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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Form 10-Q**

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

For the quarterly period ended March 31, 2007

OR

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

Commission File Number 001-33462

**INSULET CORPORATION**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**04-3523891**

(I.R.S. Employer Identification Number)

**9 Oak Park Drive**

**Bedford, Massachusetts**

(Address of principal executive offices)

**01730**

(Zip Code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Exchange Act Rule 12b-2.)

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer

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

As of June 22, 2007, 26,322,811 shares of the registrant's common stock were outstanding.

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**INSULET CORPORATION**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2007**  
**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	1
<u>Consolidated Balance Sheets at March 31, 2007 (unaudited) and December 31, 2006</u>	1
<u>Consolidated Statements of Operations for the Three Months Ended March 31, 2007 and 2006 (unaudited)</u>	2
<u>Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2007 and 2006 (unaudited)</u>	3
<u>Notes to Consolidated Financial Statements (unaudited)</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	27
<u>Item 4T. Controls and Procedures</u>	27
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	29
<u>Item 1A. Risk Factors</u>	29
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	45
<u>Item 3. Defaults Upon Senior Securities</u>	46
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	46
<u>Item 5. Other Information</u>	46
<u>Item 6. Exhibits</u>	46
<u>Signatures</u>	47

**PART I – FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**INSULET CORPORATION  
CONSOLIDATED BALANCE SHEETS**

	<b>As of March 31, 2007 (unaudited)</b>	<b>As of December 31, 2006</b>
(In thousands, except share data)		
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash	\$ 19,076	\$ 33,231
Accounts receivable, net	2,118	1,417
Inventories	4,256	3,390
Prepaid expenses and other current assets	1,797	1,827
<b>Total current assets</b>	<b>27,247</b>	<b>39,865</b>
Property and equipment, net	18,484	16,999
Other assets	1,951	276
<b>Total assets</b>	<b>\$ 47,682</b>	<b>\$ 57,140</b>
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 4,687	\$ 3,450
Accrued expenses	4,325	4,193
Deferred revenue	679	284
Current portion of long-term debt	29,225	29,222
Preferred stock warrant liability	2,015	1,931
<b>Total current liabilities</b>	<b>40,931</b>	<b>39,080</b>
Other long-term liabilities	317	316
<b>Total liabilities</b>	<b>41,248</b>	<b>39,396</b>
<b>Redeemable convertible preferred stock, \$0.001 par value:</b>		
Authorized: 46,408,050 shares at March 31, 2007 and December 31, 2006		
Issued and outstanding Series A: 1,000,000 shares stated at liquidation and redemption value at March 31, 2007 and December 31, 2006	1,000	1,000
Issued and outstanding Series B: 5,945,946 shares stated at liquidation and redemption value at March 31, 2007 and December 31, 2006	11,000	11,000
Issued and outstanding Series C: 10,476,191 shares stated at liquidation and redemption value at March 31, 2007 and December 31, 2006	22,000	22,000
Issued and outstanding Series D: 14,669,421 shares stated at liquidation and redemption value at March 31, 2007 and December 31, 2006	35,500	35,500
Issued and outstanding Series E: 13,738,661 shares stated at liquidation and redemption value at March 31, 2007 and December 31, 2006	50,009	50,009
<b>Stockholders' deficit</b>		
Common stock \$.001 par value:		
Authorized: 65,000,000 shares at March 31, 2007 and December 31, 2006		
Issued: 485,444 and 457,076 shares at March 31, 2007 and December 31, 2006, respectively	1	1
Additional paid-in capital	524	293
Accumulated deficit	(113,600)	(102,040)
Subscription receivable	—	(19)
<b>Total stockholders' deficit</b>	<b>(113,075)</b>	<b>(101,765)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 47,682</b>	<b>\$ 57,140</b>

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

**INSULET CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(unaudited)

	Three Months Ended March 31,	
	2007	2006
	(In thousands, except share and per share data)	
Revenue	\$ 2,008	\$ 222
Cost of revenue	4,572	2,753
Gross loss	(2,564)	(2,531)
Operating expenses:		
Research and development	2,470	1,750
General and administrative	2,660	1,553
Sales and marketing	3,104	1,072
Total operating expenses	8,234	4,375
Operating loss	(10,798)	(6,906)
Interest income	304	235
Interest expense	(982)	(269)
Increase in value of preferred stock warrant liability	(84)	—
Net loss	(11,560)	(6,940)
Accretion of redeemable convertible preferred stock	—	(222)
Net loss attributable to common shareholders	\$ (11,560)	\$ (7,162)
Net loss per share basic and diluted	\$ (23.86)	\$ (21.06)
Weighted-average number of shares used in calculating net loss per share	484,431	340,106
Pro forma net loss per share basic and diluted	\$ (0.64)	\$ (0.45)
Pro forma weighted-average number of shares used in calculating net loss per share	18,152,203	15,995,946

