

INSULET CORP
Form 10-Q
May 07, 2010

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 March 31, 2010

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 No.)

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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)

Edgar Filing: INSULET CORP - Form 10-Q

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 May 5, 2010, the registrant had 37,944,711 shares of common stock outstanding.

INSULET CORPORATION
TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Consolidated Financial Statements	3
Consolidated Balance Sheets as of March 31, 2010 and December 31, 2009 (unaudited)	3
Consolidated Statements of Operations for the three months ended March 31, 2010 and 2009 (unaudited)	4
Consolidated Statements of Cash Flows for the three months ended March 31, 2010 and 2009 (unaudited)	5
Notes to Consolidated Financial Statements (unaudited)	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3. Quantitative and Qualitative Disclosures About Market Risk	22
Item 4. Controls and Procedures	22
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	22
Item 1A. Risk Factors	22
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	24
Item 3. Defaults Upon Senior Securities	24
Item 4. (Removed and Reserved)	24
Item 5. Other Information	24
Item 6. Exhibits	24
Signatures	25

PART I — FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

INSULET CORPORATION
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	As of March 31, 2010	As of December 31, 2009
(In thousands, except share and per share data)		
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 118,338	\$ 127,996
Accounts receivable, net	15,206	14,962
Inventories	6,600	10,086
Prepaid expenses and other current assets	2,029	1,260
Total current assets	142,173	154,304
Property and equipment, net	15,134	15,482
Other assets	1,730	1,862
Total assets	\$ 159,037	\$ 171,648
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 3,277	\$ 5,870
Accrued expenses	10,128	9,973
Deferred revenue	4,527	3,970
Total current liabilities	17,932	19,813
Long-term debt, net of current portion	98,217	96,979
Other long-term liabilities	1,964	1,999
Total liabilities	118,113	118,791
Stockholders' Equity		
Preferred stock, \$.001 par value:		
Authorized: 5,000,000 shares at March 31, 2010 and December 31, 2009.		
Issued and outstanding: zero shares at March 31, 2010 and December 31, 2009		
	-	-
Common stock, \$.001 par value:		
Authorized: 100,000,000 shares at March 31, 2010 and December 31, 2009. Issued and outstanding: 37,939,752 and 37,755,254 shares at March 31, 2010 and December 31, 2009, respectively		
	39	39
Additional paid-in capital	384,631	382,709
Accumulated deficit	(343,746)	(329,891)
Total stockholders' equity	40,924	52,857
Total liabilities and stockholders' equity	\$ 159,037	\$ 171,648

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2010	2009
	(In thousands, except share and per share data)	
Revenue	\$ 20,807	\$ 12,469
Cost of revenue	12,422	10,474
Gross profit	8,385	1,995
Operating expenses:		
Research and development	3,847	3,204
General and administrative	6,959	7,491
Sales and marketing	8,309	8,772
Total operating expenses	19,115	19,467
Operating loss	(10,730)	(17,472)
Interest income	24	101
Interest expense	(3,149)	(2,274)
Net interest expense	(3,125)	(2,173)
Net loss	\$ (13,855)	\$ (19,645)
Net loss per share basic and diluted	\$ (0.37)	\$ (0.71)
Weighted average number of shares used in calculating basic and diluted net loss per share	37,888,258	27,804,603

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

Three Months Ended
March 31,
2010 2009
(In thousands)

Cash flows from operating activities		
Net loss	\$ (13,855)	\$ (19,645)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,438	1,306
Amortization of debt discount	1,238	1,039
Stock compensation expense	1,311	1,201
Provision for bad debts	1,083	1,238
Non cash interest expense	132	121
Changes in operating assets and liabilities:		
Accounts receivable	(1,327)	(2,591)
Inventory	3,486	1,723
Prepays and other current assets	(769)	(357)
Accounts payable and accrued expenses	(2,437)	2,715
Other long term liabilities	(35)	172
Deferred revenue, short-term	557	107
Net cash used in operating activities	(9,178)	(12,971)
Cash flows from investing activities		
Purchases of property and equipment	(1,090)	(165)
Net cash used in investing activities	(1,090)	(165)
Cash flows from financing activities		
Proceeds from issuance of facility agreement, net of financing expenses	-	24,513
Proceeds from issuance of common stock, net of offering expenses	610	124
Net cash provided by financing activities	610	24,637
Net increase (decrease) in cash and cash equivalents	(9,658)	11,501
Cash and cash equivalents, beginning of period	127,996	56,663
Cash and cash equivalents, end of period	\$ 118,338	\$ 68,164
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 681	\$ -
Non-cash financing activities		
Allocation of fair value of warrants from net proceeds from issuance of facility agreement	\$ -	\$ 6,065

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

INSULET CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of the Business

Insulet Corporation (the “Company”) is principally engaged in the development, manufacture and marketing 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 designing, developing, manufacturing and marketing 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 January 2010, the Company entered into a 5 year distribution agreement with Ypsomed Distribution AG, or Ypsomed, to become the exclusive distributor of the OmniPod System in eleven countries. The Company expects that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in Germany and the United Kingdom in the second quarter of 2010, and in several other markets in the second half of 2010 and in the first half of 2011. To date, no significant revenue has been recognized from the agreement.

The Company has fully adopted the Financial Accounting Standard Board Accounting Standards Codification. The FASB Accounting Standards Codification (“Codification”) has become the single source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in accordance with accounting principles generally accepted in the United States (“GAAP”). All existing accounting standard documents are superseded by the Codification and any accounting literature not included in the Codification will not be authoritative. However, rules and interpretive releases of the Securities and Exchange Commission (“SEC”) issued under the authority of federal securities laws will continue to be sources of authoritative GAAP for SEC registrants. All references made to GAAP in the Company’s consolidated financial statements now use the new Codification numbering system. The Codification does not change or alter existing GAAP and, therefore, did not have a material impact on its consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited consolidated financial statements in this Quarterly Report on Form 10-Q have been prepared in accordance with GAAP for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these unaudited consolidated financial statements 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 month period ended March 31, 2010, are not necessarily indicative of the results that may be expected for the full year ending December 31, 2010, or for any other subsequent interim period.

The unaudited 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, 2009.

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, accounts receivable, equity instruments, the lives of property and equipment, as well as warranty reserves, and allowance for doubtful accounts calculations. Actual results may differ from those estimates.

Principles of Consolidation

The unaudited consolidated financial statements in this Quarterly Report on Form 10-Q include the accounts of the Company and its wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated in consolidation.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of amounts due from third-party payors, patients and third-party distributors. The allowance for doubtful accounts is recorded in the period in which the revenue is recorded or at the time potential collection risk is identified. The Company estimates its allowance based on historical experience, assessment of specific risk, discussions with individual customers or various assumptions and estimates that are believed to be reasonable under the circumstances.

