequate to result in per-unit costs that were lower than the current market price for the OmniPod. Since June 30, 2008, the Company's

inventory of finished OmniPods has been presented at cost, as the costs to produce OmniPods are lower than the Company's selling price. The Company's inventory of PDMs continue to be stated at the market value as the costs to produce PDMs continue to be greater than the Company's selling price.



**Table of Contents****7. 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 estimated and 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:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>		<b>(In thousands)</b>	
Balance at the beginning of period	\$ 1,500	\$ 392	\$ 865	\$ 193
Warranty expense	1,103	509	2,873	1,129
Warranty claims settled	(669)	(331)	(1,804)	(752)
Balance at the end of the period	\$ 1,934	\$ 570	\$ 1,934	\$ 570
Composition of balance:				
Short-term	801	276	801	276
Long-term	1,133	294	1,133	294
Total warranty balance	\$ 1,934	\$ 570	\$ 1,934	\$ 570

**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 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.

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.

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

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.

**Table of Contents**

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 and nine months ended September 30, 2008, 44,052 and 518,347 common shares were issued related to exercises of employee stock options, respectively.

***Stock-Based Compensation Plans***

Activity under the Company's stock option plans:

	<b>Number of Options(#)</b>	<b>Weighted Average Exercise Price(\$)</b>	<b>Aggregate Intrinsic Value(\$)</b>
Balance, December 31, 2007	2,691,973	6.94	
Granted	816,329	16.99	
Exercised	(518,347)	2.29	7,845,200 (1)
Canceled	(102,777)	16.61	
Balance, September 30, 2008	2,887,178	10.27	
Vested, September 30, 2008	1,341,395	4.82	12,276,206 (2)
Vested and expected to vest, September 30, 2008 (3)	2,471,806		

(1) The aggregate intrinsic value was calculated based on the positive difference between the fair market 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 fair market value of the Company's common stock as of September 30, 2008, and the exercise price of the underlying options.

- (3) Represents the number of vested options as of September 30, 2008, plus the number of unvested options expected to vest as of September 30, 2008, based on the unvested options outstanding at September 30, 2008, adjusted for an estimated forfeiture rate of 12%.

In the three and nine months ended September 30, 2008 and 2007, no shares were contingently issued under the employee stock purchase plan ( ESPP ). In the three and nine months ended September 30, 2008, the Company recorded compensation charges of approximately \$10,000 and \$24,000 respectively, of stock-based compensation charges related to the ESPP. For the three and nine months ended September 30, 2007, the Company recognized \$5,000 of compensation charges related to the ESPP.

Employee stock-based compensation expense under SFAS 123R recognized in the three and nine months ended September 30, 2008 was \$1.0 million and \$2.6 million, respectively. For the three and nine months ended September 30, 2007, the Company recognized employee stock-based compensation expense of approximately \$0.4 million and \$0.9 million, respectively.

**Table of Contents**

**10. Impairment of Property and Equipment**

The Company evaluates financial and operational impact of possible improvements of its manufacturing processes. The evaluation of new processes involves assessment of vendors, product cost and product quality, among other things, and there is no assurance that process improvements are implemented. During the three months ended September 30, 2007, the Company completed the evaluation of an upgrade of its manufacturing processes, and as a result, the Company performed a review of certain production equipment. The review resulted in a non-cash charge of \$1.0 million for the write-down of certain impaired assets. The impaired assets, which had no future use, consist of manufacturing equipment. The impairment charges were recorded following determination of the fair value of cash flows resulting from use of the affected assets, and the carrying value of the assets has been reduced to reflect their fair value. There were no impairment charges recorded in the three or nine months ended September 30, 2008.

**11. 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.

**Table of Contents****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 condensed consolidated financial statements and the accompanying notes to those financial statements included in this Quarterly Report on Form 10-Q. This Quarterly Report on Form 10-Q contains forward-looking statements. These forward-looking statements are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have 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; 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 effects 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 raise additional funds in the future; our ability to maintain compliance with the restrictions and related to our indebtedness; 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 disposable OmniPod 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, to having full availability of the OmniPod System in the entire United States. We focus our sales towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetic patients.