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

**INSULET CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(unaudited)

	Three Months Ended March 31,	
	2007	2006
(In thousands)		
<b>Cash flows from operating activities</b>		
Net loss	\$ (11,560)	\$ (6,940)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	846	509
Amortization of debt discount	60	14
Redeemable convertible preferred stock warrant expense	84	—
Stock compensation expense	209	28
Provision for bad debts	120	9
Non cash interest expense	(57)	—
Changes in operating assets and liabilities:		
Accounts receivable	(821)	(99)
Inventory	(866)	(809)
Prepays and other current assets	30	209
Other assets	(1,675)	1
Accounts payable and accrued expenses	1,369	2,084
Other long term liabilities	1	120
Deferred revenue	395	(25)
Net cash used in operating activities	<u>(11,865)</u>	<u>(4,899)</u>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(2,331)	(3,992)
Net cash used in investing activities	<u>(2,331)</u>	<u>(3,992)</u>
<b>Cash flows from financing activities</b>		
Proceeds from sale of Series E preferred stock, net of issuance cost	—	49,787
Proceeds from exercise of stock options	22	23
Proceeds from payment of subscription receivable	19	11
Net cash provided by financing activities	41	49,821
Net increase (decrease) in cash and cash equivalents	<u>(14,155)</u>	<u>40,930</u>
Cash and cash equivalents, beginning of period	33,231	7,660
Cash and cash equivalents, end of period	<u>\$ 19,076</u>	<u>\$ 48,590</u>

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

**INSULET CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. Nature of Business**

Insulet Corporation (the "Company"), located in Bedford Massachusetts, is principally engaged in the development, manufacture and commercialization of an insulin infusion system for people with insulin-dependent diabetes. The Company was incorporated in Delaware in 2000. Since inception, the Company has devoted substantially all of its efforts to designing and developing the OmniPod Insulin Management System, raising capital and recruiting personnel. As a result, the Company was considered a development stage company pursuant to Statement of Financial Accounting Standards ("SFAS") No. 7, *Accounting and Reporting by Development Stage Enterprises*, through December 31, 2005. The year 2006 was the first year during which the Company was an operating company and was no longer in the development stage. The Company commercially launched the OmniPod Insulin Management System in August 2005 after receiving FDA 510(k) approval in January 2005. The first commercial product was shipped in October 2005.

**2. Summary of Significant Accounting Policies**

***Unaudited Interim Financial Statements***

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for the complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three month period ended March 31, 2007 are not necessarily indicative of the results that may be expected for the full fiscal year ending December 31, 2007.

The consolidated balance sheet at December 31, 2006 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's registration statement on Form S-1 for the year ended December 31, 2006.

***Use of Estimates in Preparation of Financial Statements***

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

***Principles of Consolidation***

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

***Cash and Cash Equivalents***

For the purposes of the financial statement classification, the Company considers all highly liquid investment instruments with original maturities of ninety days or less, when purchased, to be cash equivalents. Cash

equivalents consist of money market accounts and are carried at cost, which approximates their fair values. Outstanding letters of credit, principally relating to security deposits for lease obligations, totaled \$200,000 at March 31, 2007 and December 31, 2006.

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

Accounts receivable consist of amounts due from third-party payors and patients. In estimating the collectibility of accounts receivable, the Company analyzes payor and patient concentrations, payor and patient credit-worthiness, and competitive benchmarks. These allowances are recorded in the period when the revenue is recorded. The allowances are adjusted currently for any changes in estimated collections.

Bad debt expense for the three months ended March 31, 2007 and 2006 amounted to \$120,000 and \$9,000, respectively. There was \$26,000 in write-offs or other adjustments to the allowance for doubtful accounts during the three months ended March 31, 2007. There were no write-offs or adjustments during 2006.

### ***Inventories***

Inventories are valued at the lower of actual cost or market, using the first-in, first-out ("FIFO") method. Inventory has been written down to market for all periods presented as the Company currently manufactures its product at a loss. Work in process is calculated based upon a build up in the stage of completion using estimated labor inputs for each stage in production. Costs for PDMs and OmniPods include raw material, labor and manufacturing overhead. The Company evaluates inventory valuation on a quarterly basis for obsolete or slow-moving items.

### ***Property & Equipment***

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

### ***Impairment of Property & Equipment***

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

### ***Revenue Recognition***

The Company generates revenue from the sale of its OmniPod Insulin Management System to diabetes patients. The initial sale to a new customer typically includes OmniPods and a Starter Kit, which include the Personal Diabetes Manager ("PDM"), two OmniPods, the OmniPod System User Guide and the OmniPod System Interactive Training CD. The Company offers a 45-day right of return for its Starter Kits sales (the Company changed from a 30-day right of return effective for shipments prior to December 1, 2006). Subsequent sales to existing customers typically consist of OmniPods sales. Revenues are recognized in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements ("SAB 104"), which requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

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

- Transfer of title and risk and rewards of ownership are passed to the patient upon shipment from the Company.
- The selling prices for all sales are fixed and agreed with the patient, and if applicable, the patient's third-party insurance provider(s) prior to shipment and are based on established list prices or, in the case of certain third-party insurers, contractually agreed upon prices.

The Company has considered the requirements of Emerging Issues Task Force ("EITF") No. 00-21, *Revenue Arrangements with Multiple Deliverables*, when accounting for the OmniPods and Starter Kits. EITF 00-21 requires that the Company assess whether the different elements qualify for separate accounting. The Company recognizes revenue for the Starter Kits once all elements have been delivered and the right of return has expired.

The Company has applied Statement of Financial Accounting Standards ("SFAS") No. 48, *Revenue Recognition When the Right of Return Exists*. In accordance with SFAS No. 48, the Company defers the revenue and, to the extent allowed, all related costs of all initial shipments until the right of return has lapsed. The Company had deferred revenue of \$679,000 and \$284,000 as of March 31, 2007 and December 31, 2006, respectively.

The Company recognizes subsequent sales of OmniPods upon shipment in accordance with the provisions set forth by SAB 104.

