INSULET CORP
Form 10-Q
November 09, 2010

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

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

For the quarterly period ended September 30, 2010

OR

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

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

Delaware	**04-3523891**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
9 Oak Park Drive **Bedford, Massachusetts**	**01730**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s Telephone Number, Including Area Code: **(781) 457-5000**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant 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 o No o

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

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company o
		(Do not check if a smaller reporting company)	

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

As of November 4, 2010, the registrant had 41,844,763 shares of common stock outstanding.

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PART I FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

INSULET CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEET
(Unaudited)

	As of September 30, 2010	As of December 31, 2009 (Restated)
	(In thousands, except share data)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 103,918	$ 127,996
Accounts receivable, net	15,442	14,962
Inventories	12,909	10,086
Prepaid expenses and other current assets	1,059	1,260
Total current assets	133,328	154,304
Property and equipment, net	14,147	15,482
Other assets	2,379	3,072
Total assets	$ 149,854	$ 172,858
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 5,154	$ 5,870
Accrued expenses	11,462	9,973
Deferred revenue	3,826	3,970
Total current liabilities	20,442	19,813
Long-term debt, net of current portion	94,179	89,136
Other long-term liabilities	1,728	1,999
Total liabilities	116,349	110,948
Stockholders Equity		
Preferred stock, $.001 par value: Authorized: 5,000,000 shares at September 30, 2010 and December 31, 2009. Issued and outstanding: zero shares at September 30, 2010 and December 31, 2009, respectively		
Common stock, $.001 par value: Authorized: 100,000,000 shares at September 30, 2010 and December 31, 2009. Issued and outstanding: 40,171,434 and 37,755,254 shares at September 30, 2010 and December 31, 2009, respectively	41	39
Additional paid-in capital	396,459	384,565

Accumulated deficit	(362,995)	(322,694)
Total stockholders equity	33,505	61,910
Total liabilities and stockholders equity	$ 149,854	$ 172,858

December 31, 2009 balances have been restated to reflect the correction of the accounting treatment for the modification of the Facility Agreement as described in Note 13.

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

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INSULET CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009 (Restated)	2010	2009 (Restated)
	(In thousands, except share and per share data)			
Revenue	$ 25,455	$ 18,735	$ 69,199	$ 45,821
Cost of revenue	13,826	12,936	39,299	34,858
Gross profit	11,629	5,799	29,900	10,963
Operating expenses:				
Research and development	3,698	3,404	12,128	9,880
General and administrative	7,230	6,246	20,379	19,575
Sales and marketing	8,979	9,629	26,301	28,905
Total operating expenses	19,907	19,279	58,808	58,360
Operating loss	(8,278)	(13,480)	(28,908)	(47,397)
Interest income	49	22	109	204
Interest expense	(3,871)	(3,464)	(11,502)	(9,613)
Net interest expense	(3,822)	(3,442)	(11,393)	(9,409)
Net loss	$ (12,100)	$ (16,922)	$ (40,301)	$ (56,806)
Net loss per share basic and diluted	$ (0.30)	$ (0.60)	$ (1.04)	$ (2.04)
Weighted average number of shares used in calculating basic and diluted net loss per share	40,155,277	28,008,699	38,784,692	27,894,775

Results for the three and nine months ended September 30, 2009 have been restated to reflect the correction of the accounting treatment for the modification of the Facility Agreement as described in Note 13.

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

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INSULET CORPORATION
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2010	2009 (Restated)
	(In thousands)	
Cash flows from operating activities		
Net loss	$ (40,301)	$ (56,806)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	3,946	4,001
Amortization of debt discount	5,511	3,983
Stock compensation expense	3,957	3,185
Provision for bad debts	2,519	2,820
Non cash impairment charges	1,021	
Non cash interest expense	654	466
Changes in operating assets and liabilities:		
Accounts receivable	(2,999)	(7,239)
Inventory	(2,823)	7,695
Prepaids and other current assets	201	1,463
Other assets	34	
Accounts payable and accrued expenses	773	214
Other long term liabilities	(271)	(281)
Deferred revenue, short term	(144)	1,034
Net cash used in operating activities	(27,922)	(39,465)
Cash flows from investing activities		
Purchases of property and equipment	(3,632)	(1,968)
Net cash used in investing activities	(3,632)	(1,968)
Cash flows from financing activities		
Net proceeds from facility agreement	(468)	57,015
Repayment of long term loan		(27,500)
Proceeds from issuance of common stock, net of offering expenses	7,944	27,949
Net cash provided by financing activities	7,476	57,464
Net increase (decrease) in cash and cash equivalents	(24,078)	16,031
Cash and cash equivalents, beginning of period	127,996	56,663
Cash and cash equivalents, end of period	$ 103,918	$ 72,694
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 4,358	$ 4,077

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, 2009 have been restated to reflect the correction of the accounting treatment for the modification of the Facility Agreement as described in Note 13.

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

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INSULET CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Nature of the Business

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

In January 2010, the Company entered into a 5 year distribution agreement with Ypsomed Distribution AG, or Ypsomed, to become the exclusive distributor of the OmniPod System in eleven countries. The Company commenced sales of the OmniPod System to Ypsomed for distribution in Germany and the United Kingdom beginning in the second quarter of 2010 and for distribution in Sweden, Norway and the Netherlands in the third quarter of 2010. The Company expects that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in the fourth quarter of 2010 and in 2011.

2. Summary of Significant Accounting Policies

Restatement of Previously Issued Financial Statements

As discussed below and further described in Note 13, the Company restated its financial results in certain prior periods to reflect the correction of the accounting treatment for the modification of the Facility Agreement.

In September 2009, the Company entered into an amendment to its existing Facility Agreement which was determined at the time to be an early extinguishment of the debt borrowed thereunder. As a result, the Company expensed $7.6 million of non-cash interest related to the write-off of remaining debt discount and fees such as deferred financing costs on the original loan. Upon subsequent review, the Company determined on July 29, 2010 that the amendment should have been treated as a modification of the original loan as compared to an early extinguishment as reflected in its previously issued financial statements. A debt modification recognizes the remaining debt discount and fees relating to the original borrowings, as well as additional discount on the new borrowing over the term of the new borrowing as a non-cash adjustment to interest expense rather than as a non-cash loss on debt extinguishment at the time the original borrowing is amended. Accordingly, the Company has concluded that a correction was required to recognize the amendment as a modification and recognize as non-cash interest expense the debt discount and fees related to the original borrowings from the date of the amendment in September 2009 through the maturity of the Facility Agreement in September 2012.

The restatement resulted in an increase in other assets of $1.2 million at December 31, 2009, related to the capitalization of issuance costs incurred net of interest expense recognized over the term of the loan and a decrease of long-term debt of $7.8 million related to the debt discount on the warrants and shares issued in connection with the Facility Agreement, net of interest expense recognized. The restatement resulted in an increase in interest expense of $0.6 million in the three months ended March 31, 2010, with an equivalent increase in net interest expense and net loss. In addition, the restatement resulted in a reduction in interest expense of $7.8 million in the three and nine months ended September 30, 2009, with an equivalent reduction in net interest expense and net loss. The restatement had no effect on any amounts reported in periods prior to the quarter ended September 30, 2009.

Basis of Presentation

The unaudited consolidated financial statements in this Quarterly Report on Form 10-Q have been prepared in accordance with GAAP for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these unaudited consolidated financial statements do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2010, are not necessarily indicative of the results

that may be expected for the full year ending December 31, 2010, or for any other subsequent interim period.

The unaudited consolidated financial statements in this Quarterly Report on Form 10-Q should be read in conjunction with the Company s consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2009.

Use of Estimates in Preparation of Financial Statements

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expense during the reporting periods. The most significant estimates used in these financial statements include the valuation of inventories, accounts receivable and equity instruments, the lives of property and equipment, as well as warranty

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reserves and allowance for doubtful accounts calculations. Actual results may differ from those estimates.

Principles of Consolidation

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

Accounts Receivable and Allowance for Doubtful Accounts

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

Inventories

Inventories are stated at the lower of cost or market, determined under the first-in, first-out (FIFO) method. Inventory has been recorded at cost as of September 30, 2010 and December 31, 2009. Work in process is calculated based upon a build up in the stage of completion using estimated labor inputs for each stage in production. Costs for PDMs and OmniPods include raw material, labor and manufacturing overhead. The Company periodically reviews inventories for potential impairment based on quantities on hand and expectations of future use.

Property and Equipment

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

Warranty

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

Restructuring Expenses and Impairment of Assets

In connection with its efforts to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing of assets, the Company periodically performs an evaluation of its manufacturing processes and reviews the carrying value of its property and equipment to assess the recoverability of these assets whenever events indicate that impairment may have occurred. As part of this assessment, the Company reviews the future undiscounted operating cash flows expected to be generated by those assets. If impairment is indicated through this review, the carrying amount of the asset would be reduced to its estimated fair value. This review of manufacturing processes and equipment can result in restructuring activity or an impairment of assets based on current net book value and potential future use of the assets.