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.

## **Table of Contents**

To achieve profitability, we are seeking to reduce the per unit production cost for the OmniPod through installation of automated manufacturing equipment, collaboration with contract manufacturers and reduction of cost of supplies of raw materials and sub-assemblies.

We are currently producing the OmniPod on a partially automated manufacturing line at a facility in China, operated by a subsidiary of Flextronics International Ltd. We also produce certain sub-assemblies for the OmniPod as well as maintain packaging operations in our facility in Bedford, Massachusetts. We have automated certain steps in the manufacturing process which were being performed manually in the past, allowing us to increase our manufacturing capacity and decrease our per-unit cost of goods sold, thereby beginning to generate gross profits.

We purchase complete OmniPods from Flextronics, pursuant to our agreement with Flextronics entered into on January 3, 2007 and revised on October 4, 2007. We began to purchase complete OmniPods from Flextronics during the three months ended June 30, 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 September 30, 2008 was in excess of 200,000 OmniPods per month. By increasing production volumes of the OmniPod, we will be able to reduce our per-unit 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, third-party payors and third-party distributors. 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. In addition, we are using third-party distributors to improve our access to managed care and government reimbursement programs, expand our commercial presence and provide access to additional potential patients.

During the nine months ended September 30, 2008, we made the OmniPod System available in all 50 states, the District of Columbia and Puerto Rico. We also increased our direct-to-consumer promotion and advertising activities. Among other activities, we began television advertising, and we intend to maintain, improve and refine our marketing efforts.

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 and nine months ended September 30, 2008, we incurred net losses of \$20.8 million and \$64.5 million, respectively. As of September 30, 2008, we had an accumulated deficit of \$220.1 million. We have financed our operations through the private placement of equity securities, public offerings of our common stock as well as a private placement of our convertible debt. As of September 30, 2008, we had \$85 million of convertible debt outstanding. Since inception, we have received aggregate net proceeds of \$327.0 million from the issuance of redeemable convertible preferred stock, common stock and convertible debt.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts for the remainder of 2008 will be focused primarily on reducing our per-unit production 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 losses in the near term in

**Table of Contents**

order to achieve these objectives, although we believe that the accomplishment of these combined efforts will have a positive impact on our financial condition in the future.

*Convertible Notes and Repayment and Termination of Term Loan*

In June 2008, we sold \$85 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the 5.375% Notes ) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year, beginning December 15, 2008. The 5.375% Notes are convertible into the Company's common stock at an initial conversion rate of 46.8467 shares of common stock per \$1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately \$21.35 per share, representing a conversion premium of 34% to the last reported sale price of our common stock on the NASDAQ Global Market on June 10, 2008, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of our common stock for the remainder of the conversion value in excess of the principal amount. We do not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require us to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest, to, but excluding, the date of repurchase.

If a holder elects to convert its 5.375% Notes upon the occurrence of a make-whole fundamental change, as defined in the Indenture for the 5.375% Notes, the holder may be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option, and are set forth in the Indenture for the 5.375% Notes. In no event will the shares issuable upon conversion of a note exceed 62.7746 per \$1,000 principal amount (subject to adjustment as described in the Indenture for the 5.375% Notes).

We incurred interest expense of approximately \$1.1 million and \$1.3 million for the three and nine months ended September 30, 2008, respectively, related to the 5.375% Notes. We incurred deferred financing costs related to this offering of approximately \$3.5 million, which are recorded in the condensed consolidated balance sheet and are being amortized as a component of interest expense over the five year term of the notes.