### ***Concentration of Credit Risk***

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents. The Company maintains the majority of its cash with one accredited financial institution. Although revenues are recognized from shipments directly to patients, the majority of shipments are billed to third party insurance payors.

### ***Research and Development***

The Company's research and development expenses consist of engineering, product development, quality assurance, clinical function and regulatory expenses. These expenses are primarily related to employee compensation, including salary, benefits and stock-based compensation. The Company also incurs expense related to consulting fees, materials and supplies, and marketing studies, including data management and associated travel expenses. Research and development costs are expensed as incurred.

### ***Income Taxes***

In June 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation ("FIN") No. 48, "*Accounting for Uncertainty in Income Taxes*", which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on the Company's financial position or results of operations. Upon adoption and as of March 31, 2007, the Company had no unrecognized tax benefits recorded.

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

The Company recognizes interest and penalties for uncertain tax positions in income tax expense. Upon adoption and as of March 31, 2007, the Company had no interest and penalty accrual or expense.

### **Stock Based Compensation**

Effective January 1, 2006, the Company adopted SFAS No. 123 (revised 2004), *Share Based Payment*, or SFAS 123R, which is a revision of Statement No. 123 ("SFAS 123") *Accounting for Stock Based Compensation*. SFAS 123R supersedes Accounting Principles Board ("APB") No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and amends FASB Statement No. 95 *Statement of Cash Flows*. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Prior to January 1, 2006, the Company accounted for employee stock based compensation in accordance with the provisions of APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation — an Interpretation of APB No. 25*, and complied with the disclosure provisions of SFAS 123, and related SFAS No. 148, *Accounting for Stock-Based Compensation — Transaction and Disclosure*. Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the stock and the exercise price of the option. The stock based compensation is amortized using the straight-line method over the vesting period.

SFAS 123R requires nonpublic companies that used the minimum value method in SFAS 123R for either recognition or pro forma disclosures to apply SFAS 123R using the prospective-transition method. As such, the Company will continue to apply APB 25 in future periods to equity awards outstanding at the date of SFAS 123R's adoption that were measured using the minimum value method. In accordance with the requirements of SFAS 123R, the Company will not present pro forma disclosures for periods prior to the adoption of SFAS 123R, as the estimated fair value of the Company's stock options granted through December 31, 2005 was determined using the minimum value method.

Effective January 1, 2006 with the adoption of SFAS 123R, the Company elected to use the Black-Scholes option pricing model to determine the weighted-average fair value of options granted. In accordance with SFAS 123R, the Company will recognize the compensation expense of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The Company does not have a history of market prices of its common stock as it was not a public company, and as such estimates volatility in accordance with Securities and Exchange Commission's Staff Accounting Bulletin No. 107, *Share-Based Payment* (SAB 107) using historical volatilities of similar public entities. The expected life of the awards is estimated based on the "SEC Shortcut Approach" as defined in SAB 107, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the awards. The dividend yield assumption is based on company history and expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock based compensation expense recognized in the financial statements in 2006 and thereafter is based on awards that are ultimately expected to vest. The Company evaluates the assumptions used to value the awards on a quarterly basis and if factors change and different assumptions are utilized, stock based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned stock based compensation expense.

Prior to April 1, 2006, the exercise prices for options granted were set by the Company's board of directors based upon guidance set forth by the American Institute of Certified Public Accountants (AICPA) in the AICPA Technical Practice Aid, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation", or the AICPA Practice Aid. To that end, the board considered a number of factors in determining the option price, including the following factors: (1) prices for the Company's preferred stock, which the Company had sold to outside investors in arms-length transactions, and the rights, preferences and privileges of the Company's preferred

stock and common stock in the Series A through Series E financing, (2) obtaining FDA 510(k) clearance, (3) launching the OmniPod System and (4) achievement of budgeted revenue and results.

In connection with the preparation of the financial statements for the initial public offering, the Company retrospectively estimated the fair value of its common stock based upon several factors, including the following factors: (1) operating and financial performance, (2) progress and milestones attained in the business, (3) past sales of convertible preferred stock, (4) the results of the retrospective independent valuations, and (5) the expected valuation obtained in an initial public offering. The Company believes this to have been a reasonable methodology based on the factors above and based on several arm's-length transactions involving the Company's stock supportive of the results produced by this valuation methodology.

See Note 8 for a summary of the stock option activity under our stock based employee compensation plan.

### Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company will be required to adopt SFAS 157 in the first quarter of fiscal year 2008. The Company is currently evaluating the requirements of SFAS 157 and has not yet determined the impact on its financial statements.

In February 2007, the FASB issued SFAS No. 159, *Fair Value Option for Financial Assets and Financial Liabilities – Including an amendment of FASB Statement 115* ("SFAS 159"), which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The Company is currently evaluating if it will elect the fair value option for any of its eligible financial instruments and other items.