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

Asset Valuation

Asset valuation includes assessing the recorded value of certain assets, including accounts receivable, inventory and fixed assets. The Company uses a variety of factors to assess valuation, depending upon the asset. Actual values may differ materially from the Company s estimates. 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. The Company reviews 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. The Company also reviews 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.

Revenue Recognition

The Company generates nearly all of its revenue from sales of its OmniPod Insulin Management System to diabetes patients and third-

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party distributors who resell the product to diabetes patients. The initial sale to a new customer or third party distributor typically includes OmniPods and a Starter Kit, which includes the PDM, the OmniPod System User Guide and the OmniPod System Interactive Training CD. Subsequent sales to existing customers typically consist of additional OmniPods.

Revenue recognition requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval for sales directly to patients or a purchase order for sales to a third-party distributor.

Transfer of title and risk and rewards of ownership are passed to the customer typically upon transfer to the third party carrier.

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

The Company assesses whether different elements qualify for separate accounting. The Company recognizes revenue for the initial shipment to a patient or other third party once all elements have been delivered.

The Company offers a 45-day right of return for its Starter Kits sales, and defers revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of the Company s historical return data to their related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. When doubt exists about reasonable assuredness of collectibility from specific customers, the Company defers revenue from sales of products to those customers until payment is received.

In March 2008, the Company received a cash payment from Abbott Diabetes Care, Inc. (Abbott) for an agreement fee in connection with execution of the first amendment to the development and license agreement between the Company and Abbott. The Company recognizes revenue on the agreement fee from Abbott over the initial 5-year term of the agreement, and the non-current portion of the agreement fee is included in other long-term liabilities. Under the amended Abbott agreement, beginning July 1, 2008, Abbott agreed to pay certain amounts to the Company for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to certain customers in the United States and Israel. In July 2010, the Company entered into a second amendment to the development and license agreement with Abbott. Under the terms of the second amendment, Abbott agreed to pay certain amounts to the Company for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to customers in certain additional territories. The Company recognizes revenue related to this portion of the Abbott agreement at the time it meets the criteria for revenue recognition, typically at the time of sale of the PDM to the patient. In the three and nine month periods ended September 30, 2010, the Company recognized revenue related to the amended Abbott agreement of $1.5 million and $3.9 million, respectively. In the three and nine month periods ended September 30, 2009, the Company recognized revenue related to the amended Abbott agreement of $2.3 million and $4.5 million, respectively. No revenue was recognized related to the second amendment to the development and license agreement in the three and nine months ended September 30, 2010. There was no impact to cost of revenue related to this agreement.

The Company had deferred revenue of $4.5 million and $5.1 million as of September 30, 2010 and December 31, 2009, respectively. The deferred revenue recorded as of September 30, 2010 was comprised of product-related revenue as well as the non-amortized agreement fee related to the Abbott agreement.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents and accounts receivable. The Company maintains the majority of its cash with two accredited financial institutions. Although revenue is recognized from shipments directly to patients or third-party distributors, the majority of

shipments are billed to third-party insurance payors. There were no third-party payors that accounted for more than 10% of gross accounts receivable as of September 30, 2010 or December 31, 2009.

Segment Reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. In light of the Company s current product offering, and other considerations, management has determined that the primary form of internal reporting is aligned with the offering of the OmniPod System. Therefore, the Company believes that it operates in one segment. For the three and nine month periods ended September 30, 2010, minimal revenue was generated from sales outside of the United States.

Income Taxes

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

The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense. As of September 30, 2010,

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interest and penalties are immaterial to the financial statements.

3. Facility Agreement and Common Stock Warrants

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

In connection with the execution of the Facility Agreement, the Company issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock of the Company at an exercise price of $3.13 per share. Pursuant to the original terms of the Facility Agreement, the Company would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. The warrants qualified for permanent treatment as equity, and their relative fair value of $6.1 million on the issuance date was recorded as additional paid-in capital and debt discount. The debt discount is being amortized as non-cash interest expense over the term of the loan.

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.

In September 2009, the Company entered into an Amendment to the Facility Agreement whereby the Company repaid the $27.5 million of outstanding debt and promptly drew down the remaining $32.5 million available under the Facility Agreement. The lenders eliminated all future performance milestones associated with the remaining $32.5 million available on the credit facility and reduced the annual interest rate to 8.5%. In connection with the Amendment to the Facility Agreement, the Company entered into a Securities Purchase Agreement with the lenders whereby the Company sold 2,855,659 shares of its common stock to the lenders at $9.63 per share, a $1.9 million discount based on the closing price of the Company s common stock of $10.28 on that date. The Company recorded the $1.9 million as a debt discount which is being amortized as interest expense over the remaining term of the loan. The Company received aggregate proceeds of $27.5 million in connection with the sale of its shares.

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 repay 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 certain prepayment penalties in the event that the Company repays the debt prior to its maturity.

In June 2010, the Company entered into a Second Amendment to its Facility Agreement whereby the Company paid a $0.5 million amendment fee in exchange for the reduction of the prepayment penalties and the modification of certain other terms of the Agreement. The fee was recorded as additional debt discount and is being amortized as interest expense over the remaining term of the loan.

All references herein to the Facility Agreement refer to the Facility Agreement entered into in March 2009 and amended in September 2009 and June 2010.

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 prepayment penalty could be paid by the Company in the event that it repays the debt prior to maturity, the prepayment penalty is also considered a derivative. The prepayment penalty does not meet the criteria to be accounted for separately. Any changes in fair value of the premium feature will be recorded as interest expense. The difference between the face value of the outstanding

principal on the Facility Agreement and the amount remaining after the bifurcation will be recorded as a discount to be amortized over the term of the Facility Agreement. As of September 30, 2010, the premium feature associated with the Facility Agreement had no value as the Company does not currently expect a change in control transaction to occur. The embedded derivatives related to the Facility Agreement will be reassessed and marked-to-market through earnings on a quarterly basis.

As of September 30, 2010 and December 31, 2009, outstanding debt related to the Facility Agreement of $26.0 million and $24.7 million, respectively, is included in long-term debt in the consolidated balance sheet.

In the three and nine months ended September 30, 2010, the Company recorded cash interest related to the Facility Agreement of approximately $0.7 million and $2.1 million, respectively. In addition, in the three and nine months ended September 30, 2010, the Company recorded non-cash interest of approximately $0.7 million and $2.1 million, respectively. Non-cash interest in the three and nine months ended September 30, 2010 consists of amortization of the debt discount from the issuance of warrants and transaction fee in March 2009, amortization of the discount on the shares sold in connection with the amendment in September 2009, amortization of the transaction fee in connection with the amendment in June 2010 and amortization of the issuance costs associated with the debt.

In the three and nine months ended September 30, 2009, the Company recorded cash interest related to the Facility Agreement of

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approximately $0.9 million and $1.8 million, respectively. In addition, in the three and nine months ended September 30, 2009, the Company recorded non-cash interest of approximately $0.3 million and $0.9 million, respectively. Non-cash interest in the three and nine months ended September 30, 2009 consists of amortization of the debt discount from the issuance of warrants and transaction fee in March 2009 and amortization of the issuance costs associated with the debt.

In March 2009, in connection with the execution of the Facility Agreement, the Company issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock of the Company at an exercise price of $3.13 per share. Pursuant to the original terms of the Facility Agreement, the Company would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. In connection with the Amendment to the Facility Agreement in September 2009, the lenders agreed to forego the remaining 1.5 million additional warrants that would have been issued upon these future draws. The warrants issued in connection with the Facility Agreement qualify for permanent classification as equity and their relative fair value of $6.1 million on the issuance date was recorded as additional paid in capital and debt discount. The debt discount is being amortized as non-cash interest expense over the term of the loan. In June 2010, the lenders exercised warrants to acquire 2,125,000 shares of the Company s common stock at an exercise price of $3.13 in cash. The Company received cash totaling $6.7 million as a result of this exercise.

As of September 30, 2010, warrants to acquire 1,625,000 shares of the Company s common stock issued under the Facility Agreement remain unexercised, expire on March 13, 2015 and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it to exceed 9.98% of the total number of shares of the Company s common stock then issued and outstanding.

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

4. Convertible Notes

In June 2008, the Company sold $85.0 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the 5.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 5.375% Notes are convertible into the Company s common stock at an initial conversion rate of 46.8467 shares of common stock per $1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately $21.35 per share, representing a conversion premium of 34% to the last reported sale price of the Company s common stock on the NASDAQ Global Market on June 10, 2008, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of the Company s common stock for the remainder of the conversion value in excess of the principal amount. The Company does not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require the Company to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest, to, but excluding, the date of repurchase. If a holder elects to convert its 5.375% Notes upon the occurrence of a make-whole fundamental change, as defined in the Indenture for the 5.375% Notes, the holder may be entitled to receive an additional number of shares of common stock on the conversion date. These additional shares are intended to compensate the holders for the loss of the time value of the conversion option and are set forth in the Indenture to the 5.375% Notes. In no event will the number of shares issuable upon conversion of a note exceed 62.7746 per $1,000 principal amount (subject to adjustment as described in the Indenture for the 5.375% Notes).