We received net proceeds of approximately \$81.5 million from this offering. Approximately \$23.2 million of the net proceeds from this offering were used to repay and terminate our outstanding term loan and we intend to use the remainder for general corporate purposes. On June 16, 2008, we repaid the entire outstanding principal balance, plus accrued and unpaid interest, under our existing term loan in the aggregate of approximately \$21.8 million. Additionally, we paid a prepayment fee related to the term loan of approximately \$0.4 million, a termination fee related to the term loan of \$0.9 million, and incurred certain other expenses related to the repayment and termination of the term loan. We incurred interest expense of approximately \$0 and \$1.5 million for the three and nine months ended September 30, 2008, respectively, and approximately \$0.9 million and \$2.6 million for the three and nine months ended September 30, 2007, respectively, related to the term loan. The term loan was subject to a loan origination fee of \$0.9 million, which was recorded in the condensed consolidated balance sheet and was amortized as a component of interest expense over the term of the loan. The remaining balance of deferred financing costs of approximately \$0.6 million was written off at the repayment and termination date. In connection with this term loan, we 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 our initial public offering in May 2007. We recorded the \$0.8 million fair value of the warrants as a discount to the term loan. Upon repayment and termination of the term loan, we recognized approximately \$0.5 million as interest expense for the unamortized balance of the warrants' fair value. The difference between the amount paid, including the prepayment fee, and the carrying value of the term loan, including the remaining deferred financing costs and unamortized warrants to purchase common stock, was recognized as a \$1.5 million loss from early extinguishment of the term loan.





**Table of Contents****Financial Operations Overview**

**Revenue.** Revenue is recognized in accordance with Securities and Exchange Staff Accounting Bulletin No. 104 ( SAB 104 ) and Statement of Financial Accounting Standards No. 48, *Revenue Recognition when the Right of Return Exists* ( SFAS 48 ). We derive nearly all of our revenue from the sale of the OmniPod System directly to patients and third-party distributors who resell the product to diabetes patients. The OmniPod System is comprised of two devices: the OmniPod, a disposable insulin infusion device that the patient wears for up to three days and then replaces; and the Personal Diabetes Manager ( PDM ), a handheld device much like a personal digital assistant that wirelessly programs the OmniPod with insulin delivery instructions, assists the patient with diabetes management and incorporates a blood glucose meter. Revenue is derived from the sale to new customers or third-party distributors of OmniPods and Starter Kits, which include the PDM, two OmniPods, the OmniPod System User Guide and OmniPod System Interactive Training CD, and from the subsequent sales of additional OmniPods to existing customers. Customers generally order a three-month supply of OmniPods. For the three and nine months ended September 30, 2008 and for preceding periods, materially all of our revenue was derived from sales within the United States.

In March 2008, we 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 with Abbott. We are recognizing the payment as revenue over the 5 year term of the agreement. Under the amended Abbott agreement, beginning July 1, 2008, Abbott agreed to pay us an amount for services performed by us in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to a new customer. We recognize the revenue related to this portion of the Abbott agreement at the time the revenue is recognized on the sale of the PDM to the patient. In the three and nine months ended September 30, 2008, we recognized \$1.2 million and \$1.4 million of revenue, respectively, related to the amended Abbott agreement. There was no impact to cost of revenue related to this agreement.

Prior to January 1, 2008, we deferred recognition of revenue from the OmniPods and Starter Kit shipped as part of a customer's initial shipment for 45 days during which time the items could be returned and completely refunded. Effective for shipments made after December 31, 2007, we have deferred revenue based on estimated returns, assessment of collectibility and the transfer of risk and title. If we had continued to defer all initial shipments until the 45-day right of return had expired, deferred revenue as of September 30, 2008 would have been larger by approximately \$1.2 million. As of September 30, 2008, the balance of deferred revenue was \$2.3 million, which includes the current portion of deferred revenue related to the agreement fee received under the first amendment to our development agreement with Abbott.

**Cost of revenue.** Cost of revenue consists primarily of raw materials, labor, warranty and overhead costs related to the OmniPod System. Cost of revenue also includes depreciation, distribution, freight and packaging costs. For the remainder of 2008, we expect the cost of revenue to decrease as a percentage of revenue due to expected reductions in per-unit raw materials costs associated with volume purchase discounts and increases in our OmniPod manufacturing capacity as the supply of complete OmniPods and subassemblies from Flextronics increases. The increase in our OmniPod manufacturing capacity is expected to reduce the per-unit cost of manufacturing the OmniPods by allowing us to spread our fixed and semi-fixed overhead costs over a greater number of units. However, if sales volumes do not continue to increase, then the average cost of revenue per OmniPod may not decrease and we may continue to incur gross losses.