### 3. Net Loss Per Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. For all periods presented there were no unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options and warrants (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method). Because the Company reported a net loss for the three months ended March 31, 2007 and 2006, respectively, all potential common shares have been excluded from the computation of the dilutive net loss per share for all periods presented because the effect would have been antidilutive. Such potential common share equivalents consist of the following:

	Three Months Ended March 31,	
	2007	2006
Series A redeemable convertible preferred stock	380,705	380,705
Series B redeemable convertible preferred stock	2,263,651	2,263,651
Series C redeemable convertible preferred stock	3,988,337	3,988,337
Series D redeemable convertible preferred stock	5,584,722	5,584,722
Series E redeemable convertible preferred stock	5,230,376	5,230,376
Outstanding options	2,511,691	2,173,256
Outstanding warrants	219,981	125,853
Total	<u>20,179,463</u>	<u>19,746,900</u>

### Pro forma net loss per share (unaudited)

The calculation of pro forma basic and diluted net loss per share attributable to common stockholders assumes the conversion of all shares of Series A, B, C, D and E redeemable convertible preferred stock into shares of common stock using the as-if-converted method. In accordance with Rule 11-02 under Regulation S-X, the Company is presenting pro forma net loss per share for the three month ending March 31, 2007 as well as for the same period ending March 31, 2006. The Company's computation of pro forma net loss per share calculation is as follows:

	Three Months Ended	
	March 31,	
	2007	2006
	(In thousands, except share data)	
<b>Numerator</b>		
Net loss attributable to common stockholders	\$ (11,560)	\$ (7,162)
<b>Denominator</b>		
Basic and diluted weighted average common shares outstanding	484,431	340,106
Adjustment to reflect the conversion of preferred stock and warrants:		
Conversion of Series A redeemable convertible preferred stock	380,705	380,705
Conversion of Series B redeemable convertible preferred stock	2,263,651	2,263,651
Conversion of Series C redeemable convertible preferred stock	3,988,337	3,988,337
Conversion of Series D redeemable convertible preferred stock	5,584,722	5,584,722
Conversion of Series E redeemable convertible preferred stock	5,230,376	3,312,572
Conversion of warrant (Series D redeemable convertible preferred stock)	125,853	125,853
Conversion of warrant (Series E redeemable convertible preferred stock)	94,128	—
Pro forma basic and diluted weighted average common shares outstanding	18,152,203	15,995,946
Pro forma net loss per share basic and diluted	\$ (0.64)	\$ (0.45)

### 4. Inventories

Inventories consist of the following:

	As of	As of
	March 31,	December 31,
	2007	2006
	(In thousands)	
Raw materials	\$ 2,043	\$ 1,177
Work-in-process	445	367
Finished goods	1,768	1,846
	<u>\$ 4,256</u>	<u>\$ 3,390</u>

Inventory was adjusted by \$767,000 and \$1.5 million as of March 31, 2007 and December 31, 2006, respectively, to reflect values at the lower of cost or market. At March 31, 2007 and December 31, 2006, 42% and 54%, respectively, of the total inventory is valued below the Company's cost. The Company's production process has a high degree of fixed costs due to the early stage of capacity build-up and market penetration of its products. Consequently, sales and production volumes have not been adequate to result in per unit costs that are lower than the current market price for the Company's products.

## 5. Property and Equipment

Property and equipment consist of the following:

	<u>Estimated Useful Life (Years)</u>	<u>As of March 31, 2007</u>	<u>As of December 31, 2006</u>
		(In thousands)	
Machinery and equipment	5	\$ 8,712	\$ 8,559
Construction in process		9,831	7,987
Computer	3	1,040	975
Software	3	1,252	1,061
Leasehold improvements	*	1,763	1,730
Office furniture and fixtures	5	748	703
Total property and equipment		\$ 23,346	\$ 21,015
Less: Accumulated depreciation		(4,862)	(4,016)
Total		<u>\$ 18,484</u>	<u>\$ 16,999</u>

\* Lesser of term of lease or useful life of asset

Depreciation expense related to property and equipment was \$846,000 and \$509,000 for the three months ended March 31, 2007 and 2006.

Construction in process consists of machinery and equipment in the process of being constructed for use in the Company's automated manufacturing process. Depreciation on the machinery and equipment does not begin until the machinery and equipment is installed and integrated into the manufacturing process.

## 6. Indebtedness and Warrants to Purchase Shares Subject to Redemption

### Loan and Security Agreements

On June 2, 2005, the Company entered into a \$10.0 million term loan and security agreement with Lighthouse Capital Partners V, L.P. Interest on this term loan was charged at a rate of 8%. This term loan required only interest payments through June 1, 2006. After that date, the principal and interest was payable ratably over 42 months. At the end of the amortization period of the term loan, the Company was obligated to make a final payment of \$1.0 million, which was being amortized as interest expense over the life of the loan. Upon payment of the term loan in December 2006, the remaining unamortized balance of the final \$1.0 million payment was recognized as interest expense.

In connection with this term loan, the Company issued a warrant to the lender to purchase up to 330,579 shares of Series D preferred stock. The Company recorded the \$251,000 fair value of the warrant as a discount to the term loan. The cost of the warrant was being amortized to interest expense over the 54-month life of this term loan. The remaining balance of the discount was expensed upon payment of the term loan in December 2006.

On December 27, 2006, the Company entered into a credit and security agreement with a group of lenders led by Merrill Lynch Capital pursuant to which the Company borrowed \$30.0 million in a term loan. The Company used \$9.5 million of the proceeds from this term loan to repay all amounts owed under the term loan with Lighthouse Capital Partners V, L.P. This term loan is secured by all the assets of the Company other than its intellectual property. The borrowings under the term loan bear interest at a floating rate equal to the LIBOR rate plus 6% per annum. Interest is payable on a monthly basis during the term of the loan and, beginning on October 1, 2007;

principal will be paid in 33 equal monthly installments of \$909,091. This term loan is also subject to a loan origination fee amounting to \$900,000. The Company has capitalized these costs as deferred financing costs as of December 31, 2006. The deferred cost asset will be amortized to interest expense over the 42-month life of this term loan. This term loan is subject to acceleration upon the occurrence of any fact, event or circumstance that has resulted or could reasonably be expected to result in a material adverse effect. Consequently, such debt has been classified as a current liability at December 31, 2006 in accordance with the provisions set forth by FASB Technical Bulletin No. 79-3 Subjective Acceleration Clause in Long-Term Debt Agreements.