Inventories

Inventories are stated at the lower of cost or market, determined under the first-in, first-out (“FIFO”) method. Inventory has been recorded at cost as of March 31, 2010 and December 31, 2009. Work in process is calculated based upon a build up in the stage of completion using estimated labor inputs for each stage in production. Costs for PDMs and OmniPods include raw material, labor and manufacturing overhead. The Company periodically reviews inventories for potential impairment based on quantities on hand and expectations of future use.

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.

Warranty

The Company provides a four-year warranty on its PDMs and may replace any OmniPods that do not function in accordance with product specifications. The Company estimates its warranty reserves at the time the product is shipped based on historical experience and the estimated cost to service the claims. Cost to service the claims reflects the current product cost which has been decreasing over time. Because the Company continues to introduce new products and new versions of existing products, the Company also considers the anticipated performance of the product over its warranty period in estimating warranty reserves.

Restructuring Expenses and Impairment of Assets

In connection with its efforts to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing of asset costs, the Company periodically performs an evaluation of its manufacturing processes and 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. This review of manufacturing processes and equipment can result in restructuring activity or an impairment of assets based on current net book value and potential future use of the assets.

The Company’s restructuring expenses may also include workforce reduction and related costs for one-time termination benefits provided to employees who are involuntarily terminated under the terms of a one-time benefit arrangement. The Company records these one-time termination benefits upon incurring the liability provided that the employees are notified, the plan is approved by the appropriate level of management, the employees to be terminated and the expected completion date are identified, and the benefits the identified employees will be paid are established. Significant changes to the plan are not expected when the Company records the costs. In recording the workforce reduction and related costs, the Company estimates related costs such as taxes and outplacement services which may be provided under the plan. If changes in these estimated services occur, the Company may be required to record or reverse restructuring expenses associated with these workforce reduction and related costs.

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 or

third party distributor typically includes OmniPods and a Starter Kit, which includes the PDM, the OmniPod System User Guide and the OmniPod System Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

Revenue recognition 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 upon transfer to the third party carrier; transfer of title and risk and rewards of ownership are passed to the distributor typically 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.

The Company assesses whether 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 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. 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.

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 revenue on 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 certain customers. The Company recognizes the revenue related to this portion of the Abbott agreement at the time it meets the criteria for revenue recognition, typically at the time the revenue is recognized on the sale of the PDM to the patient. In both of the three month periods ended March 31, 2010 and 2009, the Company recognized \$1.1 million for revenue related to the Abbott agreement. There was no impact to cost of revenue related to this agreement.

The Company had deferred revenue of \$5.5 million and \$5.1 million as of March 31, 2010 and December 31, 2009, respectively. The deferred revenue recorded as of March 31, 2010 was comprised of product-related revenue as well as the non-amortized agreement fee related to the Abbott agreement.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents and accounts receivable. The Company maintains the majority of its cash with two accredited financial institutions. Although revenue is recognized from shipments directly to patients or third-party distributors, the majority of shipments are billed to third-party insurance payors. There were no third-party payors that accounted for more than 10% of gross accounts receivable as of March 31, 2010 or December 31, 2009.

Segment Reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. In light of the Company's current product offering, and other considerations, management has determined that the primary form of internal reporting is aligned with the offering of the OmniPod System. Therefore, the Company believes that it operates in one segment.

Income Taxes

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 (subject to any applicable limitations), 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. As of March 31, 2010, the Company had no interest and penalty accrual or expense.

3. Facility Agreement and Common Stock Warrants

In March 2009, the Company entered into a Facility Agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan the Company up to \$60 million, subject to the terms and conditions set forth in the Facility Agreement. Following the initial disbursement of \$27.5 million on March 31, 2009, the Company could, but was not required to, draw down on the facility in \$6.5 million increments at any time until November 2010 provided that the Company met certain financial performance milestones. In connection with this financing, the Company paid Deerfield Management Company, L.P., an affiliate of the lead lender, a one-time transaction fee of \$1.2 million. Total financing costs, including the transaction fee, were \$3.0 million and were being amortized as interest expense over the 42 months of the Facility Agreement.

The amounts initially drawn under the Facility Agreement accrued interest at a rate of 9.75% per annum, and the undrawn amounts under the Facility Agreement accrued interest at a rate of 2.75% per annum. Accrued interest is payable quarterly in cash in arrears. The Company had the right to prepay any amounts owed without penalty unless the prepayment was in connection with a major transaction.

In September 2009, the Company entered into an Amendment to the Facility Agreement whereby the Company repaid the \$27.5 million of outstanding debt and promptly drew down the remaining \$32.5 million available under the Facility Agreement. The lender eliminated all future performance milestones associated with the remaining \$32.5 million available on the credit facility and reduced the annual interest rate to 8.5%. In connection with the Amendment to the Facility Agreement, the Company entered into a Securities Purchase Agreement with the lenders whereby the Company sold 2,855,659 shares of its common stock to the lenders at \$9.63 per share. The Company received aggregate proceeds of \$27.5 million in connection with the sale of its shares. All references herein to the "Facility Agreement" refer to the Facility Agreement entered into in March 2009 and amended in September 2009.

All principal amounts outstanding under the Facility Agreement are payable in September 2012. Any amounts drawn under the Facility Agreement may become immediately due and payable upon (i) an "event of default," as defined in the Facility Agreement, in which case the lenders would have the right to require the Company to re-pay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the consummation of certain change of control transactions, in which case the lenders would have the right to require the Company to re-pay 106% of the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon. The Facility Agreement also provides for higher interest rates to be paid by the Company in certain events.

Because the consummation of certain change in control transactions would result in the payment of a premium of the outstanding principal, the premium feature is a derivative that is required to be bifurcated from the host debt instrument and recorded at fair value at each quarter end. As a higher interest rate could be paid by the Company upon the occurrence of certain events, the higher interest feature is also considered a derivative. The higher interest payment does not meet the criteria to be accounted for separately. Any changes in fair value of the premium feature will be recorded as interest expense. The difference between the face value of the outstanding principal on the Facility Agreement and the amount remaining after the bifurcation will be recorded as a discount to be amortized over the term of the Facility Agreement. As of March 31, 2010, the premium feature associated with the Facility Agreement had no value as the Company does not currently expect a change in control transaction to occur. The embedded derivatives related to the Facility Agreement will be reassessed and marked-to-market through earnings on a quarterly basis.

