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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2009

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 ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

As of October 22, 2009, the registrant had 30,793,863 shares of common stock outstanding.

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PART I — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

INSULET CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of September 30, 2009	As of December 31, 2008 (Restated)
	(Unaudited) (In thousands, except share data)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 72,694	$ 56,663
Accounts receivable, net	16,357	11,938
Inventories	9,175	16,870
Prepaid expenses and other current assets	1,565	3,028
Total current assets	99,791	88,499
Property and equipment, net	15,531	17,564
Other assets	1,806	2,170
Total assets	$ 117,128	$ 108,233
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 5,183	$ 7,291
Accrued expenses	9,623	7,300
Deferred revenue	3,411	2,377
Total current liabilities	18,217	16,968
Long-term debt, net of current portion	95,902	60,172
Other long-term liabilities	2,706	2,987
Total liabilities	116,825	80,127
Stockholders' Equity		
Preferred stock, $.001 par value:		
Authorized: 5,000,000 shares at September 30, 2009 and December 31, 2008.		
Issued and outstanding: zero shares at September 30, 2009 and December 31, 2008, respectively	—	—
Common stock, $.001 par value:		
Authorized: 100,000,000 shares at September 30, 2009 and December 31, 2008		
Issued and outstanding: 30,789,239 and 27,778,921 shares at September 30, 2009 and December 31, 2008, respectively	32	29
Additional paid-in capital	315,230	278,427
Accumulated deficit	(314,959)	(250,350)
Total stockholders' equity	303	28,106
Total liabilities and stockholders' equity	$ 117,128	$ 108,233

December 31, 2008 balances have been restated to reflect the retrospective adoption of certain provisions of FASB ASC 470-20.

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

INSULET CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008 (Restated)	2009	2008 (Restated)
	(In thousands, except share and per share data) (Unaudited)			
Revenue	$ 18,735	$ 10,110	$ 45,821	$ 24,198
Cost of revenue	12,936	10,197	34,858	29,980
Gross profit (loss)	5,799	(87)	10,963	(5,782)
Operating expenses:				
Research and development	3,404	3,263	9,880	9,569
General and administrative	6,246	6,308	19,575	16,900
Sales and marketing	9,629	10,176	28,905	29,735
Total operating expenses	19,279	19,747	58,360	56,204
Operating loss	(13,480)	(19,834)	(47,397)	(61,986)
Interest income	22	481	204	1,554
Interest expense	(11,267)	(2,313)	(17,416)	(5,142)
Net interest expense	(11,245)	(1,832)	(17,212)	(3,588)
Net loss	$ (24,725)	$ (21,666)	$ (64,609)	$ (65,574)
Net loss per share basic and diluted	$ (0.88)	$ (0.78)	$ (2.32)	$ (2.38)
Weighted average number of shares used in calculating basic and diluted net loss per share	28,008,699	27,716,473	27,894,775	27,560,258

Results for the three and nine months ended September 30, 2008 have been restated to reflect the retrospective adoption of certain provisions of FASB ASC 470-20.

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

INSULET CORPORATION
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

	Nine Months Ended September 30,	
	2009	2008 (Restated)
	(In thousands) (Unaudited)	
Cash flows from operating activities		
Net loss	$ (64,609)	$ (65,574)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	4,001	4,665
Amortization of debt discount	10,495	1,726
Stock compensation expense	3,185	2,618
Provision for bad debts	2,820	2,012
Non cash interest expense	1,757	856
Changes in operating assets and liabilities:		
Accounts receivable	(7,239)	(9,071)
Inventory	7,695	(8,477)
Prepaids and other current assets	1,463	(2,185)
Accounts payable and accrued expenses	214	4,544
Other long term liabilities	(281)	2,330
Deferred revenue, short term	1,034	921
Net cash used in operating activities	(39,465)	(65,635)
Cash flows from investing activities		
Purchases of property and equipment	(1,968)	(9,441)
Net cash used in investing activities	(1,968)	(9,441)
Cash flows from financing activities		
Principal payments of long term loan	—	(5,454)
Proceeds from convertible note offering, net of financing expenses	—	81,532
Proceeds from issuance of facility agreement, net of financing expenses	57,015	—
Repayment of long term loan	(27,500)	(22,719)
Proceeds from issuance of common stock, net of offering expenses	27,949	1,254
Proceeds from payment of subscription receivable	—	9
Net cash provided by financing activities	57,464	54,622
Net increase (decrease) in cash and cash equivalents	16,031	(20,454)
Cash and cash equivalents, beginning of period	56,663	94,588
Cash and cash equivalents, end of period	$ 72,694	$ 74,134
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 4,077	$ 1,746
Non-cash financing activities		
Allocation of fair value of warrants from net proceeds from issuance of facility agreement	$ 6,065	$ —

Results for the nine months ended September 30, 2008 have been restated to reflect the retrospective adoption of certain provisions of FASB ASC 470-20.

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

INSULET CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2009, are not necessarily indicative of the results that may be expected for the full year ending December 31, 2009, or for any other subsequent interim period.

The condensed consolidated financial statements in this Quarterly Report on Form 10-Q should be read in conjunction with the Company's consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

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, stock options and warrants, the lives of property and equipment, and warranty and doubtful account allowance reserve calculations. Actual results may differ from those estimates.

Principles of Consolidation

The consolidated financial statements in this Quarterly Report on Form 10-Q include the accounts of the Company and its wholly-owned subsidiary, Sub-Q Solutions, Inc. All material intercompany balances and transactions have been eliminated in consolidation. To date there has been minimal activity in Sub-Q Solutions, Inc.

Reclassifications

Certain previously reported amounts have been reclassified to conform to the current year presentation.

Accounts Receivable and Allowance for Doubtful Accounts

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

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 at December 31, 2008 and September 30, 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. In the second quarter of 2009, the Company introduced a new version of its PDM. The Company evaluates inventory valuation on a quarterly basis for obsolete or slow-moving items. The Company expects to use the majority of the remaining earlier version PDMs to satisfy warranty obligations.

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.

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 that 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 typically includes OmniPods and a Starter Kit, which is comprised of the PDM, two OmniPods, the OmniPod System User Guide and the OmniPod System Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

Revenue is recognized in accordance with FASB ASC 605-10, *Revenue Recognition — Overall,* which requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

- The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval for sales directly to patients or a purchase order for sales to a third-party distributor.
- Transfer of title and risk and rewards of ownership are passed to the patient 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 has considered the requirements of FASB ASC 605-25 *Revenue Recognition — Multiple Element Arrangements*, when accounting for the OmniPods and Starter Kits. FASB ASC 605-25 requires the Company to assess whether the different elements qualify for separate accounting. The Company recognizes revenue for the initial shipment to a patient or other third party once all elements have been delivered.

The Company offers a 45-day right of return for its Starter Kits sales, and, in accordance with FASB ASC 605-15 *Revenue Recognition — Products*, the Company defers revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of the Company's historical return data to their related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. Historically, sales returns have amounted to approximately 3% of gross product sales.

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

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 revenue is recognized on the sale

of the PDM to a new patient. In the three and nine months ended September 30, 2009, the Company recognized $2.3 million and $4.5 million of revenue related to the Abbott agreement, respectively. In the three and nine months ended September 30, 2008, the Company recognized $1.2 million and $1.4 million of revenue related to the Abbott agreement, respectively. There was no impact to cost of revenue related to this agreement.

The Company had deferred revenue of $4.6 million and $4.0 million as of September 30, 2009 and December 31, 2008, respectively. The deferred revenue recorded as of September 30, 2009 was comprised of product-related revenue as well as the unrecognized portion of the agreement fee related to the Abbott agreement.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents and accounts receivable. The Company maintains the majority of its cash with one accredited financial institution. Although revenue is recognized from shipments directly to patients or third-party distributors, the majority of shipments are billed to third-party insurance payors. There were no third-party payors that account for more than 10% of gross accounts receivable at September 30, 2009 or December 31, 2008.

Income Taxes

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

The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense. As of September 30, 2009, the Company had no interest and penalty accrual or expense.

Adoption of New Accounting Standards

FASB ASC 470-20 *Debt — Debt with Conversion and Other Options* clarifies that convertible debt instruments that may be settled in cash upon conversion should be separated between the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. These provisions of FASB ASC 470-20 were applied retrospectively to all periods presented. The cumulative effect of the change in accounting principle on prior periods was recognized as of the beginning of the first period presented. The Company adopted these provisions of FASB ASC 470-20 as of January 1, 2009 and has reclassified $26.9 million of its long-term debt to equity as of the issuance date of the convertible notes. During the three and nine months ended September 30, 2009, the Company recorded $1.1 million and $3.2 million, respectively, of additional interest expense related to these provisions of FASB ASC 470-20. During the three and nine months ended September 30, 2008, the Company recorded $1.0 million and $1.1 million, respectively, of additional interest expense related to the provisions of FASB ASC 470-20.

The Company adopted certain provisions of FASB ASC 825-10, *Subsequent Events — Overall* as of June 30, 2009. FASB ASC 825-10 provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. FASB ASC 825-10 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. FASB ASC 825-10 requires additional disclosures only, and therefore did not have an impact on the Company's condensed consolidated financial statements. The Company has evaluated subsequent events through October 26, 2009, the date it has issued this Quarterly Report on Form 10-Q.

The Company adopted the Financial Accounting Standard Board Accounting Standards Codification in the three months ended September 30, 2009. 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 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 the Company's condensed consolidated financial statements.

3. Facility Agreement and Common Stock Warrants

On March 13, 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 beginning on June 1, 2009. The Company had the right to prepay any amounts owed without penalty unless the prepayment is in connection with a major transaction.