In connection with this term loan, the Company issued warrants to the lenders to purchase up to 247,252 of Series E preferred stock. The Company recorded the \$835,000 fair value of the warrants as a discount to the term loan. The costs of the warrants are being amortized to interest expense over the 42-month life of this term loan.

### Warrants

In connection with the term loans with Lighthouse Capital Partners and a group of lenders led by Merrill Lynch Capital, the Company issued warrants to the lenders to purchase shares of its redeemable convertible preferred stock. These warrants have been recorded as "preferred stock warrant liability" in current liabilities in accordance with FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* and FASB Staff Position No. 150-5 *Issuer's Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable*.

Significant terms and fair values of warrants to purchase redeemable convertible preferred stock are as follows (in thousands except share and per share data):

Stock	Expiration Date	Exercise Price Per Share	Shares as of		Fair Value as of	
			March 31, 2007	December 31, 2006	March 31, 2007	December 31, 2006
Series D preferred	June 2, 2012	\$2.42	330,579	330,579	\$1,150	\$1,096
Series E preferred	December 27, 2013	3.64	247,252	247,252	865	835
Total			577,831	577,831	\$2,015	\$1,931

All warrants automatically converted upon the closing of the Company's initial public offering into warrants to purchase shares of common stock at a ratio of one share of common stock for every 2.6267 shares of redeemable convertible preferred stock. In connection with this conversion, the exercise prices of the warrants were also adjusted to an exercise price of \$6.36 per share in the case of the Series D warrant and an exercise price of \$9.56 per share in the case of the Series E warrants.

The Company recorded the \$251,000 and \$835,000 fair value of the warrants for Series D and Series E preferred stock, respectively as a discount to the term loans.

The fair value of the Series D and Series E warrants was calculated as of March 31, 2007, using the Black-Scholes option-pricing model with the following assumptions: 5.25 (Series D) and 6.75 year (Series E) expected lives, risk-free interest rate of 4.54% (Series D) and 4.58% (Series E), expected volatility of 67.00%, and no dividend yield. The fair value of the Series D and Series E warrants was calculated as of December 31, 2006, using the Black-Scholes option-pricing model with the following assumptions: 5.5 (Series D) and 7 year (Series E) expected lives, risk-free interest rate of 4.70%, expected volatility of 71.36%, and no dividend yield.

The Company recorded \$84,000 of other expense for the three months ended March 31, 2007 to reflect increases in the estimated fair value of the Series D and Series E warrants during the period.

Upon the closing of the Company's initial public offering on May 18, 2007, all outstanding warrants to purchase shares of our preferred stock automatically converted into warrants to purchase shares of our common stock and, as a result, will no longer be subject to FSP 150-5 for periods ended or ending on or after that date. The aggregate fair value of these warrants as of May 18, 2007, after a final remeasurement of fair value, will be

reclassified from liabilities to additional paid-in capital, a component of stockholders' deficit, and we will cease to record any related periodic fair value adjustments.

## 7. 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. The Company entered into a new lease in 2004 which contains renewal options, escalating payments and leasehold allowances over the life of the lease. The Company has considered FASB Technical Bulletin 88-1, Issues Relating to Accounting for Leases, and FASB Technical Bulletin 85-3, Accounting for Operating Leases with Scheduled Rent Increases, in accounting for these lease provisions.

### Legal Proceedings

The Company is not currently subject to any material pending legal proceedings.

### 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.

## 8. Stock Option Plan

Under the Company's 2000 Stock Option and Incentive Plan (the "Plan"), options may be granted to persons who are, at the time of grant, employees, officers, or directors of, or consultants or advisors to, the Company. The Plan provides for the granting of nonstatutory stock options, incentive stock options, stock bonuses, and rights to acquire restricted stock. The option price at the date of grant is determined by the Board of Directors and, in the case of incentive stock options, may not be less than the fair market value of the common stock at the date of grant, as determined by the Board of Directors. Options generally vest over a period of four years and expire 10 years from the date of grant. The provisions of the Plan limit the exercise of incentive stock options. At the time of grant, options are typically immediately exercisable, but subject to restrictions. The restrictions generally lapse over a period of four years. At March 31, 2007, the Company had reserved 3,314,828 shares of common stock for issuance under the Plan. At March 31, 2007, 364,586 options are available for future grant.

The Plan activity follows:

	Number of Options(#)	Weighted Average Exercise Price(\$)	Aggregate Intrinsic Value(\$)
Balance, December 31, 2006	2,318,250	3.15	
Granted	223,303	11.64	
Exercised	(28,368)	0.80	307,687(1)
Canceled	(1,494)	5.38	

	Number of Options(#)	Weighted Average Exercise Price(\$)	Aggregate Intrinsic Value(\$)
Balance, March 31, 2007	2,511,691	3.93	20,098,792(2)
Vested, March 31, 2007	1,800,562	1.89	14,300,592(2)
Vested and expected to vest, March 31, 2007(3)	2,260,020		

- (1) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of the date of exercise and the exercise price of the underlying options.
- (2) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of March 31, 2007, and the exercise price of the underlying options.
- (3) Represents the number of vested options as of March 31, 2007, plus the number of unvested options expected to vest as of March 31, 2007, based on the unvested options outstanding at March 31, 2007, adjusted for the estimated forfeiture rate of 10.02%.