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

The Company incurred deferred financing costs related to this offering of approximately $3.5 million, of which $1.1 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the 5.375% Notes. The Company incurred interest expense related to the 5.375% Notes of approximately $2.5 million and $7.5 million for the three and nine months ended September 30, 2010, respectively. Of the $2.5 million recorded in the three months ended September 30, 2010, approximately $1.4 million relates to amortization of the debt discount and deferred financing costs and $1.1 million relates to cash interest. Of the $7.5 million recorded in the nine months ended September 30, 2010, approximately $4.1 million relates to amortization of the debt discount and deferred financing costs and $3.4 million relates to cash interest. For the three and nine months ended September 30, 2009, the Company incurred interest expense related to the 5.375% Notes of approximately $2.3 million and $7.1 million, respectively. Of the $2.3 million recorded in the three months ended September 30, 2009, approximately $1.2 million relates to amortization of the debt discount and deferred financing costs and $1.1 million relates to cash interest. Of the $7.1 million recorded in the nine months ended September 30, 2009, approximately $3.7 million relates to amortization of the debt discount and deferred financing costs and $3.4 million relates to cash interest.

As of September 30, 2010, the outstanding amounts related to the 5.375% Notes of $68.2 million are included in long-term debt in the

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consolidated balance sheet and reflect the debt discount of $16.8 million. As of December 31, 2009, the outstanding amounts related to the 5.375% Notes of $64.5 million are included in long-term debt and reflect the debt discount of $20.5 million. The debt discount includes the equity allocation of $25.8 million (which represents $26.9 million less the $1.1 million of allocated financing costs) offset by the accretion of the debt discount through interest expense from the issuance date over the 5 year term of the notes. The Company recorded $1.2 million and $3.7 million of interest expense related to the debt discount in the three and nine months ended September 30, 2010, respectively. 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. As of September 30, 2010, the 5.375% Notes have a remaining term of 2.75 years.

The Company received net proceeds of approximately $81.5 million from this offering. Approximately $23.2 million of the proceeds from this offering was used to repay and terminate the Company s then-existing term loan, including outstanding principal and accrued and unpaid interest of $21.8 million, a prepayment fee related to the term loan of approximately $0.4 million and a termination fee of $0.9 million. In connection with this term loan, the Company issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock at a purchase price of $3.64 per share. The warrants automatically converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share at the closing of the Company s initial public offering in May 2007. As of September 30, 2010, warrants to purchase 62,752 shares of common stock remain outstanding and exercisable at a price of $9.56 per share.

5. Restructuring Expenses and Impairments of Assets

As of September 30, 2009, the Company s accrued expenses for restructuring was $0.1 million for final payments of severance. These amounts were paid in full in 2009. The Company had no accrued expenses for restructuring at September 30, 2010 or December 31, 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 June 2010, the Company performed an evaluation of its Construction in Process related to its manufacturing equipment for its next generation OmniPod. As a result of this evaluation as well as the additional information obtained in connection with the completion of the Company s pilot manufacturing line for its next generation OmniPod, the Company determined that approximately $1.0 million of previously capitalized costs relating to the project no longer meet the capitalization criteria. Accordingly, the Company expensed these costs as research and development expense in the nine months ended September 30, 2010.

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, 2010 and 2009, all potential common shares have been excluded from the computation of the diluted net loss per share for all periods presented, as the effect would have been anti-dilutive. Such potentially dilutive common share equivalents consist of the following:

	Three and Nine Months Ended September 30,	
	2010	**2009**
Convertible notes	3,981,969	3,981,969
Unvested restricted common shares	374,887	2,664
Outstanding options	3,370,576	3,627,277
Outstanding warrants	1,687,752	3,812,752
Total	9,415,184	11,424,662

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7. Accounts Receivable

The components of accounts receivable are as follows:

	As of	
	September 30, 2010	December 31, 2009
	(In thousands)	
Trade receivables	$ 21,504	$ 22,152
Allowance for doubtful accounts	(6,062)	(7,190)
	$ 15,442	$ 14,962

8. Inventories

Inventories consist of the following:

	As of	
	September 30, 2010	December 31, 2009
	(In thousands)	
Raw materials	$ 2,023	$ 1,657
Work-in-process	3,398	496
Finished goods	7,488	7,933
	$ 12,909	$ 10,086

The Company is currently producing the OmniPod on a partially automated manufacturing line at a facility in China, operated by a subsidiary of Flextronics International Ltd. The Company also produces certain sub-assemblies for the OmniPod and maintains packaging operations in its facility in Bedford, Massachusetts. The Company purchases complete OmniPods from Flextronics.

9. Product Warranty Costs

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(In thousands)		(In thousands)	
Balance at the beginning of period	$ 1,940	$ 2,609	$ 1,820	$ 2,268
Warranty expense	347	638	1,316	2,574
Warranty claims settled	(502)	(736)	(1,351)	(2,331)
Balance at the end of the period	$ 1,785	$ 2,511	$ 1,785	$ 2,511
Composition of balance:				
Short-term	$ 803	$ 1,032	$ 803	$ 1,032

Long-term	982	1,479	982	1,479
Total warranty balance	$ 1,785	$ 2,511	$ 1,785	$ 2,511

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 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. In June 2010, the Company extended its lease for additional office space in Bedford, Massachusetts. The lease cannot be cancelled prior to its expiration, in September 2014 and provides for a renewal option of five years and escalating payments escalate over the life of the lease. The Company also leases warehouse facilities in Billerica, Massachusetts. This lease expires in December 2012.

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The 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 consolidated balance sheet.

Indemnifications

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

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

11. Equity

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

In June 2010, the lenders in the Company s Facility Agreement exercised warrants to purchase 2,125,000 shares of the Company s common stock in exchange for $6.7 million. The Company had originally granted warrants to purchase 3,750,000 shares of its common stock at $3.13 per share in connection with the Facility Agreement.

Restricted Stock Units

In the nine months ended September 30, 2010, the Company awarded 399,999 restricted stock units to certain employees. The restricted stock units were granted under the Company s 2007 Stock Option and Incentive Plan (the 2007 Plan) and vest annually over three years from the grant date. The restricted stock units granted have a weighted average fair value of $14.99 based on the closing price of the Company s common stock on the date of grant. The restricted stock units were valued at approximately $6.0 million at their grant dates, and the Company is recognizing the compensation expense over the three year vesting period. Approximately $0.7 million and $1.1 million of stock-based compensation expense related to the vesting of restricted stock units was recognized in the three and nine months ended September 30, 2010, respectively, and approximately $4.9 million of the fair value of the restricted stock units remained unrecognized as of September 30, 2010. Under the terms of the award, the Company will issue shares of common stock on each of the vesting dates. None of the restricted stock units awarded to employees vested during the three and nine months ended September 30, 2010.

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

	Number of Shares	Weighted Average Fair Value
Balance, December 31, 2009		$
Granted	399,999	14.99
Vested		
Forfeited	(26,000)	15.11
Balance, September 30, 2010	373,999	$ 14.98

Restricted Common Stock

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

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

	Number of Shares	Weighted Average Fair Value
Balance, December 31, 2009	2,220	$ 8.04
Granted		
Vested	(1,332)	8.04
Forfeited		
Balance, September 30, 2010	888	$ 8.04

Stock Options

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

	Number of Options(#)	Weighted Average Exercise Price($)	Aggregate Intrinsic Value($)
Balance, December 31, 2009	3,542,590	$ 8.36	
Granted	326,500	14.81	
Exercised	(283,562)	4.28	$ 3,002,690(1)
Canceled	(214,952)	13.09	
Balance, September 30, 2010	3,370,576	$ 9.03	$ 19,375,295
Vested, September 30, 2010	2,052,333	$ 8.30	$ 13,351,358(2)
Vested and expected to vest, September 30, 2010 (3)	2,875,300		$ 17,055,324

(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, 2010, and the exercise price of the underlying options.

(3) Represents the number of vested options as of September 30, 2010, plus the number of unvested options expected to vest as of September 30, 2010, based on the unvested options outstanding as of September 30, 2010, adjusted for the estimated forfeiture rate of 16%.

At the time of grant, options granted under the Company s 2000 Stock Option and Incentive Plan (the 2000 Plan) are typically immediately exercisable, but subject to restrictions. Therefore, under the 2000 Plan, the number of options exercisable is greater than the number of options vested until all options are fully vested.

As of September 30, 2010 and 2009, no shares were contingently issued under the employee stock purchase plan (ESPP). In the three and nine months ended September 30, 2010 and 2009, the Company recorded no significant stock-based compensation charges related to the ESPP.

Employee stock-based compensation expense recognized in the three and nine months ended September 30, 2010 was $1.3 million and $4.0 million, respectively. Employee stock-based compensation expense recognized in the three and nine months ended September 30, 2009 was $1.0 million and $3.2 million, respectively. The employee stock-based compensation expense relates to all stock awards granted.