As of March 31, 2010 and December 31, 2009, \$32.5 million of outstanding debt related to the Facility Agreement is included in long-term debt in the consolidated balance sheet. In the three months ended March 31, 2010, approximately \$0.7 million of cash interest related to the Facility Agreement was recorded. In the three months ended March 31, 2009, no interest expense was recorded related to the Facility Agreement

In March 2009, in connection with the execution of the Facility Agreement, the Company issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock of the Company at an exercise price of \$3.13 per share. Pursuant to the original terms of the Facility Agreement, the Company would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining \$32.5 million under the facility. In connection with the Amendment to the Facility Agreement in September 2009, the lenders agreed to forego the remaining 1.5 million additional warrants that would have been issued upon these future draws.

If the Company issues or sells shares of its common stock (other than (i) pursuant to a registered public offering or shelf takedown, (ii) in a transaction that does not require shareholder approval, (iii) to partners in connection with a joint venture, distribution or other partnering arrangement in a transaction that does not require shareholder approval, (iv) upon the exercise of options granted to our employees, officers, directors and consultants, (v) of restricted stock to, or purchases of, our common stock under our employee stock purchase plan by employees, officers, directors or consultants or (vi) upon the exercise of the warrants) after March 13, 2009, the Company will issue concurrently therewith additional warrants to purchase such number of shares of common stock as will entitle the lenders to maintain the same beneficial ownership in the Company after the issuance as they had prior to such issuance, as adjusted on a pro rata basis for repayments of the outstanding principal amount under the loan, with such warrants being issued at an exercise price equal to the greater of \$3.13 per share and the closing price of the common stock on the date immediately prior to the issuance.

All warrants issued under the Facility Agreement remain unexercised as of March 31, 2010, expire on March 13, 2015 and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it to exceed 9.98% of the total number of shares of the Company's common stock then issued and outstanding.

In addition, upon certain change of control transactions, or upon certain “events of default” (as defined in the warrant agreement), the holder has the right to net exercise the warrants for an amount of shares of the Company’s common stock equal to the Black-Scholes value of the shares issuable under the warrants divided by 95% of the closing price of the common stock on the day immediately prior to the consummation of such change of control or event of default, as applicable. In certain circumstances where a warrant or portion of a warrant is not net exercised in connection with a change of control or event of default, the holder will be paid an amount in cash equal to the Black-Scholes value of such portion of the warrant not treated as a net exercise.

The warrants issued in connection with the Facility Agreement qualify for permanent classification as equity and their relative fair value of \$6.1 million on the issuance date was recorded as additional paid in capital and debt discount. The remaining unamortized value of the warrants was recorded as interest expense in the year ended December 31, 2009, in connection with the repayment and termination of the initial disbursement.

4. Convertible Notes

In June 2008, the Company sold \$85.0 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 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 recorded a debt discount of \$26.9 million to equity to reflect the value of its nonconvertible debt borrowing rate of 14.5% per annum. This debt discount is being amortized as interest expense over the 5 year term of the 5.375% Notes.

The Company incurred deferred financing costs related to this offering of approximately \$3.5 million, of which \$1.1 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the 5.375% Notes. The Company incurred interest expense of approximately \$2.5 million for the three months ended March 31, 2010, related to the 5.375% Notes. Of the \$2.5 million, approximately \$1.4 million relates to amortization of the debt discount and deferred financing costs and \$1.1 million relates to cash interest. For the three months ended March 31, 2009, the Company incurred interest expense of approximately \$2.2 million, related to the 5.375% Notes. Of the \$2.2 million, approximately \$1.1 million relates to amortization of the debt discount and deferred financing costs, and \$1.1 million relates to cash interest.

As of March 31, 2010, the outstanding amounts related to the 5.375% Notes of \$65.7 million are included in long-term debt in the consolidated balance sheet and reflect the debt discount of \$19.3 million. As of December 31, 2009, the outstanding amounts related to the 5.375% Notes of \$64.5 million are included in long-term debt and reflect the debt discount of \$20.5 million. The debt discount includes the equity allocation of \$25.8 million (which represents \$26.9 million less the \$1.1 million of allocated financing costs) offset by the accretion of the debt discount through interest expense from the issuance date over the 5 year term of the notes. The Company recorded \$1.2 million of interest expense related to the debt discount in the three months ended March 31, 2010. As of March 31, 2010, the 5.375% Notes have a remaining term of 3.25 years. The Company recorded \$1.1 million of interest expense related to the debt discount in the three months ended March 31, 2009.

The Company received net proceeds of approximately \$81.5 million from this offering. Approximately \$23.2 million of the proceeds from this offering was used to repay and terminate the Company's then-existing term loan, including outstanding principal and accrued and unpaid interest of \$21.8 million, a prepayment fee related to the term loan of approximately \$0.4 million and a termination fee of \$0.9 million. The Company is using the remainder for general corporate purposes. 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. As of March 31, 2010, warrants to purchase 62,752 shares of common stock remain outstanding and exercisable at a price of \$9.56 per share.

5. Restructuring Expenses and Impairments of Assets

As of March 31, 2009, the Company's accrued expenses for restructuring was \$0.4 million for final payments of severance. These amounts were paid in full in 2009. During the three months ended, March 31, 2010, the Company had no restructuring or impairment activity.

The following is a summary of restructuring activity for the three months ended March 31, 2009.

Three Months Ended

March 31, 2009

Balance at the beginning of year	\$	612
Utilization		(211)
Balance at the end of the year	\$	401

6. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options and warrants (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method). Because the Company reported a net loss for the three months ended March 31, 2010 and 2009, all potential common shares have been excluded from the computation of the diluted 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:

10

	Three Months Ended March 31,	
	2010	2009
Convertible debt	3,981,969	3,981,969
Unvested restricted common shares	307,775	3,552
Outstanding options	3,505,216	3,448,215
Outstanding warrants	3,812,752	3,812,752
Total	11,607,712	11,246,488

7. Accounts Receivable

The components of accounts receivable are as follows:

	As of	
	March 31, 2010	December 31, 2009
	(In thousands)	
Trade receivables	\$ 22,242	\$ 22,152
Allowance for doubtful accounts	(7,036)	(7,190)
	\$ 15,206	\$ 14,962

8. Inventories

Inventories consist of the following:

	As of	
	March 31, 2010	December 31, 2009
	(In thousands)	
Raw materials	\$ 1,945	\$ 1,657
Work-in-process	474	496
Finished goods	4,181	7,933
	\$ 6,600	\$ 10,086

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.