**Research and development.** Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical functions, as well as the costs of market studies and product development projects. We expense all research and development costs as incurred. For the remainder of 2008, we expect overall research and development spending to remain significant and at a level comparable with previous periods in order to support our current research and development efforts, which are focused primarily on increased functionality, design for ease of use and reduction of production cost, as well as developing a new OmniPod System that incorporates continuous glucose monitoring technology.

**Sales and marketing.** Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support, customer support and training functions, sales commissions paid to our sales representatives and costs associated with participation in medical conferences, physician symposia and promotional



**Table of Contents**

activities, including distribution of units used in our demonstration kit programs. In 2008, we expect sales and marketing expenses to continue to increase significantly compared to 2007, as we hired additional sales and marketing personnel, are incurring additional sales commission expense related to sales growth and are expanding our sales and marketing efforts, which include the implementation of broader direct-to-consumer marketing programs and the continuation of our Patient Demonstration Kit Program.

*General and administrative.* General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, finance, information technology and human resource functions, as well as legal fees, accounting fees, insurance costs and costs related to our facilities. We expect general and administrative expenses to continue to increase compared to 2007 as we add personnel and increase our use of external services in support of our commercial expansion.

**Results of Operations**

The following table presents certain statement of operations information for the three and nine months ended September 30, 2008 and 2007:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2008	2007	% Change (In thousands) (Unaudited)	2008	2007	% Change
Revenue	\$ 10,110	\$ 3,791	167%	\$ 24,198	\$ 9,011	169%
Cost of revenue	10,197	7,583	34%	29,980	19,054	57%
Gross loss	(87)	(3,792)	98%	(5,782)	(10,043)	42%
Operating expenses:						
Research and development	3,263	2,231	46%	9,569	7,221	33%
General and administrative	6,308	3,388	86%	16,900	8,845	91%
Sales and marketing	10,176	4,144	146%	29,735	10,652	179%
Impairment of assets		1,027			1,027	
Total operating expenses	19,747	10,790	83%	56,204	27,745	103%
Operating loss	(19,834)	(14,582)	36%	(61,986)	(37,788)	64%
Other income (expense), net	(918)	943	197%	(2,522)	(83)	2939%
Net loss	\$ (20,752)	\$ (13,639)	52%	\$ (64,508)	\$ (37,871)	70%

**Comparison of the Three and Nine Months Ended September 30, 2008 and 2007****Revenue**

Our total revenue was \$10.1 million and \$24.2 million for the three and nine months ended September 30, 2008, respectively, compared to \$3.8 million and \$9.0 million for the same periods in 2007. The increase in revenue is primarily due to an increased number of patients using the OmniPod. In addition, the increase in patients resulted in additional revenue related to the Abbott agreement of \$1.2 million and \$1.4 million in the three and nine months ended September 30, 2008, respectively. Furthermore, due to a change in our estimate of deferred revenue, revenue for the three and nine months ended September 30, 2008 was impacted favorably by \$0.1 million and \$1.2 million,

respectively. As we continue our sales and marketing efforts, and add more patients that use the OmniPod System, we expect our revenue to increase.

*Cost of Revenue*

Cost of revenue was \$10.2 million and \$30.0 million for the three and nine months ended September 30, 2008, respectively, compared to \$7.6 million and \$19.1 million for the same periods in 2007. The increase is due to increased sales volume offset by efficiencies resulting from increased manufacturing capacity. Cost of revenue includes adjustment of inventory to lower of cost or market and indirect costs. The per-unit cost to manufacture the

**Table of Contents**

OmniPod decreased in the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, resulting in improvement of our gross margin. The decrease is a result of increased production volumes, which improved the absorption of manufacturing overhead costs, increased automation in our manufacturing process, increased purchases of subassemblies with a lower cost from Flextronics, and supplies of complete OmniPods from Flextronics.