On September 25, 2009, the Company entered into an Amendment to the Facility Agreement whereby the Company agreed to repay the $27.5 million of outstanding debt and promptly draw down the remaining $32.5 million available under the Facility Agreement. The lender agreed to eliminate all future performance milestones associated with the remaining $32.5 million available on the credit facility and reduce the annual interest rate on any borrowed funds to 8.5%. In addition, the lender agreed to forego the remaining warrants to purchase an additional 1.5 million shares of common stock that would have been issued upon future draws. 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 Amendment to the Facility Agreement closed on September 30, 2009. 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 on March 13, 2009 and amended on September 25, 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 on 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 and 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. At September 30, 2009, 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 premium feature related to the Facility Agreement will be reassessed and marked-to-market through earnings on a quarterly basis.

At September 30, 2009, $32.5 million of outstanding debt related to the Facility Agreement is included in long-term debt in the condensed consolidated balance sheet. Upon repayment of the initial tranche of the Facility Agreement, the Company recognized approximately $7.6 million as interest expense. Of the $7.6 million of interest expense, $6.4 million related to the debt discount for the unamortized balance of the fair value of the warrants issued on March 13, 2009 and the transaction fee paid to the lenders and $1.2 million related to the remaining deferred financing costs. Approximately $9.0 million and $10.5 million of interest expense was recorded in the three and nine months ended September 30, 2009, respectively. Of the $9.0 million recorded in the three months ended September 30, 2009, approximately $0.9 million relates to cash interest, $0.5 million relates to amortization of the debt discount and deferred financing costs and $7.6 million relates to the charge taken related to the unamortized portion of the debt discount and deferred financing costs. Of the $10.5 million recorded in the nine months ended September 30, 2009, approximately $1.8 million relates to cash interest, $1.1 million relates to amortization of the debt discount and deferred financing costs and $7.6 million relates to the charge taken related to the unamortized portion of the debt discount and deferred financing costs. The difference between the amount paid and the carrying value of the outstanding amounts under the Facility Agreement was recognized as a $7.6 million loss from extinguishment of debt.

Common Stock Warrants

On March 13, 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 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 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 September 30, 2009, 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 Company 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 Company 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.

In accordance with FASB ASC 460-10 *Guarantees — Overall*, 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 quarter ended September 30, 2009, in connection with the repayment and termination of the initial disbursement.

4. Convertible Notes and Repayment and Termination of Term Loan

In June 2008, the Company sold $85 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the "5.375% Notes") in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year, beginning December 15, 2008. The 5.375% Notes are convertible into the Company's common stock at an initial conversion rate of 46.8467 shares of common stock per $1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately $21.35 per share, representing a conversion premium of 34% to the last reported sale price of the Company's common stock on the NASDAQ Global Market on June 10, 2008, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of 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 adopted certain provisions of FASB ASC 470-20 on January 1, 2009. FASB ASC 470-20 clarifies that convertible debt instruments that may be settled in cash upon conversion should be separated between the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FASB ASC 470-20 was applied retrospectively to all periods presented. Accordingly, 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 beginning June 15, 2008 over the 5 year life of the 5.375% Notes.

The Company incurred interest expense of approximately $2.2 million and $6.7 million for the three and nine months ended September 30, 2009, respectively, related to the 5.375% Notes. Of the $2.2 million recorded in the three months ended September 30, 2009, approximately $1.1 million relates to additional interest expense recognized under the provisions of FASB ASC 470-20. Of the $6.7 million recorded in the nine months ended September 30, 2009, approximately $3.2 million relates to additional interest expense recognized under the provisions of FASB ASC 470-20. 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 in the condensed consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the 5.375% Notes.

At September 30, 2009, the outstanding amounts related to the 5.375% Notes of $63.4 million are included in long-term debt in the condensed consolidated balance sheet and reflect the debt discount of $21.6 million. At December 31, 2008, the outstanding amounts related to the 5.375% Notes of $60.2 million are included in long-term debt and have been retroactively restated as required by FASB ASC 470-20 to reflect the debt discount of $24.8 million. The debt discount includes the equity allocation of $25.8 million ($26.9 million less the financing costs allocated to the equity of $1.1 million) offset by the accretion of the debt discount through interest expense from the issuance date in 2008 over the 5 year life of the notes. The Company recorded $1.1 million and $3.2 million of interest expense related to the debt discount in the three and nine months ended September 30, 2009, respectively. At September 30, 2009, the 5.375% Notes have a remaining life of 3.75 years. The statement of operations for the 2008 periods subsequent to the debt issuance on June 15, 2008, has been retroactively restated to reflect the additional interest expense pursuant to FASB ASC 470-20. The Company recorded $1.0 million and $1.1 million of interest expense related to the debt discount in the three and nine months ended September 30, 2008, respectively.

The Company received net proceeds of approximately $81.5 million from this offering. Approximately $23.2 million of the proceeds from this offering were used to repay and terminate the Company's outstanding term loan and the Company is using the remainder for general corporate purposes. On June 16, 2008, the Company repaid the entire outstanding principal balance, plus accrued and unpaid interest, under its existing term loan in the aggregate of approximately $21.8 million. Additionally, the Company

paid a prepayment fee related to the term loan of approximately $0.4 million, a termination fee related to the term loan of $0.9 million, and incurred certain other expenses related to the repayment and termination of the term loan. The Company incurred interest expense related to the term loan of approximately $0 and $1.5 million for the three and nine months ended September 30, 2008, respectively. The term loan was subject to a loan origination fee of $0.9 million, which was recorded in the condensed consolidated balance sheet and was amortized as a component of interest expense over the term of the loan. The remaining balance of deferred financing costs of approximately $0.6 million was written off at the repayment and termination date. In connection with this term loan, the Company issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock at a purchase price of $3.64 per share. The warrants automatically converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share at the closing of the Company's initial public offering in May 2007. The Company recorded the $0.8 million fair value of the warrants as a discount to the term loan. Upon repayment and termination of the term loan, the Company recognized approximately $0.5 million as interest expense for the unamortized balance of the warrants' fair value. The difference between the amount paid, including the prepayment fee, and the carrying value of the term loan, including the remaining deferred financing costs and unamortized warrants to purchase common stock, was recognized as a $1.5 million loss from early extinguishment of the term loan.

5. Restructuring Expenses and Impairments of Assets

In December 2008, the Company recorded restructuring and impairment charges of $8.2 million for the impairment of certain manufacturing equipment no longer in use as well as workforce reduction and related costs. As part of the Company's strategic goal to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing, the Company transitioned the manufacturing of completed OmniPods to Flextronics International Ltd., which is located in China. The Company determined that it would no longer use certain manufacturing equipment located in its Bedford facility. In addition, this transition resulted in a reduction in workforce of approximately 30 employees, mainly in the manufacturing and quality departments in response to the successful transition of portions of the manufacturing process to Flextronics as well as on-going alignment of the Company's infrastructure.. As a result of these actions, the Company recorded $7.4 million as a non-cash charge related to impairments of assets and $0.8 million in workforce and related charges.

During the third quarter of 2008, the Company successfully transitioned its production of completed OmniPods to the manufacturing line operated by Flextronics. Pursuant to the Company's agreement with Flextronics, Flextronics will supply, as a non-exclusive supplier, OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast provided by the Company. 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 Company continues to manufacture certain sub-assemblies and maintain packaging operations in its Bedford, Massachusetts facility.

The Company ceased to use certain assets in its Bedford facility in connection with the transition of manufacturing to Flextronics. The Company continued to evaluate Flextronics' ability to manufacture completed OmniPods against the rolling forecast as well as anticipated capacity and demand throughout the fourth quarter of 2008. During the fourth quarter of 2008 the Company concluded that the capacity of the manufacturing line operated by Flextronics is considered adequate to meet anticipated demand and quality standards in the future. As the Company determined that it would no longer use the Bedford equipment on December 1, 2008, the Company recorded an impairment charge for the remaining net book value of the assets of $7.4 million on that date. The equipment has no expected salvage value as it is highly customized equipment that can only be used for the manufacture of OmniPods.

At September 30, 2009 and December 31, 2008, the Company's accrued expense for restructuring was $0.1 million and $0.6 million, respectively, for final payments of severance and will be fully utilized in 2009.

The following is a summary of restructuring activity for the three and nine months ended September 30, 2009.

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
	(In thousands)	
Beginning balance	$ 262	$ 612
Expense	—	—
Payments	(129)	(479)
Ending balance	$ 133	$ 133

In September 2009, the Company recorded a charge to operating expenses of $0.6 million for workforce reduction and related costs as part of the Company's continued focus on aligning the Company's infrastructure. This focus resulted in a reduction of workforce of approximately 30 employees throughout the organization, including certain members of senior management. At September 30, 2009, the Company has accrued severance of approximately $0.6 million related to the workforce reduction.

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 and nine months ended September 30, 2009 and 2008, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Convertible notes	3,981,969	3,981,969	3,981,969	3,981,969
Unvested restricted common shares	2,664	—	2,664	—
Outstanding options	3,627,277	2,887,178	3,627,277	2,887,178
Outstanding warrants	3,812,752	62,752	3,812,752	62,752
Total	11,424,662	6,931,899	11,424,662	6,931,899

7. Accounts Receivable

The components of accounts receivable are as follows:

	As of	
	September 30, 2009	December 31, 2008
	(In thousands)	
Trade receivables	$ 22,541	$ 15,738
Allowance for doubtful accounts	(6,184)	(3,800)
	$ 16,357	$ 11,938

8. Inventories

Inventories consist of the following:

	As of	
	September 30, 2009	December 31, 2008
	(In thousands)	
Raw materials	$ 1,172	$ 3,518
Work-in-process	531	997
Finished goods	7,472	12,355
	$ 9,175	$ 16,870

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

Inventories of finished goods were held at cost at September 30, 2009 and December 31, 2008. The Company's production process has a high degree of fixed costs and sales and production volumes may vary significantly from one period to another.