12. Income Taxes

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

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13. Restatement of Previously Issued Financial Statements

Subsequent to the issuance of the Company s Quarterly Report on Form 10-Q for the three months ended March 31, 2010, the Company and its audit committee concluded that it should restate its consolidated balance sheet at December 31, 2009, and its consolidated statements of operations for the three months ended March 31, 2010 and the three and nine months ended September 30, 2009 and its consolidated statements of cash flows for the three months ended March 31, 2010 and the nine months ended September 30, 2009 to correct the following error:

In September 2009, the Company entered into an amendment to its existing Facility Agreement which was determined at the time to be an early extinguishment of the debt borrowed thereunder. As a result, the Company expensed $7.6 million of non-cash interest related to the write-off of remaining debt discount and fees such as deferred financing costs on the original loan. Upon subsequent review the Company determined on July 29, 2010 that the amendment should have been treated as a modification of the original loan as compared to an early extinguishment as reflected in its previously issued financial statements. A debt modification recognizes the remaining debt discount and fees relating to the original borrowings, as well as additional discount on the new borrowing over the term of the new borrowing, as a non-cash adjustment to interest expense rather than as a non-cash loss on debt extinguishment at the time the original borrowing is amended. Accordingly, the Company has concluded that a correction was required to recognize the amendment as a modification and recognize as non-cash interest expense the debt discount and fees related to the original borrowings from the date of the amendment in September 2009 through the maturity of the Facility Agreement in September 2012.

The following tables summarize the effect of the restatement by major financial statement line item for the relevant periods (in thousands). The restatement resulted in an increase in other assets of $1.2 million at December 31, 2009 related to the capitalization of issuance costs incurred net of interest expense recognized over the term of the loan and an decrease of long-term debt of $7.8 million related to the debt discount on the warrants and shares issued in connection with the Facility Agreement, net of interest expense recognized. The restatement resulted in an increase in interest expense of $0.6 million in the three months ended March 31, 2010 with an equivalent increase in net interest expense and net loss. In addition, the restatement resulted in a reduction in interest expense of $7.8 million in the three and nine months ended September 30, 2009, with an equivalent reduction in net interest expense and net loss. The restatement had no effect on any additional amounts reported in periods prior to the quarter ended September 30, 2009.

Consolidated Balance Sheet

	December 31, 2009	
	As Previously Reported	As Restated
Other assets	$ 1,862	$ 3,072
Total assets	171,648	172,858
Long-term debt, net of current portion	96,979	89,136
Total liabilities	118,791	110,948
Additional paid-in capital	382,709	384,565
Accumulated deficit	(329,891)	(322,694)
Total stockholders equity	52,857	61,910
Total liabilities and stockholders equity	171,648	172,858

Consolidated Statement of Operations

	Three Months Ended March 31, 2010	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
	As Previously Reported	As Previously Reported	As Previously Reported

		As Restated			As Restated		As Restated
Interest expense	$ (3,149)	$ (3,785)	$ (11,267)	$ (3,464)	(17,416)	(9,613)
Net interest expense	(3,125)	(3,761)	(11,245)	(3,442)	(17,212)	(9,409)
Net loss	(13,855)	(14,491)	(24,725)	(16,922)	(64,609)	(56,806)
Net loss per share basic and diluted	(0.37)	(0.38)	(0.88)	(0.60)	(2.32)	(2.04)

Consolidated Statement of Cash Flows

	Three Months Ended March 31, 2010		Nine Months Ended September 30, 2009	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Net loss	$ (13,855)	$ (14,491)	$ (64,609)	$ (56,806)
Amortization of debt discount	1,238	1,789	10,495	3,983
Non cash interest expense	132	217	1,757	466

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

You should read the following discussion of our financial condition and results of operations in conjunction with our consolidated financial statements and the accompanying notes to those financial statements included in this Quarterly Report on Form 10-Q. This Quarterly Report on Form 10-Q contains forward-looking statements. These forward-looking statements are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: our historical operating losses; our dependence on the OmniPod System; our ability to achieve and maintain market acceptance of the OmniPod System; our ability to increase customer orders and manufacturing volume; adverse changes in general economic conditions; our ability to raise additional funds in the future; our ability to anticipate and effectively manage risks associated with doing business internationally, particularly in China; our dependence on third-party suppliers; our ability to obtain favorable reimbursement from third-party payors for the OmniPod System and potential adverse changes in reimbursement rates or policies relating to the OmniPod; potential adverse effects resulting from competition; technological innovations adversely affecting our business; potential termination of our license to incorporate a blood glucose meter into the OmniPod System; our ability to protect our intellectual property and other proprietary rights; conflicts with the intellectual property of third parties; adverse regulatory or legal actions relating to the OmniPod System; the potential violation of federal or state laws prohibiting kickbacks and false and fraudulent claims or adverse affects of challenges to or investigations into our practices under these laws; product liability lawsuits that may be brought against us; unfavorable results of clinical studies relating to the OmniPod System or the products of our competitors; our ability to attract and retain key personnel; our ability to manage our growth; our ability to maintain compliance with the restrictions and related to our indebtedness; our ability to successfully maintain effective internal controls; the volatility of the price of our common stock; and other risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2009, which was filed with the Securities and Exchange Commission on March 9, 2010 as updated by Part II, Item 1A., Risk Factors of this Quarterly Report on Form 10-Q. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements.

Restatement of Previously Issued Financial Statements

Financial data when presented throughout the MD&A includes the effect of the restatement of certain prior period amounts, as described in Note 13 to our consolidated financial statements. The restatement resulted in an increase in other assets of $1.2 million at December 31, 2009 related to the capitalization of issuance costs incurred net of interest expense recognized over the term of the loan and a decrease of long-term debt of $7.8 million related to the debt discount on the warrants and shares issued in connection with the Facility Agreement, net of interest expense recognized. The restatement resulted in an increase in interest expense of $0.6 million in the three months ended March 31, 2010 with an equivalent increase in net interest expense and net loss. In addition, the restatement resulted in a reduction in interest expense of $7.8 million in the three and nine months ended September 30, 2009, with an equivalent reduction in net interest expense and net loss. The restatement had no effect on any amounts reported in periods prior to the quarter ended September 30, 2009.

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Consolidated Balance Sheet

	December 31, 2009	
	As Previously Reported	As Restated
Other assets	$ 1,862	$ 3,072
Total assets	171,648	172,858
Long-term debt, net of current portion	96,979	89,136
Total liabilities	118,791	110,948
Additional paid-in capital	382,709	384,565
Accumulated deficit	(329,891)	(322,694)
Total stockholders equity	52,857	61,910
Total liabilities and stockholders equity	171,648	172,858

Consolidated Statement of Operations

	Three Months Ended March 31, 2010		Three Months Ended September 30, 2009		Nine Months Ended September 30, 2009	
	As Previously Reported	As Restated	As Previously Reported	As Restated	As Previously Reported	As Restated
Interest expense	$ (3,149)	$ (3,785)	$ (11,267)	$ (3,464)	(17,416)	(9,613)
Net interest expense	(3,125)	(3,761)	(11,245)	(3,442)	(17,212)	(9,409)
Net loss	(13,855)	(14,491)	(24,725)	(16,922)	(64,609)	(56,806)
Net loss per share basic and diluted	(0.37)	(0.38)	(0.88)	(0.60)	(2.32)	(2.04)

Consolidated Statement of Cash Flows

	Three Months Ended March 31, 2010		Nine Months Ended September 30, 2009	
	As Previously Reported	As Restated	As Previously Reported	As Restated
Net loss	$ (13,855)	$ (14,491)	$ (64,609)	$ (56,806)
Amortization of debt discount	1,238	1,789	10,495	3,983
Non cash interest expense	132	217	1,757	466

Overview

We are a medical device company that develops, manufactures and markets an insulin infusion system for people with insulin-dependent diabetes. Our proprietary OmniPod Insulin Management System consists of our disposable OmniPod insulin infusion device and our handheld, wireless Personal Diabetes Manager.

The U.S. Food and Drug Administration, or FDA, approved the OmniPod System in January 2005, and we began commercial sale of the OmniPod System in the United States in October 2005. We have progressively expanded our marketing and sales efforts from an initial focus in the Eastern United States, to having availability of the OmniPod System in the entire United States through internal sales and distribution channels as well as third-party distributors.

We focus our sales towards key diabetes practitioners, academic centers and clinics specializing in the treatment of diabetes patients, as well as individual diabetes patients.

In January 2010, we entered into a five-year exclusive distribution agreement with Ypsomed Distribution AG, or Ypsomed, which intends to distribute and sell our OmniPod System in eleven countries, subject to approved reimbursement. We sold the OmniPod System to Ypsomed for distribution in Germany and the United Kingdom beginning in the second quarter of 2010 and for distribution in Sweden, Norway and the Netherlands in the third quarter of 2010. We expect that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in the fourth quarter of 2010 and in 2011.