9. 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:

	Three Months Ended March 31,	
	2010	2009
	(In thousands)	

Edgar Filing: INSULET CORP - Form 10-Q

Balance at the beginning of period	\$	1,820	\$	2,268
Warranty expense		320		1,139
Warranty claims settled		(392)		(735)
Balance at the end of the period	\$	1,748	\$	2,672
Composition of balance:				
Short-term	\$	770	\$	991
Long-term		978		1,681
Total warranty balance	\$	1,748	\$	2,672

11

10. 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-cancelable lease for additional office space in Bedford, Massachusetts. The lease expires in September 2010 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 research and development and manufacturing space. Following the extension, the lease expires in September 2014. The lease is non-cancelable 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 liabilities in the accompanying balance sheet.

Indemnifications

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

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

11. Equity

In October 2009, in a public offering, the Company issued and sold 6,900,000 shares of its common stock at a price to the public of \$10.25 per share. In connection with the offering, the Company received total gross proceeds of \$70.7 million, or approximately \$66.1 million in net proceeds after deducting underwriting discounts and offering expenses.

Restricted Stock Units

On March 1, 2010, the Company awarded 305,999 restricted stock units to certain employees. The restricted stock units were granted under the Company's 2007 Stock Option and Incentive Plan (the "2007 Plan") and vest annually over three years from the grant date. The restricted stock units granted had a weighted average fair value of \$15.16 based on the closing price of the Company's common stock on the date of grant. The restricted stock units were valued at approximately \$4.6 million at their grant date, and the Company is recognizing the compensation expense over the three year vesting period. Approximately \$0.1 million of stock-based compensation expense related to the vesting of restricted stock units was recognized in the three months ended March 31, 2010, and approximately \$4.5 million of the fair value of the restricted stock units remained unrecognized as of March 31, 2010. Under the terms of the award, the Company will issue shares of common stock on each of the vesting dates. None of the restricted stock units awarded to employees vested during the three months ended March 31, 2010.

The following table summarizes the status of the Company's restricted stock units:

	Number of Shares	Weighted Average Fair Value
Balance, December 31, 2009	-	\$ -
Granted	305,999	15.16
Vested	-	-
Forfeited	-	-
Balance, March 31, 2010	305,999	\$ 15.16

Restricted Common Stock

During the year ended December 31, 2008, the Company awarded 4,000 shares of restricted common stock to a non-employee in exchange for \$0.001 per share. The shares of restricted common stock were granted under the 2007 Plan and vest over two years. The shares of restricted common stock granted had a weighted average fair value of \$8.04 based on the closing price of the Company's common stock on the date of grant. The Company is recognizing the total compensation expense of \$32,000 over the two year vesting period.

The following table summarizes the status of the Company's restricted shares:

	Number of Shares	Weighted Average Fair Value
Balance, December 31, 2009	2,220	\$ 8.04
Granted	-	-
Vested	(444)	8.04
Forfeited	-	-
Balance, March 31, 2010	1,776	\$ 8.04

Stock Options

The following summarizes the activity under the Company's stock option plans:

	Number of Options(#)	Weighted Average Exercise Price(\$)	Aggregate Intrinsic Value(\$) (In thousands)
Balance, December 31, 2009	3,542,590	8.36	
Granted	190,500	15.07	
Exercised	(184,498)	3.41	2,114(1)
Canceled	(43,376)	15.28	
Balance, March 31, 2010	3,505,216	8.90	23,274(2)
Vested, March 31, 2010	1,806,365	7.94	13,743(2)
Vested and expected to vest, March 31, 2010 (3)	2,893,909		19,939(2)

- (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 March 31, 2010, and the exercise price of the underlying options.
- (3) Represents the number of vested options as of March 31, 2010, plus the number of unvested options expected to vest as of March 31, 2010, based on the unvested options outstanding as of March 31, 2010, adjusted for the estimated forfeiture rate of 16%.

At the time of grant, options granted under the Company's 2000 Stock Option and Incentive Plan (the "2000 Plan") are typically immediately exercisable, but subject to restrictions. Therefore, under the 2000 Plan, the number of options exercisable is greater than the number of options vested until all options are fully vested. As of March 31, 2010 and 2009, no shares were contingently issued under the employee stock purchase plan ("ESPP"), respectively. In the three months ended March 31, 2010 and 2009, the Company recorded no significant stock-based compensation charges related to the ESPP.

Employee stock-based compensation expense recognized in the three months ended March 31, 2010 and 2009 was \$1.3 million and \$1.2 million, respectively. The employee stock-based compensation expense relates to all stock awards granted.

12. 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.

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 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: our historical operating losses; our dependence on the OmniPod System; our ability to achieve and maintain market acceptance of the OmniPod System; our ability to increase customer orders and manufacturing volume; adverse changes in general economic conditions; our ability to raise additional funds in the future; our ability to anticipate and effectively manage risks associated with doing business internationally, particularly in China; our dependence on third-party suppliers; 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 affects of challenges to or investigations into our practices under these laws; product liability lawsuits that may be brought against us; unfavorable results of clinical studies relating to the OmniPod System or the products of our competitors; our ability to attract and retain key personnel; our ability to manage our growth; our ability to maintain compliance with the restrictions and related to our indebtedness; our ability to successfully maintain effective internal controls; the volatility of the price of our common stock; and other risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the Securities and Exchange Commission on March 9, 2010 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 and markets an insulin infusion system for people with insulin-dependent diabetes. Our proprietary OmniPod Insulin Management System consists of our disposable OmniPod insulin infusion device and our handheld, wireless Personal Diabetes Manager.

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 availability of the OmniPod System in the entire United States through internal sales and distribution channels as well as limited third-party distributors. In January 2010, we entered into an exclusive distribution agreement with Ypsomed Distribution AG, or Ypsomed, which intends to distribute and sell our OmniPod System in eleven countries beginning with Germany and the United Kingdom in the first half of 2010, subject to approved reimbursement. We focus our sales towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetes patients, as well as individual diabetes patients.

We currently produce the OmniPod on a partially automated manufacturing line at a facility in China operated by a subsidiary of Flextronics International Ltd. We purchase complete OmniPods pursuant to our agreement with Flextronics. 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 specified number of days is intended to provide the parties with sufficient time to make alternative arrangements in the event of termination. By purchasing OmniPods manufactured by Flextronics in China, we have been able to substantially increase production volumes for the OmniPod and reduce our per unit production cost.

To achieve profitability, we seek to increase manufacturing volume and reduce the per unit production cost for the OmniPod by collaborating with contract manufacturers and reducing the cost of raw materials and sub-assemblies. By increasing production volumes of the OmniPod, we have been able to reduce our per-unit raw material costs and improve absorption of manufacturing overhead costs. This, as well as the continued collaboration with contract manufacturers to reduce the cost of supplies of raw materials and sub-assemblies and the installation of automated manufacturing equipment are important as we strive to achieve profitability. We believe our manufacturing capacity is sufficient to meet our expected 2010 demand for OmniPods.