*Research and Development*

Research and development expenses increased \$1.0 million, or 46%, to \$3.3 million for the three months ended September 30, 2008 compared to \$2.2 million for the same period in 2007. Research and development expenses increased \$2.3 million, or 33%, to \$9.6 million for the nine months ended September 30, 2008, compared to \$7.2 million for the same period in 2007. For the three months ended September 30, 2008, the increase in research and development expenses was primarily attributable to an increase of \$0.8 million in employee related expenses, \$0.1 million for tools and supplies and \$0.2 million for other expenses. For the nine months ended September 30, 2008, the increase in research and development expenses was primarily attributable to an increase of \$0.9 million in consulting services related to our ongoing development projects, \$1.9 million increase in employee related expenses, \$0.3 million for tools and supplies, partly offset by a reduction of \$0.2 million in prototype expenses.

*General and Administrative*

General and administrative expenses increased \$2.9 million, or 86%, to \$6.3 million for the three months ended September 30, 2008, compared to \$3.4 million for the same period in 2007. General and administrative expenses increased \$8.1 million, or 91%, to \$16.9 million for the nine months ended September 30, 2008, compared to \$8.8 million for the same period in 2007. For the three months ended September 30, 2008, the increase in general and administrative expenses was primarily due to an increase of \$0.2 million in employee compensation and benefit costs associated with the hiring of additional employees, \$0.2 million in distribution expenses, \$0.6 million related to increased allowances and write-offs for doubtful trade accounts receivables, \$0.7 million in consulting and legal expenses, \$0.2 million in depreciation expense and \$0.1 million in insurance expenses. For the nine months ended September 30, 2008, the increase in general and administrative expenses was primarily due to an increase of \$2.1 million in employee compensation and benefit costs associated with the hiring of additional employees, \$1.2 million related to increased allowances and write-offs for doubtful trade accounts receivables, \$1.1 million in consulting and legal expenses, \$0.7 million in distribution expenses, \$0.4 million in insurance expenses, \$0.5 million in depreciation expense and \$0.2 million in travel expenses. .

*Sales and Marketing*

Sales and marketing expenses increased \$6.0 million, or 146%, to \$10.2 million for the three months ended September 30, 2008, compared to \$4.1 million for the same period in 2007. Sales and marketing expenses increased \$19.1 million, or 179%, to \$29.7 million for the nine months ended September 30, 2008, compared to \$10.7 million for the same period in 2007. For the three months ended September 30, 2008, the increase in sales and marketing expenses was primarily due to an increase of \$3.2 million in employee compensation and benefit costs resulting from the hiring of additional employees in our sales and marketing areas, \$0.8 million related to Patient Demonstration Kits, \$0.7 million in travel and trade show expenses used to support our selling efforts, \$0.9 million in outside consulting services, which include our external trainers, and \$0.4 million in other expenses. For the nine months ended September 30, 2008, the increase in sales and marketing expenses was primarily due to an increase of \$8.9 million in employee compensation and benefit costs resulting from the hiring of additional employees in our sales and marketing areas, \$3.5 million related to Patient Demonstration Kits, \$2.3 million in travel and trade show expenses used to support our selling efforts, \$2.2 million in outside consulting services, which include our external trainers, and \$1.2 million in printing costs.

*Asset Impairment*

From time to time, we evaluate financial and operational impact of possible improvements of our manufacturing processes. The evaluation of new processes involves assessment of vendors, product cost and product quality, among other things, and there is no assurance that process improvements are implemented. During

**Table of Contents**

the three months ended September 30, 2007, we completed the evaluation of an upgrade of our manufacturing processes, and as a result we performed a review of certain production equipment. The review resulted in a non-cash charge of \$1.0 million for the write-down of certain impaired assets. The impaired assets, which had no future use, consist of manufacturing equipment. The impairment charges were recorded following determination of the fair value of cash flows resulting from use of the affected assets, and the carrying value of the assets has been reduced to reflect their fair value. There were no impairment charges recorded in the three or nine months ended September 30, 2008.