***Employee Stock-Based Awards Granted On or Subsequent to January 1, 2006***

Effective January 1, 2006, the Company adopted SFAS 123R, using the prospective transition method, which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees, directors and consultants. The Company's financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123R. In accordance with the prospective transition method, the Company's financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123R. Stock-based compensation expense recognized is based on the value of the portion of stock-based awards that is ultimately expected to vest. Stock-based compensation expense recognized in the Company's statements of operations during the year ended December 31, 2006 includes compensation expense for stock-based awards based on the fair value estimated in accordance with the provisions of SFAS 123R. The Company attributes the value of stock-based compensation to expense using the straight-line method, which was previously used for its pro forma information required under SFAS 123.

The weighted average estimated fair value of the employee stock options granted was \$7.6384 and \$3.8670 per share for the three months March 31, 2007 and 2006, respectively.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant using a pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. The estimated grant date fair values of the employee stock options were calculated using the Black-Scholes option pricing model, based on the following assumptions for the three months ended March 31, 2007:

Risk-free interest rate	4.81%
Expected term (in years)	6.25
Dividend yield	0.00
Expected volatility	67.00%

*Risk-free interest rate.* The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

*Expected volatility.* Expected volatility measures the amount that a stock price has fluctuated or is expected to fluctuate during a period. The Company determines volatility based on an analysis of comparable companies.

*Expected term.* The expected term of stock options represents the period the stock options are expected to remain outstanding and is based on the “SEC Shortcut Approach” as defined in SAB 107, *Share-Based Payments*, which is the midpoint between the vesting date and the end of the contractual term.

*Dividend yield.* The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

*Forfeitures.* SFAS 123R also requires the Company to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. If the Company’s actual forfeiture rate is materially different from its estimate, the stock-based compensation expense could be significantly different from what the Company has recorded in the current period.

The amount of stock-based compensation expense that is expected to be recognized for outstanding, unvested options as of March 31, 2007 is as follows (in thousands):

2007	\$ 700
2008	837
2009	752
2010	444
2011	19
	<u>\$ 2,752</u>

The weighted average fair value of options granted during the three months ended March 31, 2007 was \$7.6384. Employee stock-based compensation expense under SFAS 123R recognized in the three months ended March 31, 2007 and 2006 was \$209,000 and \$28,000, respectively and was calculated based on awards ultimately expected to vest.

At March 31, 2007, the Company had \$2,752,000 of total unrecognized compensation expense under SFAS 123R, net of estimated forfeitures. The expense will be recognized over a weighted-average period of approximately two years.

## **9. Income Taxes**

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 sufficiently assured as we do not expect income in the near-term.

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.

## **10. Subsequent Events**

### ***Reverse Stock Split***

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

On May 14, 2007, a Registration Statement on Form S-1 (File No. 333-140694) (as amended or supplemented, the "Form S-1"), relating to the Company's initial public offering of common stock (the "IPO") was declared effective by the Securities and Exchange Commission.

On May 18, 2007, the Company issued and sold 7,700,000 shares of common stock at a price to the public of \$15.00 per share. On June 12, 2007, the Company issued and sold an additional 665,000 shares of common stock at a price to the public of \$15.00 per share pursuant to the underwriters' partial exercise of their over-allotment option. In connection with the IPO, the Company received total gross proceeds of \$125,475,000, or approximately \$113,791,750 in net proceeds after deducting underwriting discounts and offering commissions of \$8,783,250 and other offering costs of approximately \$2,900,000. As disclosed in the Form S-1, the Company intends to use the proceeds from the IPO for general corporate purposes, which may include: (i) the completion and improvement of its existing automated line and the construction of a second automated line to increase its manufacturing capacity; (ii) the expansion of its sales and marketing activities; and (iii) the funding of research and development.

Concurrent with the effective date of the IPO, the Company issued options to purchase an aggregate of approximately 118,963 shares under terms established by the 2000 Stock Option and Incentive Plan (the "2000 Plan"). On April 12, 2007, the Company's board of directors resolved that, subsequent to this grant, no further grants shall be made under the 2000 Plan.

On May 18, 2007, each share of the Company's preferred stock converted into 2.6267 shares of common stock.

### ***2007 Stock Option and Incentive Plan***

On May 18, 2007, upon the closing of the Company's initial public offering, the Company's 2007 Stock Option and Incentive Plan (the "2007 Plan") became effective and the Company's board of directors determined not to make any further grants under the 2000 Plan. Under the 2007 Plan, awards may be granted to persons who are, at the time of grant, employees, officers, non-employee directors or key persons (including consultants and prospective employees) of the Company. The 2007 Plan provides for the granting of stock options, stock appreciation rights, deferred stock awards, restricted stock, unrestricted stock, cash based awards, performance share awards or dividend equivalent rights. The Company has reserved 535,000 shares of common stock for issuance under the 2007 Plan, which amount will be increased on January 1, 2008, and on each January 1 thereafter through January 1, 2012, by a number of shares equal to 3% of the number of shares of common stock of the Company outstanding as of the immediately preceding December 31, up to the maximum increase of 725,000 additional shares per year. In addition, each share of deferred stock, restricted stock, unrestricted stock or performance shares awarded under the 2007 Plan will count as 1.5 shares against the total pool of shares available for issuance thereunder.