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 September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(In thousands)		(In thousands)	
Balance at the beginning of period	$ 2,609	$ 1,500	$ 2,268	$ 865
Warranty expense	638	1,103	2,574	2,873
Warranty claims settled	(736)	(669)	(2,331)	(1,804)
Balance at the end of the period	$ 2,511	$ 1,934	$ 2,511	$ 1,934
Composition of balance:				
Short-term	1,032	801	1,032	801
Long-term	1,479	1,133	1,479	1,133
Total warranty balance	$ 2,511	$ 1,934	$ 2,511	$ 1,934

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. The Company has considered FASB ASC 840-20 *Leases — Operating Leases*, in accounting for these lease provisions.

Indemnifications

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

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

11. Equity

Stock-Based Compensation Plans

Activity under the Company's stock option plans:

	Number of Options(#)	Weighted Average Exercise Price($)	Aggregate Intrinsic Value($)
Balance, December 31, 2008	2,933,832	$ 9.47	$6,080,097
Granted	1,259,440	6.75	
Exercised	(132,292)	2.51	$ 631,830(1)
Canceled	(433,703)	13.19	
Balance, September 30, 2009	3,627,277	$ 8.34	
Vested, September 30, 2009	1,655,700	7.32	$8,605,792(2)
Vested and expected to vest, September 30, 2009 (3)	2,964,841		

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

(2) The aggregate intrinsic value was calculated based on the positive difference between the fair market value of the Company's common stock as of September 30, 2009, and the exercise price of the underlying options.

(3) Represents the number of vested options as of September 30, 2009, plus the number of unvested options expected to vest as of September 30, 2009, based on the unvested options outstanding at September 30, 2009, adjusted for an estimated forfeiture rate of 16%.

As of September 30, 2009 and 2008, no shares were contingently issued under the employee stock purchase plan ("ESPP"), respectively. In the three and nine months ended September 30, 2009 and 2008, the Company recorded no significant stock-based compensation charges related to the ESPP.

Employee stock-based compensation expense under FASB ASC 718-10 *Compensation — Stock Compensation* recognized in the three and nine months ended September 30, 2009 was $1.0 million and $3.2 million, respectively. Employee stock-based compensation expense under FASB ASC 718-20 recognized in the three and nine months ended September 30, 2008 was $1.0 million and $2.6 million, respectively.

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 condensed consolidated financial statements and the accompanying notes to those financial statements included in this Quarterly Report on Form 10-Q. This Quarterly Report on Form 10-Q contains forward-looking statements. These forward-looking statements are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: 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 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. We focus our sales towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetic patients.

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

During 2008, construction was completed 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 entered into on January 3, 2007 and revised on October 4, 2007. 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 were able to substantially increase production volumes for the OmniPod and reduce our per unit production cost. We also produce certain sub-assemblies for the OmniPod as well as maintain packaging operations at our facility in Bedford, Massachusetts.

Our OmniPod manufacturing capacity as of September 30, 2009 was in excess of 300,000 OmniPods per month. 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 installation of automated manufacturing equipment, collaboration with contract manufacturers and reduction of cost of supplies of raw materials and sub-assemblies, is important as we strive to achieve profitability.

Our sales and marketing effort is focused on generating demand and acceptance of the OmniPod System among healthcare professionals, people with insulin-dependent diabetes, third-party payors and third-party distributors. Our marketing strategy is to build awareness for the benefits of the OmniPod System through a wide range of education programs, patient demonstration programs, support materials and events at the national, regional and local levels. In addition, we are using third-party distributors to improve our access to managed care and government reimbursement programs, expand our commercial presence and provide access to additional potential patients.

As a medical device company, reimbursement from third-party payors is an important element of our success. If patients are not adequately reimbursed for the costs of using the OmniPod System, it will be much more difficult for us to penetrate the market. We continue to negotiate contracts establishing reimbursement for the OmniPod System with national and regional third-party payors, and we believe that substantially all of the units sold have been reimbursed by third-party payors, subject to applicable deductible and co-payment amounts. As we expand our sales and marketing initiatives and increase our manufacturing capacity, 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 and nine months ended September 30, 2009, we incurred net losses of $24.7 million and $64.6 million, respectively. As of September 30, 2009, we had an accumulated deficit of $315.0 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. As of September 30, 2009, 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. Since inception, we have received aggregate net proceeds of $384.5 million from the issuance of redeemable convertible preferred stock, common stock and debt.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts for the remainder of 2009 will be focused primarily on continuing to reduce our per-unit production costs through higher production volumes and planned cost reduction initiatives, expanding sales to domestic markets, initiating sales to international markets and reducing our spending on manufacturing overhead and operating expenses. 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, particularly in light of the recession in the United States and the slowdown of economic growth in the rest of the world which is creating a challenging near term business environment. 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

On March 13, 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 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 beginning on June 1, 2009. We had the right to prepay any amounts owed without penalty unless the prepayment is in connection with a major transaction.

On September 25, 2009, we entered into an Amendment to the Facility Agreement whereby we agreed to repay the $27.5 million of outstanding debt and promptly draw down the remaining $32.5 million available under the Facility Agreement. The lender agreed to eliminate all future performance-related milestones associated with the remaining $32.5 million available on the credit facility and reduce the annual interest rate on any unborrowed funds to 8.5%. In addition, the lender agreed to forego the remaining warrants to purchase an additional 1.5 million shares of common stock that would have been issued upon future draws. 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 on March 13, 2009 and amended on September 25, 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 and 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. At September 30, 2009, 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.

At September 30, 2009, $32.5 million of outstanding debt related to the Facility Agreement is included in long-term debt in the condensed consolidated balance sheet. Upon repayment of the initial tranche of the Facility Agreement, we recognized approximately $7.6 million as interest expense. Of the $7.6 million of interest expense, $6.4 million related to the debt discount for the unamortized balance of the fair value of the warrants issued on March 13, 2009 and the transaction fee paid to the lenders and $1.2 million related to the remaining deferred financing costs. Approximately $9.0 million and $10.5 million of interest expense was recorded in the three and nine months ended September 30, 2009, respectively. Of the $9.0 million recorded in the three months ended September 30, 2009, approximately $0.9 million relates to cash interest, $0.5 million relates to amortization of the debt discount and deferred financing costs and $7.6 million relates to the charge taken for the unamortized portion of the debt discount and deferred financing costs. Of the $10.5 million recorded in the nine months ended September 30, 2009, approximately $1.8 million relates to cash interest, $1.1 million relates to amortization of the debt discount and deferred financing costs and $7.6 million relates to the charge taken for the unamortized portion of the debt discount and deferred financing costs. The difference between the amount paid and the carrying value of the outstanding amounts under the Facility Agreement was recognized as a $7.6 million loss from extinguishment of debt.

On March 13, 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, 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 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 September 30, 2009, 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.

In accordance with FASB ASC 460-10 *Guarantees — Overall,* 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 quarter ended September 30, 2009, in connection with the repayment and termination of the initial disbursement.

Convertible Notes and Repayment and Termination of Term Loan

In June 2008, we sold $85 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the "5.375% Notes") in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year, beginning December 15, 2008. The 5.375% Notes are convertible into 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 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).

We adopted certain provisions of FASB ASC 470-20 *Debt — Debt with Conversion and Other Options,* on January 1, 2009. FASB ASC 470-20 clarifies that convertible debt instruments that may be settled in cash upon conversion should be separated between the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. These provisions of FASB ASC 470-20 were applied retrospectively to all periods presented. Accordingly, 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 beginning June 15, 2008 over the 5 year life of the 5.375% Notes.

We incurred interest expense of approximately $2.2 million and $6.7 million for the three and nine months ended September 30, 2009, related to the 5.375% Notes. Of the $2.2 million recorded in the three months ended September 30, 2009, approximately $1.1 million relates to additional interest expense recognized under these provisions of FASB ASC 470-20. Of the $6.7 million recorded in the nine months ended September 30, 2009, approximately $3.2 million relates to additional interest expense recognized under these provisions of FASB ASC 470-20. 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 in the condensed consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the 5.375% Notes.

At September 30, 2009, the outstanding amounts related to the 5.375% Notes of $63.4 million are included in long-term debt in the condensed consolidated balance sheet and reflect the debt discount of $21.6 million. At December 31, 2008, the outstanding amounts related to the 5.375% Notes of $60.2 million are included in long-term debt and have been retroactively restated as required by FASB ASC 470-20 to reflect the debt discount of $24.8 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 in 2008 over the 5 year life of the notes. We recorded $1.1 million and $3.2 million of interest expense related to the debt discount in the three and nine months ended September 30, 2009, respectively. At September 30, 2009, the 5.375% Notes have a remaining life of 3.75 years. The statement of operations for the 2008 periods subsequent to the debt issuance on June 15, 2008, has been retroactively restated to reflect the additional interest expense pursuant to FASB ASC 470-20. We recorded $1.0 million and $1.1 million of interest expense related to the debt discount in the three and nine months ended September 30, 2008, respectively.