We currently produce the OmniPod on a partially automated manufacturing line at a facility in China operated by a subsidiary of Flextronics International Ltd. We purchase complete OmniPods pursuant to our agreement with Flextronics. Under the agreement, Flextronics has agreed to supply us, as a non-exclusive supplier, with OmniPods at agreed upon prices per unit pursuant to a rolling 12-month forecast that we provide to Flextronics. The initial term of the agreement was three years from January 3, 2007, with automatic one-year renewals. The agreement may be terminated at any time by either party upon prior written notice given no less than a specified number of days prior to the date of termination. The specified number of days is intended to provide the parties with sufficient time to make alternative arrangements in the event of termination. By purchasing OmniPods manufactured by Flextronics in China, we have been able to substantially

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increase production volumes for the OmniPod and reduce our per unit production cost.

To achieve profitability, we continue to seek to increase manufacturing volume and reduce the per unit production cost for the OmniPod. 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. These operational efficiencies as well as the continued collaboration with contract manufacturers to reduce the cost of supplies of raw materials and sub-assemblies are important as we strive to achieve profitability. Our manufacturing capacity is sufficient to meet our expected 2010 demand for OmniPods.

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

As a medical device company, reimbursement from third-party payors is an important element of our success. If patients are not adequately reimbursed for the costs of using the OmniPod System, it will be much more difficult for us to penetrate the market. We continue to negotiate contracts establishing reimbursement for the OmniPod System with national and regional third-party payors. As we expand our sales and marketing focus, increase our manufacturing capacity and expand to international markets, we will need to maintain and expand available reimbursement for the OmniPod System.

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

Since our inception in 2000, we have incurred losses every quarter. In the three and nine months ended September 30, 2010, we incurred net losses of $12.1 million and $40.3 million, respectively. As of September 30, 2010, we had an accumulated deficit of $363.0 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. In October 2009, we issued and sold 6,900,000 shares of our common stock at a price to the public of $10.25 per share. In connection with the offering, we received total gross proceeds of $70.7 million, or approximately $66.1 million in net proceeds after deducting underwriting discounts and offering expenses. As of September 30, 2010, we had $85.0 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 and June 17, 2010.

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

Facility Agreement and Common Stock Warrants

In March 2009, we entered into a Facility Agreement with certain institutional accredited investors, pursuant to which the investors agreed to loan us up to $60 million, subject to the terms and conditions set forth in the Facility

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

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 our common stock at an exercise price of $3.13 per share. Pursuant to the original terms of the Facility Agreement, we would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. The warrants qualified for permanent treatment as equity, and their relative fair value of $6.1 million on the issuance date was recorded as additional paid-in capital and debt discount. The debt discount is being amortized as interest expense over the term of the loan.

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.

In September 2009, we entered into an Amendment to the Facility Agreement whereby we repaid the $27.5 million of outstanding debt and promptly drew down the remaining $32.5 million available under the Facility Agreement. The lender eliminated all future performance milestones associated with the remaining $32.5 million available on the credit facility and reduced the annual interest rate on any borrowed funds to 8.5%. In connection with the Amendment to the Facility Agreement, we entered into a Securities Purchase Agreement with the

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lenders whereby we sold 2,855,659 shares of our common stock to the lenders at $9.63 per share, a $1.9 million discount based on the closing price of our common stock of $10.28 on that date. We recorded the $1.9 million as a debt discount which is being amortized as interest expense over the remaining term of the loan. 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. 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 repay 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 amended Facility Agreement also provides for certain prepayment penalties in the event that we repay the debt prior to its maturity.

In June 2010, we entered into a Second Amendment to the Facility Agreement whereby we paid a $0.5 million amendment fee to the lenders in exchange for the reduction of the prepayment penalties we must pay in certain events as well as the modification of certain other terms in the Facility Agreement. The fee was recorded as additional debt discount and is being amortized to interest expense over the remaining term of the loan.

All references herein to the Facility Agreement refer to the Facility Agreement entered into in March 2009 and amended in September 2009 and June 2010.

Because the consummation of certain change of 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 prepayment penalty could be paid by us in the event that we repay the debt prior to maturity, the prepayment penalty is also considered a derivative. The prepayment penalty does not meet the criteria to be accounted for separately. Any changes in fair value of the premium feature will be recorded as interest expense. The difference between the face value of the outstanding principal on the Facility Agreement and the amount remaining after the bifurcation will be recorded as a discount to be amortized over the term of the Facility Agreement. As of September 30, 2010, the premium feature associated with the Facility Agreement had no value as we do not currently expect a change in control transaction to occur. The embedded derivatives related to the Facility Agreement will be reassessed and marked-to-market through earnings on a quarterly basis.

As of September 30, 2010 and December 31, 2009, outstanding debt related to the Facility Agreement of $26.0 million and $24.7 million, respectively, was included in long-term debt in the consolidated balance sheet.

In the three and nine months ended September 30, 2010, we recorded cash interest related to the Facility Agreement of approximately $0.7 million and $2.1 million, respectively. In addition, in the three and nine months ended September 30, 2010, we recorded non-cash interest of approximately $0.7 million and $2.1 million, respectively. Non-cash interest in the three and nine months ended September 30, 2010 consists of amortization of the debt discount from the issuance of warrants and transaction fee in March 2009, amortization of the discount on the shares sold in connection with the amendment in September 2009, amortization of the transaction fee in connection with the amendment in June 2010 and amortization of the issuance costs associated with the debt.

In the three and nine months ended September 30, 2009, we recorded cash interest related to the Facility Agreement of approximately $0.9 million and $1.8 million, respectively. In addition, in the three and nine months ended September 30, 2009, we recorded non-cash interest of approximately $0.3 million and $0.9 million, respectively. Non-cash interest in the three and nine months ended September 30, 2009 consists of amortization of the debt discount from the issuance of warrants and transaction fee in March 2009 and amortization of the issuance costs associated with the debt.

In March 2009, in connection with the execution of the Facility Agreement, we issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock at an exercise price of $3.13 per share. Pursuant to the original terms of the Facility Agreement, we would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. In connection with the Amendment to the Facility Agreement in September 2009, the lenders agreed to forego the remaining 1.5 million additional warrants that would have been issued upon future draws. 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. In June 2010, the lenders exercised warrants to acquire 2,125,000 shares of our common stock at an exercise price of $3.13 in cash. We received cash totaling $6.7 million as a result of this exercise.

As of September 30, 2010, warrants to acquire 1,625,000 shares of our common stock issued under the Facility Agreement remain unexercised, 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.

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Convertible Notes

In June 2008, we sold $85.0 million principal amount of 5.375% Convertible Senior Notes due June 15, 2013 (the 5.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 5.375% Notes are convertible into our common stock at an initial conversion rate of 46.8467 shares of common stock per $1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately $21.35 per share, representing a conversion premium of 34% to the last reported sale price of our common stock on the NASDAQ Global Market on June 10, 2008, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of our common stock for the remainder of the conversion value in excess of the principal amount. We do not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require us to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest, but excluding, the date of repurchase.

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

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

We incurred deferred financing costs related to this offering of approximately $3.5 million, of which $1.1 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as a component of interest expense over the five year term of the 5.375% Notes. We incurred interest expense related to the 5.375% Notes of approximately $2.5 million and $7.5 million for the three and nine months ended September 30, 2010, respectively. Of the $2.5 million recorded in the three months ended September 30, 2010, approximately $1.4 million relates to amortization of the debt discount and deferred financing costs and $1.1 million relates to cash interest. Of the $7.5 million recorded in the nine months ended September 30, 2010, approximately $4.1 million relates to amortization of the debt discount and deferred financing costs and $3.4 million relates to cash interest. For the three and nine months ended September 30, 2009, we incurred interest expense related to the 5.375% Notes of approximately $2.3 million and $7.1 million, respectively. Of the $2.3 million recorded in the three months ended September 30, 2009, approximately $1.2 million relates to amortization of the debt discount and deferred financing cost and $1.1 million relates to cash interest. Of the $7.1 million recorded in the nine months ended September 30, 2009, approximately $3.7 million relates to amortization of the debt discount and deferred financing cost and $3.4 million relates to cash interest.

As of September 30, 2010, the outstanding amounts related to the 5.375% Notes of $68.2 million are included in long-term debt in the consolidated balance sheet and reflect the debt discount of $16.8 million. As of December 31, 2009, the outstanding amounts related to the 5.375% Notes of $64.5 million are included in long-term debt and reflect the debt discount of $20.5 million. The debt discount includes the equity allocation of $25.8 million (which represents $26.9 million less the $1.1 million of allocated financing costs) offset by the accretion of the debt discount through interest expense from the issuance date over the 5 year term of the notes. We recorded $1.2 million and $3.7 million of interest expense related to the debt discount in the three and nine months ended September 30, 2010, respectively. 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. As of September 30, 2010, the 5.375% Notes have a remaining term of 2.75 years.

We received net proceeds of approximately $81.5 million from this offering. Approximately $23.2 million of the proceeds from this offering were used to repay and terminate our then-existing term loan, including outstanding principal and accrued and unpaid interest of $21.8 million, a prepayment fee related to the term loan of approximately $0.4 million and a termination fee related to the term loan of $0.9 million. In connection with this term loan, we issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock at a purchase price of $3.64 per share. The warrants automatically converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of $9.56 per share at the closing of our initial public offering in May 2007. At September 30, 2010, warrants to purchase 62,752 shares of common stock remain outstanding and exercisable at a price of $9.56 per share.