***Other Income (Expense)***

Interest income was \$0.5 million and \$1.6 million for the three and nine months ended September 30, 2008, respectively, compared to \$1.4 million and \$2.4 million for the same periods in 2007. For the three months ended September 30, 2008, the decrease was caused primarily by lower cash balances and interest rates. For the nine months ended September 30, 2008, the impact of higher average cash balances was offset by lower interest rates. Interest income was earned from cash deposits and short-term interest bearing instruments. Interest expense was \$1.4 million and \$4.1 million for the three and nine months ended September 30, 2008, respectively, compared to \$0.5 million and \$2.4 million for the same periods in 2007. For the three months ended September 30, 2008, the increased expenses were primarily caused by \$1.1 million related to interest on the 5.375% Notes. For the nine months ended September 30, 2008, the increase was caused by \$1.3 million related to interest on the 5.375% Notes, \$1.5 million related to the repayment and termination of our term loan, partly offset by lower interest payments on our term loan due to lower principal balances and interest rates.

***Liquidity and Capital Resources***

We commenced operations in 2000 and to date we have financed our operations primarily through private placement of common and preferred stock, secured indebtedness, public offerings of our common stock and issuance of convertible debt. As of September 30, 2008, we had \$85.0 million of convertible debt outstanding. Since inception, we have received net proceeds of \$327.0 million from the issuance of redeemable convertible preferred stock, common stock and convertible debt. As of September 30, 2008, we had \$74.1 million in cash and cash equivalents. We believe that our current cash and cash equivalents, including the net proceeds from our initial and secondary public offerings and offering of convertible debt, together with the cash expected to be generated from product sales, will be sufficient to meet our projected operating and debt service requirements for at least the next twelve months.

***Resources***

In June 2008, we sold \$85 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the 5.375% Notes ) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year, beginning December 15, 2008. The 5.375% Notes are convertible into our common stock at an initial conversion rate of 46.8467 shares of common stock per \$1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately \$21.35 per share, representing a conversion premium of 34% to the last reported sale price of our common stock on the NASDAQ Global Market on June 10, 2008, per \$1,000 principal amount of the 5.375% Notes, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of our common stock for the remainder of the conversion value in excess of the principal amount. We do not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require us to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest, to, but excluding, the date of repurchase.

We received net proceeds of approximately \$81.5 million from this offering. On June 16, 2008, we used a portion of the net proceeds to repay the entire outstanding principal balance, plus accrued and unpaid interest, under

**Table of Contents**

our existing term loan in the aggregate of approximately \$21.8 million in its entirety. Additionally, we paid a prepayment fee related to the term loan of approximately \$0.4 million, a termination fee related to the term loan of \$0.9 million, and incurred certain other expenses related to the repayment and termination of the term loan.

See Overview Convertible Notes and Repayment and Termination of Term Loan above for more information about the private placement of our convertible notes and the repayment and termination of our term loan.

*Operating Activities*

The following table sets forth the amounts of cash used in operating activities and net loss for each of the periods indicated:

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Cash used in operating activities	\$ (65,635)	\$ (34,164)
Net loss	\$ (64,508)	\$ (37,871)

For each of the periods above, the increase in net cash used in operating activities was attributable primarily to the growth of our operations after adjustment for non-cash charges, such as depreciation, amortization and stock-based compensation expense as well as changes to working capital. Significant uses of cash from operations include increases in accounts receivable and inventory and other current assets. The increase in accounts receivable is primarily attributable to our increased sales, and to some extent increased aging of receivable balances. Accounts receivables are shown net of increased allowances for doubtful debt in the consolidated balance sheets. The increase in inventory balance is caused by the recent increase of our production volume made possible by increased capacity. Cash used in operating activities is partly offset by increases in accounts payable, accrued expenses and deferred revenue.

*Investing Activities*

The following table sets forth the amounts of cash used in investing activities and cash provided by financing activities for each of the periods indicated:

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Cash used in investing activities	\$ (9,441)	\$ (8,340)
Cash provided by financing activities	\$ 54,622	\$ 113,486

Cash used in investing activities in both periods was primarily for the purchase of fixed assets for use in the development and manufacturing of the OmniPod System.

*Lease Obligations*

We lease our facilities, which are accounted for as operating leases. The lease of our facilities in Bedford and Billerica, Massachusetts, generally provides for a base rent plus real estate taxes and certain operating expenses related to the lease. All operating leases contain renewal options and escalating payments over the life of the lease. As of September 30, 2008, we had an outstanding letter of credit which totaled \$0.2 million to cover our security deposits for lease obligations. This letter of credit will expire on October 30, 2009.