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 outstanding term loan, and we are using the remainder for general corporate purposes. On June 16, 2008, we repaid the entire outstanding principal balance, plus accrued and unpaid interest, under our existing term loan in the aggregate of approximately $21.8 million. Additionally, we paid a prepayment fee related to the term loan of approximately $0.4 million, a termination fee related to the term loan of $0.9 million, and incurred certain other expenses related to the repayment and termination of the term loan. We incurred interest expense related to the term loan of approximately $0 and $1.5 million for the three and nine months ended September 30, 2008, respectively. The term loan was subject to a loan origination fee of $0.9 million, which was recorded in the condensed consolidated balance sheet and was amortized as a component of interest expense over the term of the loan. The remaining balance of deferred financing costs of approximately $0.6 million was written off at the repayment and termination date. In connection with this term loan, we issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock at a purchase price of $3.64 per share. The warrants automatically converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share at the closing of our initial public offering in May 2007. We recorded the $0.8 million fair value of the warrants as a discount to the term loan. Upon repayment and termination of the term loan, we recognized approximately $0.5 million as interest expense for the unamortized balance of the warrants' fair value. The difference between the amount paid, including the prepayment fee, and the carrying value of the term loan, including the remaining deferred financing costs and unamortized warrants to purchase common stock, was recognized as a $1.5 million loss from early extinguishment of the term loan.

Financial Operations Overview

Revenue. Revenue is recognized in accordance with FASB ASC 605-10, *Revenue Recognition — Overall* and FASB ASC 605-25 *Revenue — Multiple Element Arrangements*. We derive nearly all of our revenue from the sale of the OmniPod System directly to patients and third-party distributors who resell the product to diabetes patients. The OmniPod System is comprised of two devices: the OmniPod, a disposable insulin infusion device that the patient wears for up to three days and then replaces; and the Personal Diabetes Manager ("PDM"), a handheld device much like a personal digital assistant that wirelessly programs the OmniPod with insulin delivery instructions, assists the patient with diabetes management and incorporates a blood glucose meter. Revenue is derived from the sale to new customers or third-party distributors of OmniPods and Starter Kits, which include the PDM, two OmniPods, the OmniPod System User Guide and OmniPod System Interactive Training CD, and from the subsequent sales of additional OmniPods to existing customers. Customers generally order a three-month supply of OmniPods. For the three and nine months ended September 30, 2009, 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 the three and nine months ended September 30, 2009, we recognized $2.3 million and $4.5 million of revenue related to the Abbott agreement, respectively. In the three and nine months ended September 30, 2008, we recognized $1.2 million and $1.4 million of revenue related to the Abbott agreement, respectively. There was no impact to cost of revenue related to this agreement.

As of September 30, 2009 and December 31, 2008, we had deferred revenue of $4.6 million and $4.0 million, respectively, which includes product-related revenue as well as the unrecognized portion of the agreement fee related to the Abbott agreement.

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. For the remainder of 2009, we expect the cost of revenue to decrease as a percentage of revenue due to increases in our OmniPod manufacturing capacity as the supply of complete OmniPods and subassemblies from Flextronics increases, expected reductions in per-unit raw materials costs associated with planned cost reduction initiatives and reduction in our scrap and other period expenses. The increase in our OmniPod production volume is expected to reduce the per-unit cost of manufacturing the OmniPods by allowing us to spread our fixed and semi-fixed overhead costs over a greater number of units. However, if sales volumes do not continue to increase, then the average cost of revenue per OmniPod may not decrease.

Research and development. Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical functions, as well as the costs of market studies and product development projects. We expense all research and development costs as incurred. For the remainder of 2009, we expect overall research and development spending to be in line with current levels in order to support 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.

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 2009, we expect sales and marketing expenses to decrease as a percentage of sales as we believe we have aligned our sales and marketing efforts with our current business needs.

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 2009, we expect general and administrative expenses to continue to decrease slightly from current levels.

Results of Operations

The following table presents certain statement of operations information for the three and nine months ended September 30, 2009 and 2008:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008 (Restated)	% Change	2009	2008 (Restated)	% Change
	(In thousands) (Unaudited)					
Revenue	$ 18,735	$ 10,110	85%	$ 45,821	$ 24,198	89%
Cost of revenue	12,936	10,197	27%	34,858	29,980	16%
Gross profit (loss)	5,799	(87)		10,963	(5,782)	
Operating expenses:						
Research and development	3,404	3,263	4%	9,880	9,569	3%
General and administrative	6,246	6,308	1%	19,575	16,900	16%
Sales and marketing	9,629	10,176	5%	28,905	29,735	3%
Total operating expenses	19,279	19,747	2%	58,360	56,204	4%
Operating loss	(13,480)	(19,834)	32%	(47,397)	(61,986)	24%
Other expense, net	(11,245)	(1,832)	514%	(17,212)	(3,588)	380%
Net loss	$(24,725)	$(21,666)	14%	$(64,609)	$(65,574)	1%

Comparison of the Three and Nine Months Ended September 30, 2009 and 2008

Revenue

Our total revenue was $18.7 million and $45.8 million for the three and nine months ended September 30, 2009, respectively, compared to $10.1 million and $24.2 million for the same periods in 2008. The increase in revenue is primarily due to an increased number of patients using the OmniPod System and an increase in sales to distributors. In addition to the increase in the number of reorders from our growing patient base, the increase in patients also resulted in additional revenue related to the Abbott agreement of $2.3 million and $4.5 million in the three and nine months ended September 30, 2009, respectively, compared to $1.2 million and $1.4 million in the same periods in 2008. We expect our revenue to continue to increase as we continue to add new patients and generate an increased number of reorders based on our expanding patient base. In addition, we will continue to recognize additional revenue related to the Abbott agreement.

Cost of Revenue

Cost of revenue was $12.9 million and $34.9 million for the three and nine months ended September 30, 2009, compared to $10.2 million and $30.0 million for the same periods in 2008. The increase is due to significantly increased sales volume offset by efficiencies resulting from increased manufacturing capacity, cost reduction initiatives, lower depreciation and increased utilization of Flextronics as the sole manufacturer of complete OmniPods. The per-unit cost to manufacture the OmniPod decreased in the three and nine months ended September 30, 2009, compared to the same periods in 2008, resulting in a significant improvement of our gross margin.

Research and Development

Research and development expenses increased $0.1 million, or 4%, to $3.4 million for the three months ended September 30, 2009 compared to $3.3 million for the same period in 2008. Research and development expenses increased $0.3 million, or 3%, to $9.9 million for the nine months ended September 30, 2009 compared to $9.6 million for the same period in 2008. For the three months ended September 30, 2009, the slight increase in research and development expenses was primarily attributable to an increase of $0.2 million in employee related expenses including stock-based compensation, offset by a decrease in outside services. For the nine months ended September 30, 2009, the slight increase in research and development expenses was primarily attributable to an increase of $0.6 million in employee related expenses including stock-based compensation, and an increase of $0.2 million in travel related expenses offset primarily by a decrease of $0.6 million in outside services.

General and Administrative

General and administrative expenses decreased $0.1 million, or 1%, to $6.2 million for the three months ended September 30, 2009, compared to $6.3 million for the same period in 2008. General and administrative expenses increased $2.7 million, or 16%, to $19.6 million for the nine months ended September 30, 2009, compared to $16.9 million for the same period in 2008. For the three months ended September 30, 2009, the decrease in general and administrative expenses was primarily due to a decrease of $0.5 million in outside services, $0.3 million for insurance, office supplies and travel-related expenses. These decreases were offset by an increase of $0.5 million in employee compensation and benefit costs, including stock-based compensation and an increase in allowances and write-offs for doubtful trade accounts receivables of $0.3 million. For the nine months ended September 30, 2009, the increase in general and administrative expenses was primarily due to an increase of $1.4 million in employee compensation and benefit costs, including stock-based compensation and employee severance expense, $0.8 million in allowances and write-offs for doubtful trade accounts receivables, and $0.3 million in depreciation expense. These increases were offset by a decrease in outside services costs of $0.2 million.

Sales and Marketing

Sales and marketing expenses decreased $0.5 million, or 5%, to $9.6 million for the three months ended September 30, 2009, compared to $10.2 million for the same period in 2008. Sales and marketing expenses decreased $0.8 million, or 3%, to $28.9 million for the nine months ended September 30, 2009, compared to $29.7 million for the same period in 2008. For the three months ended September 30, 2009, the decrease in sales and marketing expenses was primarily due to a decrease of $0.7 million in samples and Patient Demonstration Kits and $0.2 million in travel related expenses. These decreases were offset by an increase of $0.4 million in outside consulting services, which include our external trainers. For the nine months ended September 30, 2009, the decrease in sales and marketing expenses was primarily due to a decrease of $2.9 million in samples and Patient Demonstration Kits and $0.2 million for convention fees. This was offset by an an increase of $0.8 million in outside consulting services, which include our external trainers, and an increase of $1.6 million in employee compensation and benefit costs resulting from the growing sales organization and higher commissions and related taxes in connection with increased sales volumes.

Other Income (Expense)

Net interest expense was $11.2 million for the three months ended September 30, 2009, compared to $1.8 million for the same period in 2008. Net interest expense was $17.2 million for the nine months ended September 30, 2009, compared to $3.6 million for the same period in 2008. For the three months ended September 30, 2009, the increase in net interest expense was primarily caused by interest incurred on the credit facility entered into in March 2009 and the write-off of $7.6 million for the remaining unamortized value of the warrants, transaction fee and deferred financing costs in connection with the amendment of the credit facility in September 2009. During the nine months ended September 30, 2009, we recorded cash and non-cash interest expense related to the 5.375% Notes of $6.7 million. In addition, in the nine months ended September 30, 2009, we recorded approximately $10.5 million of interest expense related to the Facility Agreement we entered into in March 2009. Net interest expense in the nine months ended September 30, 2008 also included $2.4 million of cash and non-cash interest on the 5.375% Notes and $1.5 million related to the repayment and termination of our term loan. We anticipate net interest expense to decrease significantly from current levels throughout the remainder of 2009.