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, social networking, patient demonstration programs, support materials, media advertisements and events at the national, regional and local levels. 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. In addition, we entered into a distribution agreement with Ypsomed to become the exclusive distributor of the OmniPod System in eleven countries. We expect that Ypsomed will begin distributing and selling our OmniPod System, subject to approved reimbursement, in Germany and the United Kingdom in the second quarter of 2010, and in several other markets and in the second half of 2010 and in the first half of 2011. We expect Ypsomed to work with the appropriate agencies to establish an appropriate distribution and reimbursement process in each of these countries.

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. As we expand our sales and marketing focus, increase our manufacturing capacity and expand to international markets, we will need to maintain and expand available reimbursement for the OmniPod System.

Our continued growth is dependent on our ability to generate interest in our products through sales and marketing activities. We are also dependent on our ability to effectively and correctly evaluate the extent of patients' reimbursement coverage under applicable reimbursement programs in order to convert customer inquiries into shipments and revenue.

Since our inception in 2000, we have incurred losses every quarter. In the three months ended March 31, 2010, we incurred net losses of \$13.9 million. As of March 31, 2010, we had an accumulated deficit of \$343.7 million. We have financed our operations through the private placement of debt and equity securities, public offerings of our common stock, a private placement of our convertible debt and borrowings under certain debt agreements. In October 2009, we issued and sold 6,900,000 shares of our common stock at a price to the public of \$10.25 per share. In connection with the offering, we received total gross proceeds of \$70.7 million, or approximately \$66.1 million in net proceeds after deducting underwriting discounts and offering expenses. As of March 31, 2010, we had \$85 million of convertible debt outstanding and \$32.5 million of outstanding debt relating to a facility agreement entered into March 13, 2009 and amended on September 25, 2009.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts for the remainder of 2010 will be focused primarily on continuing to reduce our per-unit production costs, expanding sales to international markets and reducing our spending on manufacturing overhead and operating expenses as a percentage of revenue. The continued expansion of our manufacturing capacity will help us to achieve lower material costs due to volume purchase discounts and improved absorption of manufacturing overhead costs, reducing our cost of revenue as a percentage of revenue. Achieving these objectives is expected to require additional investments in certain personnel and initiatives to allow for us to increase our market penetration in the United States market and enter certain international markets. We believe that we will continue to incur net losses in the near term in order to achieve these objectives. However, we believe that the accomplishment of our near term objectives will have a positive impact on our financial condition in the future.

Facility Agreement and Common Stock Warrants

In March 2009, we entered into a Facility Agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan us up to \$60 million, subject to the terms and conditions set forth in the Facility Agreement. Following the initial disbursement of \$27.5 million on March 31, 2009, we could, but were not required to, draw down on the facility in \$6.5 million increments at any time until November 2010 provided that we met certain financial performance milestones. In connection with this financing, we paid Deerfield Management Company, L.P., an affiliate of the lead lender, a one-time transaction fee of \$1.2 million. Total financing costs, including the transaction fee, were \$3.0 million and were being amortized as interest expense over the 42 month term of the Facility Agreement.

The amounts initially drawn under the Facility Agreement accrued interest at a rate of 9.75% per annum, and the undrawn amounts under the Facility Agreement accrued interest at a rate of 2.75% per annum. Accrued interest is payable quarterly in cash in arrears. We had the right to prepay any amounts owed without penalty unless the prepayment was in connection with a major transaction.

In September 2009, we entered into an Amendment to the Facility Agreement whereby we repaid the \$27.5 million of outstanding debt and promptly drew down the remaining \$32.5 million available under the Facility Agreement. The lender eliminated all future performance milestones associated with the remaining \$32.5 million available on the credit facility and reduced the annual interest rate on any borrowed funds to 8.5%. In connection with the Amendment to the Facility Agreement, we entered into a Securities Purchase Agreement with the lenders whereby we sold 2,855,659 shares of our common stock to the lenders at \$9.63 per share. We received aggregate proceeds of \$27.5 million in connection with the sale of our shares. All subsequent references to the "Facility Agreement" refer to the Facility Agreement entered into in March 2009 and amended in September 2009.

All principal amounts outstanding under the Facility Agreement are payable in September 2012. Any amounts drawn under the Facility Agreement may become immediately due and payable upon (i) an "event of default," as defined in the Facility Agreement, in which case the lenders would have the right to require us to re-pay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the consummation of certain change of

control transactions, in which case the lenders would have the right to require us to re-pay 106% of the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon. The Facility Agreement also provides for higher interest rates to be paid by us in certain events.

Because the consummation of certain change in control transactions would result in the payment of a premium of the outstanding principal, the premium feature is a derivative that is required to be bifurcated from the host debt instrument and recorded at fair value at each quarter end. As a higher interest rate could be paid by us upon the occurrence of certain events, the higher interest feature is also considered a derivative. The higher interest payment does not meet the criteria to be accounted for separately. Any changes in fair value of the premium feature will be recorded as interest expense. The difference between the face value of the outstanding principal on the Facility Agreement and the amount remaining after the bifurcation will be recorded as a discount to be amortized over the term of the Facility Agreement. As of March 31, 2010, the premium feature associated with the Facility Agreement had no value as we do not currently expect a change in control transaction to occur. The embedded derivatives related to the Facility Agreement will be reassessed and marked-to-market through earnings on a quarterly basis.

As of March 31, 2010 and December 31, 2009, \$32.5 million of our outstanding debt related to the Facility Agreement is included in long-term debt in the consolidated balance sheet. In the three months ended March 31, 2010, approximately \$0.7 million of cash interest related to the Facility Agreement was recorded. In the three months ended March 31, 2009, no interest expense was recorded related to the Facility Agreement.

In March 2009, in connection with the execution of the Facility Agreement, we issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock at an exercise price of \$3.13 per share. Pursuant to the original terms of the Facility Agreement, we would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining \$32.5 million under the facility. In connection with the Amendment to the Facility Agreement in September 2009, the lenders agreed to forego the remaining 1.5 million additional warrants that would have been issued upon future draws.

If we issue or sell shares of our common stock (other than (i) pursuant to a registered public offering or shelf takedown, (ii) in a transaction that does not require shareholder approval, (iii) to partners in connection with a joint venture, distribution or other partnering arrangement in a transaction that does not require shareholder approval, (iv) upon the exercise of options granted to our employees, officers, directors and consultants, (v) of restricted stock to, or purchases of, our common stock under our employee stock purchase plan by employees, officers, directors or consultants or (vi) upon the exercise of the warrants) after March 13, 2009, we will issue concurrently therewith additional warrants to purchase such number of shares of common stock as will entitle the lenders to maintain the same beneficial ownership in us after the issuance as they had prior to such issuance, as adjusted on a pro rata basis for repayments of the outstanding principal amount under the loan, with such warrants being issued at an exercise price equal to the greater of \$3.13 per share and the closing price of the common stock on the date immediately prior to the issuance.