### ***2007 Employee Stock Purchase Plan***

On May 18, 2007, upon the closing of the Company's initial public offering, the Company's 2007 Employee Stock Purchase Plan became effective. The Company's 2007 Employee Stock Purchase Plan authorizes the issuance of up to a total of 380,000 shares of the Company's common stock to participating employees.

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

*You should read the following discussion of our financial condition and results of operations in conjunction with our selected financial data, our financial statements and the accompanying notes to those financial statements included in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

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

Since inception, we have devoted substantially all of our efforts to designing and developing the OmniPod System, raising capital and recruiting personnel. As a result, we were considered a development stage company pursuant to Statement of Financial Accounting Standards ("SFAS") No. 7, *Accounting and Reporting by Development Stage Enterprises*, through December 31, 2005. The year 2006 was the first year during which we were an operating company and were no longer in the development stage. In October 2005, we shipped our first commercial OmniPod System. Since October 2005, in order to align the demand for the OmniPod System with our capacity to manufacture the OmniPod, we have engaged in limited marketing efforts focused in the Eastern United States and with some key diabetes practitioners, academic centers and clinics elsewhere in the United States. Our total revenues were \$2.0 million for the three months ended March 31, 2007. As of March 31, 2007, we have approximately 1,750 patients using the OmniPod System in the United States.

At present, the expansion of our business is constrained by our current capacity to manufacture the OmniPod insulin infusion device, and our primary near-term goal is to expand our manufacturing volume for OmniPods. Currently, the sale price of the OmniPod System is not sufficient to cover our direct manufacturing costs. We are in the process of completing the construction, testing and installation of automated manufacturing equipment to be used in the assembly of the OmniPod in order to increase our manufacturing volume. Increased volumes will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs.

During 2008, we expect to complete the planned automation of our existing manufacturing line, which is designed exclusively for the manufacture of the OmniPod, and begin construction of a second manufacturing line. Pending construction and installation of the remaining automated manufacturing equipment that we plan to use, we are manually performing these steps in the manufacturing process, which limits our ability to increase our manufacturing capacity and decrease our per unit cost of goods sold, thereby causing us to incur negative gross margins. We are exploring alternative site manufacturing capabilities both domestically and abroad. No assurances can be given that we will successfully complete the planned automation of our existing manufacturing line or subsequent lines in the future or otherwise reduce the per unit cost of manufacturing the OmniPod. Failure to do so would limit our production capacity and not allow us to achieve per unit cost improvements, which could severely constrain our ability to achieve profitability. On January 3, 2007, we entered into a non-exclusive contract manufacturing agreement with a subsidiary of Flextronics International Ltd. for the supply of a sub-assembly of some of the OmniPod's components. Under this agreement, we provides to Flextronics, on a monthly basis, a rolling 12-month forecast indicating our monthly requirements. The first 90 days of such forecast constitutes our written purchase order for all work to be completed by Flextronics during that period.

Additionally, 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. As of March 31, 2007, we had entered into contracts establishing reimbursement for the OmniPod System with national and regional third-party payors covering an estimated 92 million lives, and we believe that substantially all of the units sold have been reimbursed by third-party payors,

subject to applicable deductible and co-payment amounts. As we expand our sales and marketing focus and increase our manufacturing capacity, we will need to maintain and expand available reimbursement for the OmniPod System.

Since our inception in 2000, we have incurred losses every quarter. In the three months ended March 31, 2007, we incurred a net loss of \$11.6 million compared to a net loss of \$6.9 million for the same period in 2006. As of March 31, 2007, we had an accumulated deficit of \$113.6 million. We have financed our operations through the private placement of equity securities and secured indebtedness. As of March 31, 2007, we had \$30.0 million of secured debt outstanding, and, since inception, we have received net proceeds of \$119.5 million from the issuance of redeemable convertible preferred stock.

On May 18, 2007, we issued and sold 7,700,000 shares of common stock at a price to the public of \$15.00 per share. On June 12, 2007, we issued and sold an additional 665,000 shares of common stock at a price to the public of \$15.00 per share pursuant to the underwriters' partial exercise of their over-allotment option. In connection with the IPO, we received total gross proceeds of \$125.5 million, or approximately \$113.8 million in net proceeds after deducting underwriting discounts and offering commissions.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts for the remainder of 2007 will be focused primarily on expanding our manufacturing capacity, reducing our per unit production costs and expanding our sales and marketing efforts for the OmniPod System. The expansion of our manufacturing capacity will allow us to increase production volumes which will help us to achieve lower material costs due to volume purchase discounts and improve the absorption of manufacturing overhead costs. Achieving these objectives is expected to require additional investments in manufacturing and additional hiring of sales and administrative personnel with the goal of increasing our market penetration. We believe that we will continue to incur net losses in the near term in order to achieve these objectives, although we believe that the accomplishment of these combined efforts will have a positive impact on our financial condition in the future.

### **Financial Operations Overview**

*Revenues.* Revenues are recognized in accordance with Securities and Exchange Staff Accounting Bulletin No. 104, or SAB 104 and Statement of Financial Accounting Standards No. 48, *Revenue Recognition when the Right of Return Exists*, or SFAS 48. We derive all of our revenues from the sale of the OmniPod System directly to 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, or 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. Revenues are derived from the sale to new customers of OmniPods and Starter Kits, which include the PDM, two OmniPods, the OmniPod System User Guide and our Interactive Training CD, and from the follow-on sales of OmniPods to existing customers. Customers generally order a three-month supply of OmniPods. Our first commercial shipment was in October 2005, and we recognized no revenue before this time. During the years ended December 31, 2005 and 2006, all of our revenues were derived from sales within the United States. During that period, we deferred recognition of revenue from the OmniPods and Starter Kit shipped as part of a customer's initial shipment for thirty days during which time the items could be returned and completely refunded (we changed prospectively to a forty-five day right of return effective for shipments subsequent to December 1, 2006). We deferred revenue of \$679,000 in the quarter ended March 31, 2007.