Liquidity and Capital Resources

We commenced operations in 2000 and to date we have financed our operations primarily through private placement of common and preferred stock, secured indebtedness, public offerings of our common stock and issuance of convertible debt. As of September 30, 2009, we had $72.7 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

On March 13, 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 beginning on June 1, 2009. We had the right to prepay any amounts owed without penalty unless the prepayment is in connection with a major transaction.

On September 25, 2009, we entered into an Amendment to the Facility Agreement whereby we agreed to repay the $27.5 million of outstanding debt and promptly draw down the remaining $32.5 million available under the Facility Agreement. The lender agreed to eliminate all future performance-related milestones associated with the remaining $32.5 million available on the credit facility and reduce the annual interest rate on any borrowed funds to 8.5%. In addition, the lender agreed to forego the remaining warrants to purchase an additional 1.5 million shares of common stock that would have been issued upon future draws. 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. The Amendment to the Facility Agreement closed on September 30, 2009. 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.

On March 13, 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, 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 of the Facility Agreement in September 2009, the lenders agreed to forego the additional warrants that would have been issued upon future draws. At September 30, 2009, all warrants issued under the Facility Agreement remained unexercised.

In June 2008, we sold $85 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the "5.375% Notes") in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year, beginning December 15, 2008. The 5.375% Notes are convertible into our common stock at an initial conversion rate of 46.8467 shares of common stock per $1,000 principal amount of the 5.375% Notes, which is equivalent

to a conversion price of approximately $21.35 per share, representing a conversion premium of 34% to the last reported sale price of our common stock on the NASDAQ Global Market on June 10, 2008, per $1,000 principal amount of the 5.375% Notes, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of our common stock for the remainder of the conversion value in excess of the principal amount. We do not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require us to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest, to, but excluding, the date of repurchase.

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

	Nine Months Ended September 30,	
	2009	2008
	(In thousands)	
Cash used in operating activities	$ (39,465)	$ (65,635)
Net loss	$ (64,609)	$ (65,574)

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. 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:

	Nine Months Ended September 30,	
	2009	2008
	(In thousands)	
Cash used in investing activities	$ (1,968)	$ (9,441)
Cash provided by financing activities	$ 57,464	$ 54,622

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 decreased significantly in the nine months ended September 30, 2009, compared to the nine months ended September 30, 2008 as we completed building the majority of our manufacturing equipment in 2008. Capital expenditures are expected to remain at lower levels in 2009 compared to 2008. Cash provided by financing activities in the nine months ended September 30, 2009 mainly consisted of the net proceeds from the Facility Agreement entered into on March 13, 2009 and amended on September 25, 2009 and the sale of shares in connection with the amendment on September 25, 2009. Cash provided by financing activities in the nine months ended September 30, 2008, mainly consisted of the net proceeds from the 5.375% Convertible Notes issued in June 2008, offset by the redemption of the existing term loan.

Lease Obligations

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

Off-Balance Sheet Arrangements

As of September 30, 2009, 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 most of our revenue from sales of our OmniPod Insulin Management System to diabetes patients or third-party distributors who resell the product to diabetes patients. The initial sale to a new customer or a third-party distributor typically includes OmniPods and a Starter Kit, which include the PDM, two OmniPods, the OmniPod System User Guide and the OmniPod System Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

Revenue is recognized in accordance with FASB ASC 605-10, *Revenue Recognition — Overall,*, which requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

- The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval for sales directly to patients or a purchase order for sales to a third-party distributor.
- Transfer of title and risk and rewards of ownership are passed to the patient 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 have considered the requirements of FASB ASC 605-25 *Revenue — Multiple Element Arrangements*, when accounting for the OmniPods and Starter Kits. FASB ASC 605-25 requires us to assess whether the different elements qualify for separate accounting. We recognize revenue for the initial shipment to a patient or other third party once all elements have been delivered.

We offer a 45-day right of return for our Starter Kits sales, and in accordance with FASB ASC 605-15, *Revenue — Products*, 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 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 a new patient. In the three and nine months ended September 30, 2009, we recognized $2.3 million and $4.5 million of revenue related to the Abbott agreement, respectively. In the three and nine months ended September 30, 2008, we recognized $1.2 million and $1.4 million of revenue related to the Abbott agreement, respectively. There was no impact to cost of revenue related to this agreement.

Restructuring Expense and Impairment of Assets

As part of 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 planned use of the assets as well as 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, all of our tax years remain open to examination by the major taxing jurisdictions to which we are subject.

We recognize estimated interest and penalties for uncertain tax positions in income tax expense. As of September 30, 2009, 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. In estimating whether accounts receivable can be collected, we perform evaluations of customers and continuously monitor collections and payments and estimate an allowance for doubtful accounts based on the aging of the underlying invoices, experience to date and any payor-specific collection issues that have been identified.

Adoption of New Accounting Standards

FASB ASC 470-20, *Debt — Debt with Conversion and Other Options,* clarifies that convertible debt instruments that may be settled in cash upon conversion should be separated between the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FASB ASC 470-20 should be applied retrospectively to all periods presented. The cumulative effect of the change in accounting principle on prior periods was recognized as of the beginning of the first period presented. We adopted these provisions of FASB ASC 470-20 as of January 1, 2009 and reclassified $26.9 million of our long-term debt to equity as of the issuance date of the convertible notes. During the three and nine months ended September 30, 2009, we recorded $1.1 million and $3.2 million, respectively, of additional interest expense related to these provisions of FASB ASC 470-20. During the three and nine months ended September 30, 2008, we recorded $1.0 million and $1.1 million of additional interest expense related to these provisions of FASB ASC 470-20, respectively.

We adopted the provisions of FASB ASC 855-10, *Subsequent Events — Overall*, as of June 30, 2009. FASB ASC 855-10 provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. FASB ASC 855-10 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. FASB ASC 855-10 requires additional disclosures only, and therefore did not have an impact on our condensed consolidated financial statements. We have evaluated subsequent events through October 26, 2009, the date we have issued this Quarterly Report on Form 10-Q.

We adopted the Financial Accounting Standards Board Accounting Standards Codification in the three months ended September 30, 2009. 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 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 our 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 our condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

As of September 30, 2009, we had outstanding debt recorded at $63.4 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 September 30, 2009, 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 September 30, 2009 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

Set forth below are certain risk factors that could harm our business, results of operations and financial condition. You should carefully read the following risk factors, together with the financial statements, related notes and other information contained in this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2008. This Form 10-Q contains forward-looking statements that contain risks and uncertainties. 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.

Risks Relating to Our Business

We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.

Since our inception in 2000, we have incurred losses every quarter. We began commercial sales of the OmniPod System in October 2005. Beginning in the second half of 2008, we have been able to manufacture and sell the OmniPod System at a cost and in volumes sufficient to allow us to achieve a positive gross margin. For the nine months ended September 30, 2009, our gross profit from the manufacture and sale of the OmniPod System was $11.0 million. Although we have achieved a positive gross margin, we still operate at a substantial net loss. Our net losses for the nine months ended September 2009, and the years ended December 31, 2008 and 2007 were $64.6 million, $94.8 million and $53.5 million, respectively. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve or sustain profitability. We have incurred a significant net loss since our inception, and as of September 30, 2009, we had an accumulated deficit of $315.0 million.

We currently rely entirely on sales of our sole product, the OmniPod System, to generate revenues. The failure of the OmniPod System to achieve and maintain significant market acceptance or any factors that negatively impact sales of this product will adversely affect our business, financial condition and results of operations.

Our sole product is the OmniPod System, which we introduced to the market in October 2005. We expect to continue to derive substantially all of our revenue from the sale of this product. Accordingly, our ability to generate revenue is entirely reliant on our ability to market and sell the devices that comprise the OmniPod System. Our sales of the OmniPod System may be negatively impacted by many factors, including:

- the failure of the OmniPod System to achieve wide acceptance among opinion leaders in the diabetes treatment community, insulin-prescribing physicians, third-party payors and people with insulin-dependent diabetes;
- manufacturing problems;
- actual or perceived quality problems;
- changes in reimbursement rates or policies relating to the OmniPod System by third-party payors;
- claims that any portion of the OmniPod System infringes on patent rights or other intellectual property rights owned by other parties;
- adverse regulatory or legal actions relating to the OmniPod System;
- damage, destruction or loss of any of our automated assembly units;
- conversion of patient referrals to actual sales of the OmniPod System;
- collection of receivables from our customers;
- attrition rates of customers ceasing to use the OmniPod System;
- competitive pricing and related factors; and
- results of clinical studies relating to the OmniPod System or our competitors' products.

If any of these events occurs, our ability to generate revenue could be significantly reduced.

Our ability to achieve profitability from a current net loss level will depend on our ability to reduce the per unit cost of producing the OmniPod by increasing our customer orders and manufacturing volume.

Currently, the gross profit from the sale of the OmniPod System is not sufficient to cover our operating expenses. To achieve profitability, we need to, among other things, reduce the per unit cost of the OmniPod. This can be achieved by increasing our manufacturing volume, which will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs. During 2008, we completed construction of a partially automated manufacturing line at a facility in China operated by a subsidiary of Flextronics International Ltd. Our manufacturing capacity at September 30, 2009 was in excess of 300,000 OmniPods per month. If we are unable to reduce raw material and manufacturing overhead costs through volume purchase discounts and increased production capacity, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes must be supported by a concomitant increase in customer orders. The occurrence of one or more factors that negatively impact our sales of the OmniPod System may prevent us from achieving our desired increase in manufacturing volume, which would prevent us from attaining profitability.