Financial Operations Overview

Revenue. We derive nearly all of our revenue from the sale of the OmniPod System directly to patients and third-party distributors who resell the product to diabetes patients. The OmniPod System is comprised of two devices: the OmniPod, a disposable insulin infusion device that the patient wears for up to three days and then replaces; and the Personal Diabetes Manager (PDM), a handheld device much like a personal digital assistant that wirelessly programs the OmniPod with insulin delivery instructions, assists the patient with diabetes management and incorporates a blood glucose meter. Revenue is derived from the sale to new customers or third-party distributors of OmniPods and Starter Kits, which include the PDM, the OmniPod System User Guide and our 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. In January 2010, we entered into an exclusive distribution agreement with Ypsomed which intends to distribute and sell the OmniPod

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System, subject to approved reimbursement, in eleven countries. We commenced sales of the OmniPod System to Ypsomed for distribution in Germany and the United Kingdom beginning in the second quarter of 2010 and for distribution in Sweden, Norway and the Netherlands in the third quarter of 2010. We expect that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in the fourth quarter of 2010 and in 2011.

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 certain amounts for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to certain customers in the United States and Israel. In July 2010, we entered into a second amendment to the development and license agreement with Abbott. Under the terms of the second amendment, Abbott agreed to pay certain amounts to us for services we performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to customers in certain additional territories. 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 of the sale of the PDM to a new patient. In the three and nine months ended September 30, 2010, we recognized revenue related to the amended Abbott agreement of $1.5 million and $3.9 million, respectively. In the three and nine months ended September 30, 2009, we recognized revenue related to the amended Abbott agreement of $2.3 million and $4.5 million, respectively. No revenue was recognized related to the second amendment to the development and license agreement in the three and nine months ended September 30, 2010. There was no impact to cost of revenue related to this agreement.

As of September 30, 2010 and December 31, 2009, we had deferred revenue of $4.5 million and $5.1 million, respectively, which includes product-related revenue as well as the unrecognized portion of the agreement fee related to the Abbott agreement. For the year ending December 31, 2010, we expect our revenue to continue to increase as we gain new customers in the United States and continue expansion into Europe and certain other international markets.

Cost of revenue. Cost of revenue consists primarily of raw materials, labor, warranty and overhead costs related to the OmniPod System. Cost of revenue also includes depreciation, freight and packaging costs. The increase in our OmniPod production volume, as well as our ability to gain cost savings on our bill of materials, is expected to reduce the per-unit cost of manufacturing the OmniPods by allowing us to reduce our direct costs and spread our fixed and semi-fixed overhead costs over a greater number of units.

Research and development. Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical functions, as well as the costs of market studies and product development projects. We expense all research and development costs as incurred. In 2010, we incurred higher levels of spending on our research and development efforts, which are focused primarily on increased functionality, improved design for patient convenience, ease of use, and reduction of production costs. We expect spending on research and development to increase slightly in the fourth quarter as we increase our research and development efforts related to our next generation product.

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 and facilities-related costs. We expect general and administrative expenses in the fourth quarter to remain consistent with current levels as we continue to drive efficiencies in our administrative functions.

Sales and marketing. Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support, customer support and training functions, sales commissions paid to our sales representatives and costs associated with participation in medical conferences, physician symposia and promotional activities, including distribution of units used in our demonstration kit programs. We expect sales and marketing expenses in the fourth quarter to increase compared to current levels as we expand our sales and marketing efforts to meet our business needs and international expansion.

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Results of Operations

The following table presents certain statement of operations information for the three and nine months ended September 30, 2010 and 2009:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009 (Restated)	% Change	2010	2009 (Restated)	% Change
	(In thousands)					
Revenue	$ 25,455	$ 18,735	36%	$ 69,199	$ 45,821	51%
Cost of revenue	13,826	12,936	7%	39,299	34,858	13%
Gross profit	11,629	5,799		29,900	10,963	
Operating expenses:						
Research and development	3,698	3,404	9%	12,128	9,880	23%
General and administrative	7,230	6,246	16%	20,379	19,575	4%
Sales and marketing	8,979	9,629	7%	26,301	28,905	9%
Total operating expenses	19,907	19,279	3%	58,808	58,360	1%
Operating loss	(8,278)	(13,480)	39%	(28,908)	(47,397)	39%
Other expense, net	(3,822)	(3,442)	11%	(11,393)	(9,409)	21%
Net loss	$ (12,100)	$ (16,922)	28%	$ (40,301)	$ (56,806)	29%

Comparison of the Three and Nine Months Ended September 30, 2010 and 2009

Revenue

Our total revenue was $25.5 million and $69.2 million for the three and nine months ended September 30, 2010, respectively, compared to $18.7 million and $45.8 million for the same periods in 2009. The increase in revenue is primarily due to an increased number of patients using the OmniPod System and an increase in sales to distributors. We expect our revenue to continue to increase as we continue to add new patients, both in the United States and internationally, and generate a higher volume of reorders based on our expanding patient base. In addition, we expect to continue to recognize additional revenue related to the Abbott agreement.

Cost of Revenue

Cost of revenue was $13.8 million and $39.3 million for the three and nine months ended September 30, 2010, respectively, compared to $12.9 million and $34.9 million for the same periods in 2009. The increase in cost of revenue is primarily due to the significantly increased sales volume offset by cost efficiencies related to the bill of material and production volume. The decrease in our per-unit cost was a result of cost savings on raw materials, volume discounts from our suppliers and increased production volumes. We experienced continuing improvement of our gross margin as a result of the increase in revenue as well as the decrease in the per-unit cost to manufacture the OmniPod for the three and nine months ended September 30, 2010 compared to the same periods in 2009.

Research and Development

Research and development expenses increased $0.3 million, or 9%, to $3.7 million for the three months ended September 30, 2010, compared to $3.4 million for the same period in 2009. Research and development expenses increased $2.2 million, or 23%, to $12.1 million for the nine months ended September 30, 2010 compared to $9.9 million for the same period in 2009. For the three months ended September 30, 2010, research and development expenses increased $0.5 million related to consulting and other outside services, $0.2 million for materials utilized in the development of our next generation OmniPod, and $0.2 million in travel expenses. This increase was offset by a decrease in employee related expenses including stock-based compensation of $0.6 million. For the nine months ended September 30, 2010, the increase in research and development expenses was primarily attributable to an increase of $1.8 million in consulting and other outside services, $1.0 million related to costs previously capitalized for the development of our next generation OmniPod, and $0.7 million in supplies and consumables. The increased costs were offset by a $1.3 million decrease in employee related expenses including stock-based compensation.

General and Administrative

General and administrative expenses increased $1.0 million, or 16%, to $7.2 million for the three months ended September 30, 2010, compared to $6.2 million for the same period in 2009. General and administrative expenses increased $0.8 million, or 4%, to $20.4 million for the nine months ended September 30, 2010, compared to $19.6 million for the same period in 2009. For the three months ended September 30, 2010, the increase in general and administrative expenses was primarily due to an increase of $0.8 million in outside services for legal and audit fees, $0.3 million in employee related expenses including stock-based compensation and $0.2 million in sales and use taxes. These increases were offset by a decrease of $0.3 million in allowances and write-offs of trade accounts receivable. For the nine months ended September 30, 2010, the increase in general and administrative expenses was attributable to an increase of $0.8 million in

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outside services for legal fees and temporary help and $0.4 million in employee related expenses including stock-based compensation. The increases were offset by decreases of $0.3 million in allowances and write-offs of trade receivables and $0.1 million in supplies and consumables.

Sales and Marketing

Sales and marketing expenses decreased $0.6 million, or 7%, to $9.0 million for the three months ended September 30, 2010, compared to $9.6 million for the same period in 2009. Sales and marketing expenses decreased $2.6 million, or 9%, to $26.3 million for the nine months ended September 30, 2010, compared to $28.9 million for the same period in 2009. For the three months ended September 30, 2010, the decrease in sales and marketing expenses was primarily due to a decrease of $0.5 million in consulting services, $0.1 million for samples and Patient Demonstration Kits and $0.1 million in travel related expenses. These decreases were partially offset by a $0.1 million increase in employee related expenses including stock-based compensation. For the nine months ended September 30, 2010, the decrease in sales and marketing was primarily due to a decrease of $1.4 million in samples and Patient Demonstration Kits, a decrease of $0.9 million in consulting services, a decrease of $0.5 million in travel related expenses and a decrease of $0.2 million in advertising costs. The decreases were offset by an increase of $0.4 million in employee related expenses including stock-based compensation.