## **Table of Contents**

### *Capital Expenditures*

During the remainder of 2008, we will be expending funds in connection with, among other things, our efforts to expand our automated manufacturing process and increase our production capacity, and expand our sales and marketing activities. We expect total capital expenditure purchases in the full year 2008 to be at least \$10 million in connection with our efforts to expand our automated manufacturing process and increase our manufacturing capacity.

### **Off-Balance Sheet Arrangements**

As of September 30, 2008, we did not have any off-balance sheet financing arrangements.

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

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ from those estimates, and any such differences may be material to our financial statements. We believe that the policies set forth below may involve a higher degree of judgment and complexity in their application than our other accounting policies and represent the critical accounting policies and estimates used in the preparation of our financial statements. If different assumptions or conditions were to prevail, the results could be materially different from our reported results.

### ***Revenue Recognition***

We generate nearly all of our revenue from sales of our OmniPod Insulin Management System to diabetes patients or third-party distributors who resell the product to diabetes patients. The initial sale to a new customer or a third-party distributor 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 for sales directly to patients or a purchase order for sales to a third-party distributor.

Transfer of title and risk and rewards of ownership are passed to the patient or third-party distributor upon their receipt of the products.

The selling prices for all sales are fixed and agreed with the patient or third-party distributor, 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.

We have considered the requirements of Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables* ( EITF 00-21 ), when accounting for the OmniPods and Starter Kits. EITF 00-21 requires us to assess whether the different elements qualify for separate accounting. We recognize revenue for the initial shipment to a patient or other third party once all elements have been delivered.



## **Table of Contents**

We offer 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*, we defer revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a 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 3% of gross product sales.

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

Prior to January 1, 2008, we deferred the revenue and related costs of revenue for 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, we concluded that we had sufficient historical data on which to base our estimated returns from January 1, 2008. If we had continued to defer all initial shipments until the 45-day right of return had expired, deferred revenue as of September 30, 2008 would have been larger by \$1.2 million

In March 2008, we 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 us and Abbott. We recognize 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. Under the amended Abbott agreement, beginning July 1, 2008, Abbott agreed to pay us an amount for services performed by us in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to a new customer. We recognize the revenue related to this portion of the Abbott agreement at the time the revenue is recognized on the sale of the PDM to the patient. In the three and nine months ended September 30, 2008, we recognized \$1.2 million and \$1.4 million of revenue, respectively, related to the amended Abbott agreement. There was no impact to cost of revenue related to this agreement.

### ***Asset Valuation***

Asset valuation includes assessing the recorded value of certain assets, including accounts receivable, inventory and fixed assets. We use a variety of factors to assess valuation, depending upon the asset. Actual results may differ materially from our estimates. Fixed 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. We review long-lived assets, including property and equipment and intangibles, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. We also review assets under construction to ensure certainty of their future installation and integration into the manufacturing process. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. We consider various valuation factors, principally discounted cash flows, to assess the fair values of long-lived assets.

### ***Income Taxes***

We file federal and state tax returns. We have 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 our tax years remain open to examination by the major taxing jurisdictions to which we are subject.

We recognize estimated interest and penalties for uncertain tax positions in income tax expense. As of September 30, 2008, we had no interest and penalty accrual or expense.

### ***Accounts Receivable and Allowance for Doubtful Accounts***

Accounts receivable consist of amounts due from third-party payors, patients and third-party distributors.

**Table of Contents**

In estimating whether accounts receivable can be collected, we perform 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 payor-specific collection issues that have been identified.

**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 for interim periods within those fiscal years. We adopted SFAS 157 in the first quarter of 2008. The adoption of SFAS-157 did not have a material effect on our 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 became effective for fiscal years that began after November 15, 2007. We adopted SFAS 159 in the first quarter of 2008. The adoption of SFAS-159 did not have a material effect on our financial position, results of operations or cash flows.

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 our financial position, results of operations or cash flows.