Adverse changes in general economic conditions in the United States could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions. The U.S. economy remains extremely sluggish as it seeks to recover from a severe recession and unprecedented turmoil. The U.S. economy continues to suffer from market volatility, difficulties in the financial services sector, tight credit markets, softness in the housing markets, concerns of inflation, reduced corporate profits and capital spending, significant job losses, reduced consumer spending, and continuing economic uncertainties. The turmoil and the uncertainty about future economic conditions could negatively impact our current and prospective customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures. We cannot predict the timing, strength or duration of this severe global economic downturn or subsequent recovery.

Healthcare spending in the United States has been, and is expected to continue to be, negatively affected by these recessionary trends. For example, patients who have lost their jobs may no longer be covered by an employee-sponsored health insurance plan and patients reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the OmniPod System to a new patient is generally dependent on the availability of third-party reimbursement and normally requires the patient to make a significant co-payment, the impacts of the recession on our potential customers may reduce the referrals generated by our sales force and thereby reduce our customer orders. Similarly, the impacts of the recession on our existing patients may cause some of them to

cease purchasing OmniPods and to return to MDI or other less-costly therapies, which would cause our attrition rate to increase. Any decline in new customer orders or increase in our customer attrition rate will reduce our revenues, which in turn will make it more difficult to achieve the per unit cost-savings which are expected to be attained through increases in our manufacturing volume.

The severe recession has impacted the financial stability of many private health insurers. As a result, it has been reported that some insurers are scrutinizing claims more rigorously and delaying or denying reimbursement more often. Since the sale of the OmniPod System is generally dependent on the availability of third-party reimbursement, any delay or decline in such reimbursement will adversely affect our revenues.

Healthcare reform legislation could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs. Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform and a number of bills have been proposed in Congress. A leading proposal includes an excise tax on the medical device industry that would be payable based on revenue, not income. In addition, recent legislation and many of these proposed bills include funding to assess the comparative effectiveness of medical devices. It is unclear what impact the excise tax proposal or the comparative effectiveness analysis would have on the OmniPod System or our financial results. The ultimate content or timing of any future healthcare reform legislation, and its impact on medical device companies such as us, is impossible to predict. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have a material adverse effect on our financial condition and results of operations.

We may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.

Our capital requirements will depend on many factors, including:

- revenues generated by sales of the OmniPod System and any other future products that we may develop;
- costs associated with adding further manufacturing capacity;
- costs associated with expanding our sales and marketing efforts in the United States and internationally;
- expenses we incur in manufacturing and selling the OmniPod System;
- costs of developing new products or technologies and enhancements to the OmniPod System;
- the cost of obtaining and maintaining FDA approval or clearance of our current or future products;
- costs associated with any expansion;
- costs associated with capital expenditures;
- costs associated with litigation; and
- the number and timing of any acquisitions or other strategic transactions.

We believe that our current cash and cash equivalents, including the net proceeds from our public and private offerings and draw downs on our credit facility, together with the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements through at least the end of 2010.

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

The facility agreement we entered into on March 13, 2009, as amended on September 25, 2009, with certain institutional accredited investors, contains restrictions on our ability to incur certain indebtedness without the prior consent of our lenders. In addition, our ability to raise additional capital may be adversely impacted by current economic conditions, including the effects of the recent disruptions to the credit and financial markets in the United States and worldwide. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain future additional capital on terms favorable to us or our stockholders.

If we are unable to raise additional capital due to these or other factors, we may need to further manage our operational expenses to reflect these external factors, including potentially curtailing our planned development activities. If we cannot raise additional funds in the future on acceptable terms, we may not be able to develop new products, execute our business plan, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements. If any of these events occur, it could adversely affect our business, financial condition and results of operations.

We are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on a number of suppliers who manufacture the components of the OmniPods and PDMs. For example, we rely on Phillips Plastic Corporation to manufacture and supply a number of injection molded components of the OmniPod and Freescale Semiconductor, Inc. to manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod. In addition, we expanded the scope of our existing contract manufacturing agreement with a subsidiary of Flextronics International Ltd. in China to provide the supply of complete OmniPods. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we make our purchases on a purchase order basis. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. For example, the initial term of our agreement with Flextronics is three years from January 3, 2007, with automatic one-year renewals, and 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. Additionally, our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of the OmniPod System or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers for our sole-source supplies;
- switching components may require product redesign and submission to the U.S. Food and Drug Administration, or FDA, of a 510(k) supplement;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

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

Our financial condition or results of operations may be adversely affected by international business risks.

In order to reduce our cost of goods sold and increase our production capacity, we increasingly rely on third-party suppliers located outside the United States. For example, currently all of our OmniPods are manufactured on a partially automated manufacturing line at a facility in China operated by Flextronics International Ltd. As a result, our business is subject to risks associated with doing business internationally, including:

- instability in the political or economic conditions;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;

- difficulty in staffing and managing widespread operations;
- difficulties associated with foreign legal systems;
- changes in foreign currency exchange rates;
- differing protection of intellectual property; and
- unexpected changes in regulatory requirements.

In particular, our future success will depend in large part on our ability to anticipate and effectively manage these and other risks associated with doing business in China. Any of these factors may have a material adverse effect on our production capacity and, consequently, our business, financial condition and results of operations.

Failure to secure or retain adequate coverage or reimbursement for the OmniPod System by third-party payors could adversely affect our business, financial condition and results of operations.

We expect that sales of the OmniPod System will be limited unless a substantial portion of the sales price of the OmniPod System is paid for by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations and other managed care providers. We currently have contracts establishing reimbursement for the OmniPod System with national and regional third-party payors which provide reimbursement for patients residing in all 50 states. While we anticipate entering into additional contracts with other third-party payors, we cannot assure you that we will be successful in doing so. In addition, these contracts can generally be terminated by the third-party payor without cause. Also, healthcare market initiatives in the United States may lead third-party payors to decline or reduce reimbursement for the OmniPod System. Moreover, compliance with administrative procedures or requirements of third-party payors may result in delays in processing approvals by those payors for patients to obtain coverage for the use of the OmniPod System. We are an approved Medicare provider and current Medicare coverage for CSII therapy does exist. However, existing Medicare coverage for CSII therapy is based on the pricing structure developed for conventional insulin pumps. Currently, we believe that the coding verification for Medicare reimbursement of the OmniPod System is inappropriate and we are therefore in the process of seeking appropriate coding verification. As a result, we have focused our efforts in establishing reimbursement for the OmniPod System by negotiating contracts with private insurers. Failure to secure or retain adequate coverage or reimbursement for the OmniPod System by third-party payors could have a material adverse effect on our business, financial condition and results of operations.

We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration and which may allow them to develop additional products for the treatment of diabetes that compete with the OmniPod System.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The OmniPod System competes with a number of existing insulin delivery devices as well as other methods for the treatment of diabetes. Medtronic MiniMed, a division of Medtronic, Inc., has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, and Roche Diagnostics, a division of F. Hoffman-La Roche Ltd.

All of these competitors are large, well-capitalized companies with significantly more market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we can. Many of these competitors have:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage; and/or
- greater financial and human resources for product development, sales and marketing and patent litigation.

We also compete with multiple daily injection, or MDI, therapy, which is substantially less expensive than CSII therapy. MDI therapy has been made more effective by the introduction of long-acting insulin analogs by both sanofi-aventis and Novo Nordisk A/S. While we believe that CSII therapy, in general, and the OmniPod System, in particular, have significant competitive and clinical advantages over traditional MDI therapy, improvements in the effectiveness of MDI therapy may result in fewer people with insulin-dependent diabetes converting from MDI therapy to CSII therapy than we expect and may result in negative price pressure.

In addition to the established insulin pump competitors a number of companies (including current competitors) are working to develop and market new insulin “patch” pumps or “multi channel” pump devices (insulin and glucagon). These companies are at various stages of development. The companies of which we are aware working in this area include Medtronic, Inc., Medingo Ltd.,

NiliMEDIX Ltd, Sensile Medical AG, M2 Medical, Inc., Phluid Corporation, Seattle Medical Technologies, Inc., Starbridge Systems Ltd., Novo Nordisk A/S and Abbott Laboratories.

Our current competitors or other companies may at any time develop additional products for the treatment of diabetes. For example, other diabetes-focused pharmaceutical companies, including Abbott Laboratories, Eli Lilly and Company, Novo Nordisk A/S and Takeda Pharmaceuticals Company Limited, are developing similar products. All of these competitors are large, well-capitalized companies with significantly greater product development resources than us. If an existing or future competitor develops a product that competes with or is superior to the OmniPod System, our revenues may decline. In addition, some of our competitors may compete by changing their pricing model or by lowering the price of their insulin delivery systems or ancillary supplies. If these competitors' products were to gain acceptance by healthcare professionals, people with insulin-dependent diabetes or third-party payors, a downward pressure on prices could result. If prices were to fall, we may not improve our gross margins or sales growth sufficiently to achieve profitability.

Technological breakthroughs in diabetes monitoring, treatment or prevention could render the OmniPod System obsolete.

The diabetes treatment market is subject to rapid technological change and product innovation. The OmniPod System is based on our proprietary technology, but a number of companies, medical researchers and existing pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and/or prevention of insulin-dependent diabetes. For example, FDA approval of a commercially viable "closed-loop" system that combines continuous "real-time" glucose sensing or monitoring and automatic continuous subcutaneous insulin infusion in a manner that delivers appropriate amounts of insulin on a timely basis without patient direction could have a material adverse effect on our revenues and future profitability. We have an agreement with Abbott Diabetes Care, Inc., a global healthcare company that develops continuous glucose monitoring technology, to develop a product that will integrate the receiver portion of Abbott's continuous glucose monitor, the FreeStyle Navigator, with the OmniPod System PDM. The FreeStyle Navigator has recently received FDA approval. We have a similar agreement with DexCom, Inc., a leading provider of continuous glucose monitoring systems for people with diabetes, to develop a product that will integrate the receiver portion of DexCom's continuous glucose monitor, currently marketed as the SEVEN System, with the OmniPod System PDM. Medtronic, Inc. has developed an FDA-approved product combining continuous glucose sensing and CSII therapy and if we fail to do so, we may be at a significant competitive disadvantage, which could negatively impact our business. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve the treatment of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could render the OmniPod System obsolete, which may have a material adverse effect on our business, financial condition and results of operations.