Other Income (Expense)

Net interest expense was $3.8 million for the three months ended September 30, 2010, compared to $3.4 million for the same period in 2009. Net interest expense was $11.4 million for the nine months ended September 30, 2010, compared to $9.4 million for the same period in 2009. For the three months ended September 30, 2010, the increase in net interest expense was primarily due to the additional non-cash interest associated with the amendments to the Facility Agreement in September 2009 and June 2010. For the nine months ended September 30, 2010, the increase in net interest expense was primarily due to amortization of the debt discount related to our 5.375% Notes and additional non-cash interest associated with the amendments to the Facility Agreement in September 2009 and June 2010.

Liquidity and Capital Resources

We commenced operations in 2000 and to date we have financed our operations primarily through private placement of common and preferred stock, secured indebtedness, public offerings of our common stock and issuance of convertible debt. As of September 30, 2010, we had $103.9 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.

Equity

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

In June 2010, the lenders in our Facility Agreement exercised warrants to purchase 2,125,000 shares of our common stock in exchange for $6.7 million. We had originally granted warrants to purchase 3,750,000 shares of our common stock at $3.13 per share in connection with the Facility Agreement.

Facility Agreement

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

In September 2009, we entered into an Amendment to the Facility Agreement whereby we repaid the $27.5 million of outstanding debt and promptly drew down the remaining $32.5 million available under the Facility Agreement. The lender eliminated all future performance-related milestones associated with the remaining $32.5 million available on

the credit facility and reduced the annual interest rate to 8.5%. In connection with the Amendment to the Facility Agreement, we entered into a Securities Purchase Agreement with the lenders whereby we sold 2,855,659 shares of our common stock to the lenders at $9.63 per share, a $1.9 million discount based on the closing price of our common stock of $10.28 on that date. We recorded the $1.9 million as a debt discount which is being amortized to interest expense over the remaining term of the loan. We received aggregate proceeds of $27.5 million in connection with the sale of our shares. All principal amounts outstanding under the Facility Agreement are payable in September 2012.

In June 2010, we entered into a Second Amendment to the Facility Agreement whereby we paid a $0.5 million amendment fee in exchange for the reduction of the prepayment penalties as well as the modification of certain other terms of the Agreement. The fee was

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recorded as additional debt discount and is being amortized as interest expense over the remaining term of the loan.

Common Stock Warrants

In March 2009, in connection with the execution of the Facility Agreement, we issued to the lenders fully exercisable warrants to purchase an aggregate of 3.75 million shares of common stock at an exercise price of $3.13 per share. The warrants qualified for permanent treatment as equity, and their relative fair value of $6.1 million on the issuance date was recorded as additional paid-in capital and debt discount. The debt discount is being amortized as interest expense over the term of the loan. Pursuant to the Facility Agreement, we would have been required to issue additional warrants to purchase 1.5 million shares upon drawing down the remaining $32.5 million under the facility. In connection with the Amendment of the Facility Agreement in September 2009, the lenders agreed to forego the remaining 1.5 million additional warrants that would have been issued upon future draws. In June 2010, the lenders exercised warrants to acquire 2,125,000 shares of our common stock at an exercise price of $3.13 per share. We received cash totaling $6.7 million as a result of this exercise. As of September 30, 2010, warrants issued under the Facility Agreement to acquire 1,625,000 shares of our common stock remain unexercised.

Convertible Notes

In June 2008, we sold $85.0 million principal amount of 5.375% Notes due June 15, 2013 (the 5.375% Notes) in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The interest rate on the notes is 5.375% per annum on the principal amount from June 16, 2008, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 5.375% Notes are convertible into our common stock at an initial conversion rate of 46.8467 shares of common stock per $1,000 principal amount of the 5.375% Notes, which is equivalent to a conversion price of approximately $21.35 per share, representing a conversion premium of 34% to the last reported sale price of our common stock on the NASDAQ Global Market on June 10, 2008, per $1,000 principal amount of the 5.375% Notes, subject to adjustment under certain circumstances, at any time beginning on March 15, 2013 or under certain other circumstances and prior to the close of business on the business day immediately preceding the final maturity date of the notes. The 5.375% Notes will be convertible for cash up to their principal amount and shares of our common stock for the remainder of the conversion value in excess of the principal amount. We do not have the right to redeem any of the 5.375% Notes prior to maturity. If a fundamental change, as defined in the Indenture for the 5.375% Notes, occurs at any time prior to maturity, holders of the 5.375% Notes may require us to repurchase their notes in whole or in part for cash equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest, including any additional interest, to, but excluding, the date of repurchase.

We received net proceeds of approximately $81.5 million from this offering. We used a portion of the net proceeds to repay the entire outstanding principal balance, plus accrued and unpaid interest, under our then-existing term loan in the aggregate of approximately $21.8 million in its entirety. Additionally, we paid a prepayment fee related to the term loan of approximately $0.4 million, a termination fee related to the term loan of $0.9 million, and incurred certain other expenses related to the repayment and termination of the term loan.

Operating Activities

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

	Nine Months Ended September 30,	
	2010	2009 (Restated)
	(In thousands)	
Cash used in operating activities	$ (27,922)	$ (39,465)
Net loss	$ (40,301)	$ (56,806)

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. During the nine months ended

September 30, 2010, we recorded a non-cash charge to operations of approximately $1.0 million related to our review of costs incurred on capital projects in process that we determined are no longer appropriate to capitalize. Significant uses of cash from operations include an increase in accounts receivable, offset by increases in accounts payable and accrued expenses and deferred revenue. The increase in accounts receivable is primarily attributable to our increased sales. Accounts receivables are shown net of allowances for doubtful accounts in the consolidated balance sheets. The increase in accounts payable and accrued expenses are primarily attributed to timing on payments to our contract manufacturers.

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Investing and Financing 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,	
	2010	2009 (Restated)
	(In thousands)	
Cash used in investing activities	$ (3,632)	$ (1,968)
Cash provided by financing activities	$ 7,476	$ 57,464

Cash used in investing activities in both periods was primarily for the purchase of fixed assets for use in the development and manufacturing of the OmniPod System. Our cash used in investing activities has increased significantly in the nine months ended September 30, 2010, compared to the nine months ended September 30, 2009, as we increased spending on equipment to be used to manufacture our next generation product. Capital expenditures are expected to continue to increase in 2010 compared to 2009. Cash provided by financing activities in the nine months ended September 30, 2010 mainly consisted of the net proceeds from the issuance of common stock in connection with the exercise of warrants to purchase 2,125,000 shares of common stock and employee stock options. Cash provided by financing activities in the nine months ended September 30, 2009 was mainly related to the net proceeds from the Facility Agreement entered into in March 2009 and the shares purchased in connection with the modification in September 2009.

Lease Obligations

We lease our facilities, which are accounted for as operating leases. The lease of our facilities in Bedford and Billerica, Massachusetts, generally provides for a base rent plus real estate taxes and certain operating expenses related to the lease. All operating leases contain renewal options and escalating payments over the term of the lease. As of September 30, 2010, we had an outstanding letter of credit which totaled $0.2 million to cover our security deposits for lease obligations.

Off-Balance Sheet Arrangements

As of September 30, 2010, we did not have any off-balance sheet financing arrangements.

Critical Accounting Policies and Estimates

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

Revenue Recognition

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

Revenue recognition requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval for sales directly to patients or a purchase order for sales to a third-party

distributor.

Transfer of title and risk and rewards of ownership are passed to the customer typically upon transfer to the third party carrier.

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

We assess whether the different elements qualify for separate accounting. We recognize revenue for the initial shipment to a patient or other third party once all elements have been delivered.

We offer a 45-day right of return for our Starter Kits sales, and we defer revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of historical return data to their related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. Historically, sales returns have amounted to approximately 3% of gross product sales.

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

In March 2008, we received a cash payment from Abbott Diabetes Care, Inc. (Abbott) for an agreement fee in connection with execution of the first amendment to the development and license agreement between us and Abbott. We recognize the agreement fee received from Abbott over the initial 5-year term of the agreement, and the non-current portion of the agreement fee is included in other long-term liabilities. Under the amended Abbott agreement, beginning July 1, 2008, Abbott agreed to pay us certain amounts for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to certain customers in the United States and Israel. In July 2010, we entered into a second amendment to the development and license agreement with Abbott. Under the terms and conditions of the second amendment, Abbott agreed to pay certain amounts to us for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to customers in certain additional territories. We recognize revenue related to this portion of the Abbott agreement at the time we meet the criteria for revenue recognition, typically at the time of sale of the PDM to the patient. In the three and nine month periods ended September 30, 2010, we recognized revenue related to the amended Abbott agreement of $1.5 million and $3.9 million, respectively. In the three and nine month periods ended September 30, 2009, we recognized revenue related to the amended Abbott agreement of $2.3 million and $4.5 million, respectively. No revenue was recognized relate to the second amendment to the development and license agreement in the three and nine months ended September 30, 2010. There was no impact to cost of revenue related to this agreement.

We had deferred revenue of $4.5 million and $5.1 million as of September 30, 2010 and December 31, 2009, respectively. The deferred revenue recorded as of September 30, 2010 was comprised of product-related revenue as well as the non-amortized agreement fee related to the Abbott agreement.