All warrants issued under the Facility Agreement remain unexercised as of March 31, 2010, expire on March 13, 2015 and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it to exceed 9.98% of the total number of shares of our common stock then issued and outstanding.

In addition, upon certain change of control transactions, or upon certain “events of default” (as defined in the warrant agreement), the holder has the right to net exercise the warrants for an amount of shares of our common stock equal to the Black-Scholes value of the shares issuable under the warrants divided by 95% of the closing price of the common stock on the day immediately prior to the consummation of such change of control or event of default, as applicable. In certain circumstances where a warrant or portion of a warrant is not net exercised in connection with a change of control or event of default, the holder will be paid an amount in cash equal to the Black-Scholes value of such portion of the warrant not treated as a net exercise.

The warrants issued in connection with the Facility Agreement qualify for permanent classification as equity and their relative fair value of \$6.1 million on issuance date was recorded as additional paid in capital and debt discount. The unamortized value of the warrants was recorded as interest expense in the year ended December 31, 2009, in connection with the repayment and termination of the initial disbursement.

Convertible Notes

In June 2008, we sold \$85.0 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. 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, 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 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).

We recorded a debt discount of \$26.9 million to equity to reflect the value of our nonconvertible debt borrowing rate of 14.5% per annum. This debt discount is being amortized as interest expense over the 5 year life of the 5.375% Notes.

We incurred deferred financing costs related to this offering of approximately \$3.5 million, of which \$1.1 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the 5.375% Notes. We incurred interest expense of approximately \$2.5 million for the three months ended March 31, 2010, related to the 5.375% Notes. Of the \$2.5 million, approximately \$1.4 million relates to amortization of the debt discount and deferred financing costs and \$1.1 million relates to cash interest.

As of March 31, 2010, the outstanding amounts related to the 5.375% Notes of \$65.7 million are included in long-term debt in the consolidated balance sheet and reflect the debt discount of \$19.3 million. As of December 31, 2009, the outstanding amounts related to the 5.375% Notes of \$64.5 million are included in long-term debt and reflect the debt discount of \$20.5 million. The debt discount includes the equity allocation of \$25.8 million (which represents \$26.9 million less the \$1.1 million of allocated financing costs) offset by the accretion of the debt discount through interest expense from the issuance date over the 5 year term of the notes. We recorded \$1.2 million of interest expense related to the debt discount in the three months ended March 31, 2010. As of March 31, 2010, the 5.375% Notes have a remaining term of 3.25 years. We recorded \$1.0 million of interest expense related to the debt discount in the three months ended March 31, 2009.

We 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 our then-existing term loan, including outstanding principal and accrued and unpaid interest of \$21.8 million, a prepayment fee related to the term loan of approximately \$0.4 million and a termination fee related to the term loan of \$0.9 million. We are using the remainder for general corporate purposes. 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. At March 31, 2010, warrants to purchase 62,752 shares of common stock remain outstanding and exercisable at a price of \$9.56 per share.

Financial Operations Overview

Revenue. 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, the OmniPod System User Guide and our Interactive Training CD, and from the subsequent sales of additional OmniPods to existing customers. Customers generally order a three-month supply of OmniPods. In January 2010, we entered into an exclusive distribution agreement with Ypsomed which intends to distribute and sell the OmniPod System, subject to approved reimbursement, in eleven countries, beginning with Germany and the United Kingdom in the second quarter of 2010, and in several other markets in the second half of 2010 and in the first half of 2011. For the three months ended March 31, 2010, 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 certain customers. We recognize the revenue related to this portion of the Abbott agreement at the time we meet the criteria for revenue recognition, typically at the time the revenue is recognized on the sale of the PDM to a new patient. In both of the three month periods ended March 31, 2010 and 2009, we recognized \$1.1 million of revenue related to the Abbott agreement. There was no impact to cost of revenue related to this agreement.

As of March 31, 2010 and December 31, 2009, we had deferred revenue of \$5.5 million and \$5.1 million, respectively, which includes product-related revenue as well as the unrecognized portion of the agreement fee related to the Abbott agreement.

For the year ending December 31, 2010, we expect our revenue to continue to increase as we continue to gain new customers in the United States and expand to certain international markets. Increased revenue will be dependent upon the success of our sales efforts, our ability to produce OmniPods in sufficient volumes and other risks and uncertainties.

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, freight and packaging costs. The increase in our OmniPod production volume, as well as our ability to gain cost savings on our bill of materials, is expected to reduce the per-unit cost of manufacturing the OmniPods by allowing us to reduce our direct costs and spread our fixed and semi-fixed overhead costs over a greater number of units.

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. In the first half of 2010, we will incur higher levels of spending on our current research and development efforts, which are focused primarily on increased functionality, improved design for ease of use and reduction of production cost, as well as developing a new OmniPod System that incorporates continuous glucose monitoring technology. This level of spending is expected to decrease in the second half of the year.

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, bad debt expenses, shipping, handling and facilities-related costs. For the remainder of 2010, we expect general and administrative expenses to decrease slightly compared to current levels as we continue to drive efficiencies in our administrative functions.

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 activities, including distribution of units used in our demonstration kit programs. For the remainder of 2010, we expect sales and marketing expenses to increase compared to current levels as we expand our sales and marketing efforts to meet our business needs.

Results of Operations

The following table presents certain statement of operations information for the three months ended March 31, 2010 and 2009:

	Three Months Ended		
	2010	2009	% Change
	(Dollar amounts in thousands)		
Revenue	\$ 20,807	\$ 12,469	67%
Cost of revenue	12,422	10,474	19%
Gross profit	8,385	1,995	320%
Operating expenses:			
Research and development	3,847	3,204	20%
General and administrative	6,959	7,491	7%
Sales and marketing	8,309	8,772	5%
Total operating expenses	19,115	19,467	2%
Operating loss	(10,730)	(17,472)	39%
Other expense, net	(3,125)	(2,173)	44%
Net loss	\$ (13,855)	\$ (19,645)	29%

Comparison of the Three Months Ended March 31, 2010 and 2009

Revenue

Our total revenue was \$20.8 million and \$12.5 million for the three months ended March 31, 2010 and 2009, respectively. The increase in revenue is primarily due to an increased number of patients using the OmniPod System and an increase in sales to distributors. We expect our revenue to continue to increase as we continue to add new patients, both in the United States and internationally, and generate an increased number of reorders based on our expanding patient base. In addition, we expect to continue to recognize additional revenue related to the Abbott agreement.