If our existing license agreement with Abbott Diabetes Care, Inc. is terminated or we fail to enter into new license agreements allowing us to incorporate a blood glucose meter into the OmniPod System, our business may be materially adversely impacted.

Our rights to incorporate the FreeStyle blood glucose meter into the OmniPod System are governed by a development and license agreement with Abbott Diabetes Care, Inc., as the successor to TheraSense, Inc. This agreement provides us with a non-exclusive, fully paid, non-transferable and non-sublicensable license in the United States under patents and other relevant technical information relating to the FreeStyle blood glucose meter during the term of the agreement. On March 3, 2008 we entered into a first amendment of the agreement pursuant to which the term of the original agreement was extended until February 2013, with automatic renewals for subsequent one-year periods thereafter, and the license granted therein was extended to cover Israel as well as the United States. The agreement may be terminated by Abbott if it discontinues its FreeStyle blood glucose meter or test strips or by either party if the other party is acquired by a competitor of the first party or materially breaches its obligations under the agreement. Termination of this agreement could require us to either remove the blood glucose meter from PDMs to be sold in the future, which would impair the functionality of the OmniPod System, or attempt to incorporate an alternative blood glucose meter into the PDM, which would require us to acquire rights to or develop an alternative blood glucose meter, incorporate it into the OmniPod System and obtain regulatory approval for the new OmniPod System. Any of these outcomes could have a material adverse effect on our business,financial condition and results of operations.

In addition, Abbott and a number of other major blood glucose monitor manufacturers were sued for patent infringement by Roche Diagnostics pursuant to a complaint dated November 21, 2007. The complaint alleges that the blood glucose monitors currently manufactured by Abbott and others infringe one or more recently-issued Roche patents. Abbott has indemnified us against losses arising from claims of infringement like these and, if our use of the Freestyle blood glucose meter were to be enjoined and Abbott was unable to obtain a license as required by our contract, then we would need to obtain rights to an alternative non-infringing blood glucose meter, incorporate it into the OmniPod System and obtain regulatory approval for the new OmniPod System. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

In the future, we may need additional licenses to intellectual property owned by third parties in order to commercialize new products. If we cannot obtain these additional licenses, we may not be able to develop or commercialize these future products. Our rights to use technologies licensed to us by third parties are not entirely within our control, and we may not be able to continue selling the OmniPod System or sell future products without these technologies.

The patent rights on which we rely to protect the intellectual property underlying the OmniPod System may not be adequate, which could enable third parties to use our technology and would harm our continued ability to compete in the market.

Our success will depend in part on our continued ability to develop or acquire commercially-valuable patent rights and to protect

these rights adequately. Our patent position is generally uncertain and involves complex legal and factual questions. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other parties may challenge patents, patent claims or patent applications licensed or issued to us; and
- other companies may design around technologies we have patented, licensed or developed.

We also may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection. Our patent rights underlying the OmniPod System may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to ours without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Other rights and measures we have taken to protect our intellectual property may not be adequate, which would harm our ability to compete in the market.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, confidentiality, non-disclosure and assignment of invention agreements and other contractual provisions and technical measures to protect our intellectual property rights. Despite these measures, any of our intellectual property rights could, however, be challenged, invalidated, circumvented or misappropriated. While we currently require employees, consultants and other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements, or a combination thereof where appropriate, any of the following could still occur:

- the agreements may be breached;
- we may have inadequate remedies for any breach;
- trade secrets and other proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business, financial condition and results of operations.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

- assert claims of infringement;
- enforce our patents;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and

the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Claims that our current or future products infringe or misappropriate the proprietary rights of others could adversely affect our ability to sell those products and cause us to incur additional costs.

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that we could be increasingly subject to third-party infringement claims as our revenues increase, the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe. For example, we are aware of certain patents and patent applications owned by our competitors that cover different aspects of insulin infusion and the related devices. Any of these third parties might make a claim of infringement against us. In particular, Medtronic, Inc., in a letter received in March 2007, invited us to discuss our "taking a license to certain Medtronic patents." The patents referenced by this letter relate to technology that is material to our business. We have not had any substantive discussions with Medtronic concerning this matter since our receipt of this letter. In addition, in a letter received in September 2009, Becton, Dickinson and Company offered to grant us a license under a certain patent pursuant to terms to be negotiated. The patent referenced by this letter relates to technology that is potentially material to our business; however, we believe that the OmniPod System does not infringe this patent. We have not had any substantive discussions with Becton, Dickinson and Company concerning this matter since our receipt of this letter.

Any litigation, regardless of its outcome, would likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition or results of operations.

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.

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. 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;
- 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;
- 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.

If we, our contract manufacturers or our component suppliers fail to comply with the FDA's quality system regulations, the manufacturing and distribution of our devices could be interrupted, and our product sales and operating results could suffer.

We, our contract manufacturers and our component suppliers are required to comply with the FDA's quality system regulations, which is a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its quality system regulations through periodic unannounced inspections. We cannot assure you that our facilities or our contract manufacturers' or component suppliers' facilities would pass any future quality system inspection. If our or any of our contract manufacturers' or component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our devices could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our packaging and labeling operations or the manufacturing operations of our contract manufacturers, or a recall of our devices. If any of these events occurs, we may not be able to provide our customers with the quantity of OmniPods they require on a timely basis, our reputation could be harmed and we could lose customers, any or all of which may have a material adverse effect on our business, financial condition and results of operations.

Our current or future products are subject to recalls even after receiving FDA clearance or approval, which would harm our reputation, business and financial results.

The FDA and similar governmental bodies in other countries have the authority to require the recall of our current or future products if we or our contract manufacturers fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of these products. A government-mandated recall could occur if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death. A voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers. A recall involving the OmniPod System would be particularly harmful to our business, financial condition and results of operations because it is currently our only product.

We are subject to federal and state laws prohibiting "kickbacks" and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Because we may provide some coding and billing information to purchasers of the OmniPod System, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. In addition, these laws are potentially applicable to us because we provide reimbursement to healthcare professionals for training patients on the use of the OmniPod System. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient

records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our devices. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If our current or future products are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our devices or failing to adhere to the operating guidelines of the OmniPod System could cause significant harm to patients, including death. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we believe that we are reasonably insured against these risks, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

Our ability to grow our revenues depends in part on our retaining a high percentage of our customer base.

A key to driving our revenue growth is the retention of a high percentage of our customers. We have developed retention programs aimed at both the healthcare professionals and the patients, which include appeals assistance, patient training, 24/7 customer support and an automatic re-order program for patients. Since we began shipping the OmniPod System in October 2005, we have had a satisfactory customer retention rate; however, we cannot assure you that we will maintain this retention rate in the future. Current uncertainty in global economic conditions, rising unemployment and negative financial news may negatively affect product demand and other related matters. If demand for our products fluctuates as a result of economic conditions or otherwise, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our revenue growth and may have a material adverse effect on our business, financial condition and results of operations.

We have sponsored, and expect to continue to sponsor market studies seeking to demonstrate certain aspects of the efficacy of the OmniPod System, which may fail to produce favorable results.

To help improve, market and sell the OmniPod System, we have sponsored, and expect to continue to sponsor market studies to assess various aspects of its functionality and its relative efficacy. The data obtained from the studies may be unfavorable to the OmniPod System or may be inadequate to support satisfactory conclusions. In addition, in the future we may sponsor clinical trials to assess certain aspects of the efficacy of the OmniPod System. If future clinical trials fail to support the efficacy of our current or future products, our sales may be adversely affected and we may lose an opportunity to secure clinical preference from prescribing clinicians, which may have a material adverse effect on our business, financial condition and results of operations.

If future clinical studies or other articles are published, or diabetes associations or other organizations announce positions that are unfavorable to the OmniPod System, our sales efforts and revenues may be negatively affected.

Future clinical studies or other articles regarding our existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor's product is clinically more effective or easier to use than the OmniPod System or that the OmniPod System is not as effective or easy to use as we claim. Additionally, diabetes associations or other organizations that may be viewed as authoritative could endorse products or methods that compete with the OmniPod System or otherwise announce positions that are unfavorable to the OmniPod System. Any of these events may negatively affect our sales efforts and result in decreased revenues.

If we expand, or attempt to expand, into foreign markets, we will be affected by new business risks that may adversely impact our business, financial condition and results of operations.

If we expand, or attempt to expand, into foreign markets, we will be subject to new business risks, including:

- failure to fulfill foreign regulatory requirements on a timely basis or at all to market the OmniPod System or other future products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;

- adapting to the differing laws and regulations, business and clinical practices, and patient preferences in foreign countries;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign partners, distributors or sales or marketing agents;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in economies outside of the United States;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences.

If we are successful in introducing our current or future products into foreign markets, we will be affected by these additional business risks, which may adversely impact our business, financial condition and results of operations. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments and general managerial resources. Our efforts to introduce our current or future products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

Substantially all of our operations are conducted at a single location and substantially all of our inventory is held at a single location. Any disruption at either of these locations could increase our expenses.