In May 2008, the FASB issued Staff Position Accounting Principles Board 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ), which is effective for fiscal years beginning after December 15, 2008. FSP APB 14-1 clarifies that convertible debt instruments that may be settled in cash upon conversion should be separated between the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. We are currently evaluating the effect of FSP APB 14-1 and have not yet determined the impact of the standard on our financial position, results of operations or cash flows.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 ). This standard identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. We are currently evaluating the potential effect of implementing this standard.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash, cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses and long-term obligations. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents. The primary objectives of our investment strategy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. To minimize our exposure to an adverse shift in interest rates, we invest mainly in cash equivalents and short-term investments and maintain an average maturity of six months or less. We do not believe that a 10% change in interest rates would have a material impact on the fair value of our investment portfolio or our interest income.

**Table of Contents**

As of September 30, 2008, we had outstanding debt recorded at \$85.0 million related to our 5.375% Notes. As the interest rate on the 5.375% Notes is fixed, changes in interest rates do not affect the value of our debt.

**Item 4T. Controls and Procedures**

**Disclosure Controls and Procedures**

As of September 30, 2008, management conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) under the supervision and with the participation of our chief executive officer and chief financial officer. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. Based upon that evaluation, our chief executive officer and chief financial officer have concluded that they believe that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2007, which could materially affect our business, financial condition or future results. These risks are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Other than set forth below, there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007.

***We may not be able to generate sufficient cash to service all of our indebtedness, including our 5.375% Convertible Senior Notes due June 15, 2013, and may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.***

Our ability to make scheduled payments or to refinance our debt obligations depends on our financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness, including the \$85 million in indebtedness incurred in connection with the sale in June 2008 of 5.375% Convertible Senior Notes due June 15, 2013. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness, including the notes. We cannot assure you that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations then due.

***We need to expand our distribution network to maintain and grow our business and revenues. If we fail to expand and maintain an effective sales force or successfully develop our relationship with distributors, our business, prospects and brand may be materially and adversely affected.***

We currently promote, market and sell substantially all of our OmniPod Systems through our own direct sales force. As part of our growth plan, we intend to increase the number of distributors we utilize to distribute our OmniPod System. We cannot assure you that we will be able to successfully develop our relationships with third-party distributors. If we fail to do so, our sales could fail to grow or could even decline, and our ability to grow our business could be adversely affected. Distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our products and grow or maintain product sales. If our distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

On May 14, 2007, our registration statements on Form S-1 (Registration Nos. 333-140694 and 333-142952), as amended, were declared effective for our initial public offering, pursuant to which we offered and sold 8,365,000 shares of common stock and received net proceeds of approximately \$113.4 million, after deducting underwriting discounts and offering commissions of approximately \$8.8 million and other offering costs of approximately \$3.3 million. None of the underwriting discounts and commissions or offering expenses were

**Table of Contents**

incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours. All of the shares of common stock issued pursuant to the registration statements were sold at a price to the public of \$15.00 per share. The managing underwriters were J.P. Morgan Securities Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Thomas Weisel Partners LLC and Leerink Swann & Co., Inc.

As of September 30, 2008, we have used approximately \$108 million of the net proceeds we received from the offering for working capital and other general corporate purposes, including financing our growth, the expansion of our OmniPod production capacity, the continued expansion of our sales and marketing activities and the funding of our research and development efforts. Pending such usage, we have invested the net proceeds in short-term, interest-bearing investment-grade securities. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b).

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>
10.1	Amended and Restated 2007 Stock Option and Incentive Plan
31.1	Certification of Duane DeSisto, President and Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Carsten Boess, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Duane DeSisto, President and Chief Executive Officer, and Carsten Boess, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

**SIGNATURES**

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

INSULET CORPORATION  
(Registrant)

Date: November 13, 2008

/s/ Duane DeSisto

Duane DeSisto  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 13, 2008

/s/ Carsten Boess

Carsten Boess  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

27

---

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>
10.1	Amended and Restated 2007 Stock Option and Incentive Plan
31.1	Certification of Duane DeSisto, President and Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Carsten Boess, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Duane DeSisto, President and Chief Executive Officer, and Carsten Boess, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.