Cost of Revenue

Cost of revenue was \$12.4 million and \$10.5 million for the three months ended March 31, 2010 and 2009, respectively. The increase in cost of revenue is primarily due to the significantly increased sales volume. This increase was partially offset by a decrease in per-unit costs to manufacture the OmniPod in the three months ended March 31, 2010, as compared to the same period in 2009. The decrease in our per-unit cost was a result of cost savings on raw materials, volume discounts from our suppliers and increased production volumes. We experienced continuing improvement of our gross margin as a result of the 67% increase in revenue as well as the decrease in the per-unit cost to manufacture the OmniPod, from the three months ended March 31, 2009 compared to the same period in 2010.

Research and Development

Research and development expenses increased \$0.6 million, or 20%, to \$3.8 million for the three months ended March 31, 2010 compared to \$3.2 million for the same period in 2009. For the three months ended March 31, 2010, the increase in research and development expenses was primarily attributable to an increase of \$0.8 million in outside services and \$0.3 million in products used for research and development. These increased costs were incurred mainly in connection with the development of the next generation OmniPod and were offset by a \$0.3 million decrease in

employee related expenses including stock-based compensation and a \$0.1 million decrease in travel-related costs.

General and Administrative

General and administrative expenses decreased \$0.5 million, or 7%, to \$7.0 million for the three months ended March 31, 2010, compared to \$7.5 million for the same period in 2009. For the three months ended March 31, 2010, the decrease in general and administrative expenses was primarily due to a decrease of \$0.2 million in professional services, a \$0.2 million decrease in allowances and write-offs of trade accounts receivable and a \$0.1 million decrease in freight costs. These decreases were offset by an increase of \$0.2 million in employee compensation and benefit costs, including stock-based compensation.

Sales and Marketing

Sales and marketing expenses decreased \$0.5 million, or 5%, to \$8.3 million for the three months ended March 31, 2010, compared to \$7.5 million for the same period in 2009. For the three months ended March 31, 2010, the decrease in sales and marketing expenses was primarily due to a decrease of \$0.3 million in samples and Patient Demonstration Kits, a decrease of \$0.3 million in printing costs and a decrease of \$0.1 million in travel related expenses. These decreases were partially offset by a \$0.2 million increase in promotion and advertising costs and a \$0.1 million increase in outside consulting services, which include our external trainers.

Other Income (Expense)

Net interest expense was \$3.1 million for the three months ended March 31, 2010, compared to \$2.2 million for the same period in 2009. For the three months ended March 31, 2010, the increase in net interest expense was primarily due to interest incurred on the credit facility entered into in March 2009. We anticipate net interest expense to remain consistent with current levels for the remainder of 2010.

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 March 31, 2010, we had \$118.3 million in cash and cash equivalents. We believe that our current cash and cash equivalents, 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.

Financial Resources

In October 2009, in a public offering, we issued and sold 6,900,000 shares of our common stock at a price to the public of \$10.25 per share. In connection with this offering, we received total gross proceeds of \$70.7 million, or approximately \$66.1 million in net proceeds after deducting underwriter discounts and offering expenses.

In March 2009, we entered into a Facility Agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan us up to \$60 million, subject to the terms and conditions set forth in the Facility Agreement. Following the initial disbursement of \$27.5 million on March 31, 2009, we could, but were not required to, draw down on the facility in \$6.5 million increments at any time until November 2010 provided that we met certain financial performance milestones. In connection with this financing, we paid Deerfield Management Company, L.P., an affiliate of the lead lender, a one-time transaction fee of \$1.2 million. Total financing costs, including the transaction fee, as of June 30, 2009 were \$3.0 million. The amounts initially drawn under the Facility Agreement accrued interest at a rate of 9.75% per annum, and the undrawn amounts under the Facility Agreement accrued interest at a rate of 2.75% per annum. Accrued interest is payable quarterly in cash in arrears. We had the right to prepay any amounts owed without penalty unless the prepayment was in connection with a major transaction.

In September 2009, we entered into an Amendment to the Facility Agreement whereby we repaid the \$27.5 million of outstanding debt and promptly drew down the remaining \$32.5 million available under the Facility Agreement. The lender eliminated all future performance-related milestones associated with the remaining \$32.5 million available on the credit facility and reduced the annual interest rate to 8.5%. In connection with the Amendment to the Facility Agreement, we entered into a Securities Purchase Agreement with the lenders whereby we sold 2,855,659 shares of our common stock to the lenders at \$9.63 per share. We received aggregate proceeds of \$27.5 million in connection with the sale of our shares. All principal amounts outstanding under the Facility Agreement are payable in September 2012.

In March 2009, in connection with the execution of the Facility Agreement, we issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock at an exercise price of \$3.13 per share. Pursuant to the Facility Agreement, we would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining \$32.5 million under the facility. In connection with the Amendment of the Facility Agreement in September 2009, the lenders agreed to forego the remaining 1.5 million additional warrants that would have been issued upon future draws. At March 31, 2010, all warrants issued under the Facility Agreement remained unexercised.

In June 2008, we sold \$85.0 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. 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. We used a portion of the net proceeds to repay the entire outstanding principal balance, plus accrued and unpaid interest, under our then-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.

Operating Activities

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

	Three Months Ended March 31,	
	2010	2009
	(In thousands)	
Cash used in operating activities	\$ (9,178)	\$ (12,971)
Net loss	\$ (13,855)	\$ (19,645)

For each of the periods above, the 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 of the debt discount and stock-based compensation expense as well as changes to working capital. Significant uses of cash from operations include an increase in accounts receivable and a decrease in accounts payable and accrued expenses. 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 accounts in the consolidated balance sheets. Cash used in operating activities is partly offset by decreases in inventory and other assets and an increase in 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:

	Three Months Ended March 31,	
	2010	2009
	(In thousands)	
Cash used in investing activities	\$ (1,090)	\$ (165)
Cash provided by financing activities	\$ 610	\$ 24,637

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. Our cash used in investing activities has increased significantly in the three months ended March 31, 2010, compared to the three months ended March 31, 2009, as we increased spending on equipment to be used to manufacture our next generation of the OmniPod. Capital expenditures are expected to increase in 2010 compared to 2009. Cash provided by financing activities in the three months ended March 31, 2010 mainly consisted of the net proceeds from the issuance of common stock in connection with the exercise of stock options. Cash provided by financing activities in the three months ended March 31, 2009 was mainly related to the net proceeds from the Facility Agreement entered into in March 2009.

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 term of the lease. As of March 31, 2010, we had an outstanding letter of credit which totaled \$0.2 million to cover our security deposits for lease obligations.