Substantially all of our manufacturing of complete OmniPods is currently conducted at a single location on a manufacturing line owned by us at a facility located in China, operated by a subsidiary of Flextronics International, Ltd. We take precautions to ensure Flextronics safeguards our assets, including insurance and health and safety protocols. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our manufacturing equipment, and cause us to incur additional expenses. The insurance we maintain may not be adequate to cover our losses in any particular case. With or without insurance, damage to our manufacturing equipment, or to any of our suppliers, may have a material adverse effect on our business, financial condition and results of operations.

In addition, substantially all of our inventory is held at a single location in Billerica, Massachusetts. We take precautions to safeguard our facility, including insurance, health and safety protocols and off-site storage of computer data. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods and other natural disasters may not be adequate to cover our losses in any particular case. With or without insurance, damage to our facility or our other property, due to fire, flood or other natural disaster or casualty event may have a material adverse effect on our business, financial condition and results of operations.

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

We have benefited substantially from the leadership and performance of our senior management. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as clinicians and engineers, is intense and there can be no assurances that we will be able to retain our personnel. The loss of the services certain members of our senior management, clinicians or engineers could prevent or delay the implementation and completion of our objectives, or divert management's attention to seeking a qualified replacement.

Additionally, the sale and after-sale support of the OmniPod System is logistically complex, requiring us to maintain an extensive infrastructure of field sales personnel, diabetes educators, customer support, insurance specialists, and billing and collections personnel. We face considerable challenges in recruiting, training, managing, motivating and retaining these teams, including managing geographically dispersed efforts. If we fail to maintain and grow an adequate pool of trained and motivated personnel, our reputation could suffer and our financial position could be adversely affected.

If we do not effectively manage our growth, our business resources may become strained, we may not be able to deliver the OmniPod System in a timely manner and our results of operations may be adversely affected.

Since the commercial launch of the OmniPod system, we have progressively expanded our marketing efforts throughout the entire United States. As we expand our sales internationally, we will need to obtain reimbursement agreements with government agencies or private

third-party payors in those countries. Failure to obtain such agreements would limit our ability to successfully penetrate those foreign markets. In addition, the geographic expansion of our business will require additional manufacturing capacity to supply those markets as well as additional sales and marketing resources.

We expect to continue to increase our manufacturing capacity, our personnel and the scope of our U.S. and international sales and marketing efforts. This growth, as well as any other growth that we may experience in the future, will provide challenges to our organization and may strain our management and operations. In order to manage future growth, we will be required to improve existing, and implement new, management systems, sales and marketing efforts and distribution channels. We will need to manage our relationship with Flextronics going forward. We may also need to partner with additional third-party suppliers to manufacture certain components of the OmniPod System and complete additional manufacturing lines in the future. A transition to new suppliers may result in additional costs or delays. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to manufacture sufficient inventory or attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver the OmniPod System in a timely manner and our results of operations may be adversely affected.

We may experience significant fluctuations in our quarterly results of operations.

The fluctuations in our quarterly results of operations have resulted, and will continue to result, from numerous factors, including:

- delays in shipping due to capacity constraints;
- practices of health insurance companies and other third-party payors with respect to reimbursement for our current or future products;
- market acceptance of the OmniPod System;
- our ability to manufacture the OmniPod efficiently;
- timing of regulatory approvals and clearances;
- new product introductions;
- competition; and
- timing of research and development expenditures.

These factors, some of which are not within our control, may cause the price of our stock to fluctuate substantially. In particular, if our quarterly results of operations fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe the quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

If we choose to acquire or invest in new businesses, products or technologies, instead of developing them ourselves, these acquisitions or investments could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.

From time to time we may seek to acquire or invest in new businesses, products or technologies, instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

- the inability to complete the acquisition or investment;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- risks associated with acquiring intellectual property;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated synergies, cost savings or growth;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning and maintaining key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any future acquisitions or investments may result in one or more of the following:

- dilutive issuances of equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which in future periods may result in significant charges to earnings.

Any of these factors could materially harm our stock price, business, financial condition and results of operations.

We may not be able to generate sufficient cash to service all of our indebtedness, including our 5.375% Convertible Senior Notes due June 15, 2013 and amounts outstanding under our Facility Agreement due September 15, 2012. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

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

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

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

If we are unable to successfully maintain effective internal control over financial reporting, investors may lose confidence in our reported financial information and our stock price and our business may be adversely impacted.

As a public company, we are required to maintain internal control over financial reporting and our management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Additionally, we are required to disclose in our Annual Reports on Form 10-K our management's assessment of the effectiveness of our internal control over financial reporting and a registered public accounting firm's attestation report on this assessment. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the Securities and Exchange Commission. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets or cause our stock to be delisted from The NASDAQ Global Market or any other securities exchange on which it is then listed.

The price of our common stock may be volatile.

There has been a public market for our common stock only since our initial public offering in May 2007. The market price of our common stock is affected by a number of factors, including:

- failure to maintain and increase production capacity and reduce per unit production costs;
- changes in the availability of third-party reimbursement in the United States or other countries;
- volume and timing of orders for the OmniPod System;
- developments in administrative proceedings or litigation related to intellectual property rights;
- issuance of patents to us or our competitors;
- the announcement of new products or product enhancements by us or our competitors;
- the announcement of technological or medical innovations in the treatment or diagnosis of diabetes;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- developments in our industry;
- publication of clinical studies relating to the OmniPod System or a competitor's product;
- quarterly variations in our or our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

At times, the fluctuations in the market price of our common stock have often been unrelated or disproportionate to our operating performance. These forces reached unprecedented levels in the second half of 2008, resulting in the bankruptcy or acquisition of, or government assistance to, several major domestic and international financial institutions and a material decline in economic conditions. In particular, the U.S. equity markets experienced significant price and volume fluctuations that have affected the market prices of equity securities of many technology companies. During the nine months ended September 30, 2009, our stock price has experienced volatility, with the closing price of our common stock on the NASDAQ Global Market having ranged from $2.67 on March 11, 2009 to $11.25 on September 11, 2009. These broad market and industry factors could materially and adversely affect the market price of our stock, regardless of our actual operating performance.

Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price.

We have been a public company only since May 2007. For the three month period ended September 30, 2009, the average daily trading volume of our common stock on The NASDAQ Global Market has been fewer than 300,000 shares. If our existing stockholders or their distributees sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock could also depress the trading price of our common stock. In addition, certain stockholders, including the holders of the warrants to purchase 3.75 million shares of our common stock issued in connection with the March 13, 2009 facility agreement, have rights, subject to some conditions, to require us to file registration statements covering their share or to include their shares in registration statements that we may file for ourselves or other stockholders.

A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

Anti-takeover provisions in our organizational documents, our shareholder rights plan and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;
- provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

In addition, in November 2008, our board of directors adopted a shareholder rights plan, implementing what is commonly known as a "poison pill." This poison pill significantly increases the costs that would be incurred by an unwanted third party acquirer if such party owns or announces its intent to commence a tender offer for more than 15% of our outstanding common stock or otherwise "triggers" the poison pill by exceeding the applicable stock ownership threshold. The existence of this poison pill could delay, deter or prevent a takeover of us.

Our ability to use net operating loss carryforwards may be subject to limitation.

Section 382 of the U.S. Internal Revenue Code of 1986, as amended, imposes an annual limit on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership or equity structure. Our ability to use net operating losses is limited by prior changes in our ownership, and may be further limited by any future issuances of common stock or by the consummation of other transactions. As a result, if we earn net taxable income, our ability to use net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liabilities for us.

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

None.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description of Document
4.1	Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Computershare Trust Company, N.A., as Rights Agent (incorporated herein by reference to the Registration Statement on Form 8-A filed on November 20, 2008).
4.2	Amendment, dated September 25, 2009, to Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Computershare Trust Company, N.A., as Rights Agent (incorporated herein by reference to the Registration Statement on Form 8-A/A filed on September 28, 2009).
10.1	Securities Purchase Agreement dated September 25, 2009 by and between Insulet Corporation and certain investors named therein (incorporated herein by reference to the Current Report on Form 8-K filed on September 28, 2009).
10.2	Amendment to Facility Agreement, dated September 25, 2009, by and between Insulet Corporation and the lenders named therein (incorporated herein by reference to the Current Report on Form 8-K filed on September 28, 2009).
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.

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: October 26, 2009

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

Date: October 26, 2009

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

EXHIBIT INDEX

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4.2	Amendment, dated September 25, 2009, to Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Computershare Trust Company, N.A., as Rights Agent (incorporated herein by reference to the Registration Statement on Form 8-A/A filed on September 28, 2009).
10.1	Securities Purchase Agreement dated September 25, 2009 by and between Insulet Corporation and certain investors named therein (incorporated herein by reference to the Current Report on Form 8-K filed on September 28, 2009).
10.2	Amendment to Facility Agreement, dated September 25, 2009, by and between Insulet Corporation and the lenders named therein (incorporated herein by reference to the Current Report on Form 8-K filed on September 28, 2009).
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.

Exhibit 31.1

CERTIFICATION

I, Duane DeSisto, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Insulet Corporation;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Duane DeSisto
Duane DeSisto
President and Chief Executive Officer

October 26, 2009

Exhibit 31.2

CERTIFICATION

I, Brian Roberts, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Insulet Corporation;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual filing) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Brian Roberts
Brian Roberts
Chief Financial Officer

October 26, 2009

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Insulet Corporation, a Delaware corporation (the "Company"), does hereby certify with respect to the Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2009, as filed with the Securities and Exchange Commission (the "Report") that, to his knowledge:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Duane DeSisto
Name: Duane DeSisto
Title: President and Chief Executive Officer
Date: October 26, 2009

/s/ Brian Roberts
Name: Brian Roberts
Title: Chief Financial Officer
Date: October 26, 2009