Restructuring Expense and Impairment of Assets

In connection with our efforts to pursue improved gross margins, leverage operational efficiencies and better pursue opportunities for low-cost supplier sourcing of assets, we periodically perform an evaluation of our manufacturing processes and review the carrying value of our property and equipment to assess the recoverability of these assets whenever events indicate that impairment may have occurred. As part of this assessment, we review the future undiscounted operating cash flows expected to be generated by those assets. If impairment is indicated through this review, the carrying amount of the asset would be reduced to its estimated fair value. This review of manufacturing processes and equipment can result in restructuring activity or an impairment of assets based on current net book value and potential future use of the assets.

Our restructuring expenses may also include workforce reduction and related costs for one-time termination benefits provided to employees who are involuntarily terminated under the terms of a one-time benefit arrangement. We record these one-time termination benefits upon incurring the liability provided that the employees are notified, the plan is approved by the appropriate level of management, the employees to be terminated and the expected completion date is 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. 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.

Income Taxes

We file federal and state tax returns. We have accumulated significant losses since our inception in 2000. Since the net operating losses may potentially be utilized in future years to reduce taxable income (subject to any applicable limitations), all of our tax years remain open to examination by the major taxing jurisdictions to which we are subject.

We recognize estimated interest and penalties for uncertain tax positions in income tax expense. As of September 30, 2010, interest and penalties are immaterial to the financial statements.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable consist of amounts due from third-party payors, patients and third-party distributors. The allowance for doubtful accounts is recorded in the period in which revenue is recorded or at the time potential collection risk is identified. We estimate our allowance

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based on historical experience, assessment of specific risk, discussions with individual customers and various assumptions and estimates that we believe to be reasonable under the circumstances.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

As of September 30, 2010, we had outstanding debt recorded on our consolidated balance sheet of $68.2 million related to our 5.375% Notes and $26.0 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, 2010, our management conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) under the supervision and with the participation of our chief executive officer and chief financial officer. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. Based upon that evaluation of our disclosure controls and procedures as of September 30, 2010, our chief executive officer and chief financial officer concluded that they believe that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

Except as described below, there were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In August 2010, the Company implemented a change to its internal control over financial reporting regarding the procedures used by the Company in evaluating an amendment to an existing debt agreement to determine if the amendment qualifies as a modification or an early extinguishment of debt. This change included improving the Company s consideration of the Debt Modifications and Extinguishments Subtopic of the FASB Accounting Standards Codification. Specifically, the Company implemented a procedure to ensure that in the event of future modifications to its debt instruments that it considers the various elements that could impact the calculations of the cash flows in determining whether the new debt instrument is substantially different than the old debt instrument including the effect of debt discounts and prepayment features as contemplated by ASC 470-50 *Debt Modifications and Extinguishments*. In addition, the Company has initiated revisions to its internal training program to reasonably assure that the appropriate finance personnel have been specifically trained on this new internal control.

There have been no changes in our internal control over financial reporting that occurred subsequent to September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

From time to time in the normal course of our business, we may be subject to claims and legal proceedings associated with our business operations, including those related to commercial, manufacturing, supplier, product, employment and regulatory matters. We maintain insurance coverage proceeding indemnification against certain of these potential claims.

In addition, on August 25, 2010, Becton, Dickinson and Company (BD) filed a lawsuit in the United States District Court in the State of New Jersey against us alleging that the OmniPod System infringes three of its patents. BD seeks a declaration that we have infringed its patents, equitable relief, including an injunction that would enjoin us from infringing these patents, and an unspecified award for monetary damages.

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Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2009, which could materially affect our business, financial condition or future results. These risks are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Other than as set forth below, there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009 and as updated in our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2010.

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 year ended December 31, 2009, our gross profit from the manufacture and sale of the OmniPod System was $18.3 million. Although we have achieved a positive gross margin, we still operate at a substantial net loss. Our net losses for the years ended December 31, 2009, 2008 and 2007 were $72.3 million, $94.8 million and $53.5 million, respectively. In the three and nine months ended September 30, 2010, we incurred net losses of $12.1 million and $40.3 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, 2010, we had an accumulated deficit of $363.0 million.

We currently rely entirely on sales of our sole product, the OmniPod System, to generate revenue. 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.

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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, 2010 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. In addition, we are in the process of developing our next-generation product that should reduce our per unit costs. The occurrence of one or more factors that negatively impact our sales of the OmniPod System or delay the introduction of our next-generation product 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 economic 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 revenue, 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 revenue.

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

The U.S. Congress recently passed significant reforms to the U.S. healthcare system. Included as part of this new legislation is a 2.3% excise tax on the medical device industry beginning January 1, 2013 that is payable based on revenue, not income. This future excise tax may have a material adverse effect on our financial condition and results of operations. In addition, there are provisions that provide for the creation

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of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute will be publicly disseminated. It is difficult at this time to determine what impact the comparative effectiveness analysis will have on the OmniPod System or our future financial results. There may in the future be additional changes in government policy, including additional modifications to the recently-adopted healthcare reform bill, that could increase our cost of doing business and negatively impact our ability to sell our products and achieve profitability.

We 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:

- revenue generated by sales of the OmniPod System and any other future products that we may develop;
- costs associated with adding further manufacturing capacity, including capacity to manufacture our next-generation product;
- 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, 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 2011.

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. In October 2009, we sold 6.9 million shares of our common stock in a public offering at a price of $10.25 per share, resulting in net proceeds to us of approximately $66.1 million. 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 and June 17, 2010, 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 continued disruptions to the credit and financial markets in the United States and worldwide. As a result of these and other factors, we do not

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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, a subsidiary of Flextronics International Ltd. in China provides 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 term of our agreement with Flextronics is three years from January 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;
- the occurrence of a fire, natural disaster or other catastrophe, impacting one or more of our suppliers, 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 alternative 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

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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 January 2010, we entered into a 5 year distribution agreement with Ypsomed Distribution AG, or Ypsomed, to become the exclusive distributor of the OmniPod System in eleven countries. We commenced sales of the OmniPod System to Ypsomed for distribution in Germany and the United Kingdom beginning in the second quarter of 2010 and for distribution in Sweden, Norway and the Netherlands in the third quarter of 2010. We expect that Ypsomed will begin distributing the OmniPod System, subject to approved reimbursement, in the other markets under the agreement in the fourth quarter of 2010 and in 2011. While this agreement will help us expand our global footprint, we will now be exposed to fluctuations in product demand and sales productivity outside the United States as we will have to manage the risks associated with market acceptance of the OmniPod System in foreign countries. 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. We do not have control over Ypsomed s operational and financial condition, and we will have increased foreign regulatory and export requirements.

In addition, 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:

- political instability and adverse 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 including increased costs associated with enforcing contractual obligations in foreign jurisdictions;
- changes in foreign currency exchange rates;
- differing protection of intellectual property;
- unexpected changes in regulatory requirements;
- 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 markets;
- difficulties in managing foreign relationships and operations, including any relationships that we

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establish with foreign partners, distributors or sales or marketing agents; and

difficulty in collecting accounts receivable and longer collection periods.

In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments and general management resources. Our future success will depend in large part on our ability to anticipate and effectively manage these and other risks associated with doing business outside of the United States. 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. In addition, as we expand our sales and marketing efforts outside of the United States, we face additional risks associated with obtaining and maintaining reimbursement from foreign health care payment systems on a timely basis or at all. 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;

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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., NiliMEDIX Ltd, Sensile Medical AG, M2 Medical, Inc., Phluid Corporation, Calibra Medical, Inc., Valeritas, 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 revenue 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 revenue 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 PLUS 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 competitive disadvantage, which could negatively impact our business. In addition, the National Institutes

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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. In July 2010, we entered into a second amendment to the development and license agreement with Abbott. Under the terms of the second amendment, Abbott agreed to pay certain amounts to us for services performed in connection with each sale of a PDM that includes an Abbott Discrete Blood Glucose Monitor to customers in certain additional territories. 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;

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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

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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 revenue increases, 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 August 2010, Becton, Dickinson and Company (BD) filed a lawsuit in the United States District Court in the State of New Jersey against us alleging that the OmniPod System infringes three of its patents. BD seeks a declaration that we have infringed its patents, equitable relief, including an injunction that would enjoin us from infringing these patents, and an unspecified award for monetary damages. This litigation, regardless of its outcome, will likely result in the expenditure of significant financial resources and the diversion of management s time and resources. In addition, this litigation 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 in this litigation and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue 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.

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

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

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Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current clinical applications for which we market our OmniPod System, which includes the use of U-100, which is a common form of insulin. However, our clearances can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, the OmniPod System in a timely fashion or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices.

We also are subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacturing of our devices, labeling regulations and medical device reporting regulations, which require us to report to the FDA if our devices cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. For instance, the FDA is in the process of reviewing the 510(k) approval process and criteria and has announced initiatives to improve the current premarket and postmarket regulatory processes and requirements associated with infusion pumps and other home use medical devices. As part of this effort, the FDA is reviewing the adverse event reporting and recall processes for insulin pumps. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions:

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

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.

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

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.

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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.

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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 revenue. 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 revenue 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.

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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 revenue 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 th