Off-Balance Sheet Arrangements

As of March 31, 2010, 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 and 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 includes the PDM, the OmniPod System User Guide and our Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

Revenue recognition 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 upon transfer to the third party carrier; transfer of title and risk and rewards of ownership are passed to the distributor typically 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 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.

We offer a 45-day right of return for our Starter Kits sales, and 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.

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 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 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 certain customers. We recognize the revenue related to this portion of the Abbott agreement at the time we meet the criteria for revenue recognition, typically at the time the revenue is recognized on the sale of the PDM to the patient. In both of the three month periods ended March 31, 2010 and 2009, we recognized \$1.1 million of revenue related to the amended Abbott agreement. There was no impact to cost of revenue related to this agreement.

We had deferred revenue of \$5.5 million and \$5.1 million as of March 31, 2010 and December 31, 2009, respectively. The deferred revenue recorded as of March 31, 2010 was comprised of product-related revenue as well as the non-amortized agreement fee related to the Abbott agreement.

Restructuring Expense and Impairment of Assets

In connection with our efforts to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing of asset costs, we periodically perform an evaluation of our manufacturing processes and review the carrying value of our property and equipment to assess the recoverability of these assets whenever events indicate that impairment may have occurred. As part of this assessment, we review 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. This review of manufacturing processes and equipment can result in restructuring activity or an impairment of assets based on current net book value and potential future use of the assets.

Our restructuring expenses may also include workforce reduction and related costs for one-time termination benefits provided to employees who are involuntarily terminated under the terms of a one-time benefit arrangement. We record these one-time termination benefits upon incurring the liability provided that the employees are notified, the plan is approved by the appropriate level of management, the employees to be terminated and the expected completion date are identified and the benefits the identified employees will be paid are established. Significant changes to the plan are not expected when we record the costs. In recording the workforce reduction and related costs, we estimate related costs such as taxes and outplacement services which may be provided under the plan. If changes in these estimated services occur, we may be required to record or reverse restructuring expenses associated with these workforce reduction and related costs.

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 our inception in 2000. Since the net operating losses may potentially be utilized in future years to reduce taxable income (subject to any applicable limitations), 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 March 31, 2010, 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. The allowance for doubtful accounts is recorded in the period in which the revenue is recorded or at the time potential collection risk is identified. We estimate our allowance based on historical experience, assessment of specific risk, discussions with individual customers or various assumptions and estimates that we believe to be reasonable under the circumstances.

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, 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. 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.

As of March 31, 2010, we had outstanding debt recorded at \$65.7 million related to our 5.375% Notes and \$32.5 million related to our Facility Agreement. As the interest rates on the 5.375% Notes and the Facility Agreement are fixed, changes in interest rates do not affect the value of our debt.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

As of March 31, 2010, our 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 March 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over

financial reporting.

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, 2009, 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 as 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, 2009.

Healthcare reform legislation could adversely affect our revenue and financial condition

The U.S. Congress recently passed significant reforms to the U.S. healthcare system. Included as part of this new legislation is a 2.3% excise tax on the medical device industry beginning January 1, 2013 that is payable based on revenue, not income. This future excise tax may have a material adverse effect on our financial condition and results of operations. In addition, there are provisions that provide for the creation of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute will be publicly disseminated. It is difficult at this time to determine what impact the comparative effectiveness analysis will have on the OmniPod System or our future financial results. There may in the future be additional changes in government policy, including additional modifications to the recently-adopted healthcare reform bill, that could increase our cost of doing business and negatively impact our ability to sell our products and achieve profitability.

We are subject to extensive regulation by the U.S. Food and Drug Administration, which could restrict the sales and marketing of the OmniPod System and could cause us to incur significant costs. In addition, we may become subject to additional foreign regulation as we increase our efforts to sell the OmniPod System outside of the United States.

We sell medical devices that are subject to extensive regulation by the FDA. These regulations relate to manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-market approval from the FDA, unless an exemption applies. We may be required to obtain a new 510(k) clearance or pre-market approval for significant post-market modifications to the OmniPod System. Each of these processes can be expensive and lengthy, and entail significant user fees, unless exempt. The FDA's process for obtaining 510(k) clearance usually takes three to twelve months, but it can last longer. The process for obtaining pre-market approval is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current clinical applications for which we market our OmniPod System, which includes the use of U-100, which is a common form of insulin. However, our clearances can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, the OmniPod System in a timely fashion or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. We also are subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacturing of our devices, labeling regulations and medical device reporting regulations, which require us to report to the FDA if our devices cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. For instance, the FDA is in the process of reviewing the 510(k) approval process and criteria and has announced initiatives to improve the current premarket and postmarket regulatory processes and requirements associated with infusion pumps and other home use medical devices. As part of this effort, the FDA is reviewing the adverse event reporting and recall processes for insulin pumps. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

Edgar Filing: INSULET CORP - Form 10-Q

- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;
- administrative detention by the FDA of medical devices believed to be adulterated or misbranded;
 - imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses or modifications to the OmniPod System;

23

- rescinding 510(k) clearance or suspending or withdrawing pre-market approvals that have already been granted; and
- criminal prosecution.

The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

In addition, we entered into a distribution agreement with Ypsomed to become our exclusive distributor of the OmniPod system, subject to approved reimbursement, in eleven countries, beginning with Germany and the United Kingdom in the second quarter of 2010, and in several other markets in the second half of 2010 and in the first half of 2011. By distributing our product outside of the United States we may be required to comply with additional foreign regulatory requirements. For example, in April 2009, we received CE Mark approval for our OmniPod System. The CE Mark gives us authorization to distribute the OmniPod System throughout the European Union and in other countries that recognize the CE Mark. Additionally, in September 2009, we received Health Canada approval to distribute the OmniPod System throughout Canada. As we expand our sales efforts internationally, we may need to obtain additional foreign approval certifications.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description of Document
10.1*	Distribution Agreement dated January 4, 2010 by and between Insulet Corporation and Ypsomed Distribution AG.
10.2	Insulet Corporation Amended and Restated 2007 Employee Stock Purchase 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 Brian Roberts, 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 Brian Roberts, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Portions of this exhibit have been redacted pursuant to a request for confidential treatment submitted to the Securities Exchange Commission

24

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: May 7, 2010

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

Date: May 7, 2010

/s/ Brian Roberts
Brian Roberts
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description of Document
10.1*	Distribution Agreement dated January 4, 2010 by and between Insulet Corporation and Ypsomed Distribution AG.
10.2	Insulet Corporation Amended and Restated 2007 Employee Stock Purchase 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 Brian Roberts, 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 Brian Roberts, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
*	Portions of this exhibit have been redacted pursuant to a request for confidential treatment submitted to the Securities Exchange Commission