For the remainder of 2007, we expect our revenues to increase, but we expect that this increase will continue to be limited by our OmniPod manufacturing capacity. We expect our OmniPod manufacturing capacity to grow as we continue the process of automating our OmniPod manufacturing process, but we do not expect the most significant increase in manufacturing capacity to occur until substantially all of the OmniPod manufacturing process is automated. Currently, our manufacturing capacity is approximately 30,000 OmniPods per month, and we expect our manufacturing capacity to increase five to seven fold over this level upon the completion of the planned automation of our current manufacturing line during 2008. However, we are still in the process of designing and testing the custom equipment that we will need in order to automate our OmniPod manufacturing process, and we cannot be assured that our efforts will be successful or that the expected increases will be realized. Additionally, increased revenues will be dependent upon the success of our sales efforts and subject to many risk and uncertainties.

*Cost of revenues.* Cost of revenues consists primarily of raw material, labor, warranty and overhead costs related to the OmniPod System. Cost of revenues also includes depreciation, distribution, and freight and packaging costs. Currently, the sale price of the OmniPod System is not sufficient to cover the direct manufacturing costs. Accordingly, inventory has been adjusted down to reflect the values at the lower of cost or market. For the remainder of 2007, we expect the cost of revenues to decrease as a percentage of revenues due to expected reductions in per unit raw materials costs associated with volume purchase discounts and increases in our OmniPod manufacturing capacity as our OmniPod manufacturing process becomes more automated. The increase in our OmniPod manufacturing capacity is expected to reduce the per unit cost of manufacturing the OmniPods by allowing us to spread our fixed and semi-fixed overhead costs over a greater number of units. However, if sales volumes do not increase or we are not successful in our efforts to fully automate the OmniPod manufacturing process, then the average cost of revenues per OmniPod may not decrease and we may continue to realize negative gross margins.

*Research and development.* Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical functions, and the costs of market studies and product development projects. We expense all research and development costs as incurred. For the remainder of 2007, we expect overall research and development spending to increase to support our current research and development efforts, which are focused primarily on increased functionality, design for ease of use and reduction of production cost, as well as developing a new OmniPod System that incorporates continuous glucose monitoring technology.

*Sales and marketing.* Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support, customer support and training functions, sales commissions paid to our sales representatives and costs associated with participation in medical conferences, physician symposia and promotional activities, including distribution of units used in our demonstration kit programs. In 2007, we expect sales and marketing expenses to more than double compared to 2006 as we hire additional sales and marketing personnel, incur additional sales commission expense related to sales growth and expand our sales and marketing efforts, which will include the implementation of broader direct-to-consumer marketing programs and the roll-out of our Patient Demonstration Kit Program.

*General and administrative.* General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, finance, information technology and human resource functions, as well as legal fees, accounting fees, insurance costs and facilities-related costs. We expect general and administrative expenses to increase as we increase personnel and become subject to reporting requirements as a publicly-held company.

*Stock based compensation expense.* Prior to January 1, 2006, we accounted for our stock option plan under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations, as permitted by the Financial Accounting Standards Board Statement No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS Statement No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R, using the prospective method and therefore we have not restated our financial results for prior periods.

## Results of Operations

The following table presents certain statement of operations information for the three months ended March 31, 2007 and 2006:

	Three Months Ended March 31,		% Change
	2007	2006	
	(In thousands)		
Revenues	\$ 2,008	\$ 222	805%
Cost of revenues	4,572	2,753	66%
Gross loss	(2,564)	(2,531)	1%
Operating expenses:			

	Three Months Ended March 31,		% Change
	2007	2006	
	(In thousands)		
Research and development	2,470	1,750	41%
General and administrative	2,660	1,553	71%
Sales and marketing	3,104	1,072	190%
Total operating expenses	<u>8,234</u>	<u>4,375</u>	<u>88%</u>
Loss from operations	(10,798)	(6,906)	56%
Other income (expense), net	<u>(762)</u>	<u>(34)</u>	
Net loss	<u>\$ (11,560)</u>	<u>\$ (6,940)</u>	<u>\$ 67%</u>

#### **Comparison of the Three Months Ended March 31, 2007 and March 31, 2006**

##### *Revenues*

Our total revenues were \$2.0 million for the three months ended March 31, 2007 as compared to \$221,600 for the three months ended March 31, 2006. The increase in revenues is due to the increase in customers from approximately 155 at March 31, 2006 to approximately 1,750 at March 31, 2007. As we continue our sales and marketing efforts into 2007, we expect our revenues to increase, but this increase will continue to be limited by our OmniPod manufacturing capacity.

##### *Cost of Revenues*

Cost of revenues for the three months ended March 31, 2007 was \$4.6 million as compared to \$2.7 million for the three months ended March 31, 2006. The increase is due to the increased sales volume. Cost of revenues include inventory write down and indirect costs. Since the OmniPods are sold at a price below direct manufacturing costs, inventory was adjusted down \$767,000 for the quarter ending March 31, 2007 to reflect values at the lower of cost or market. The per unit cost to manufacture the OmniPod has decreased at March 31, 2007 from the same period in 2006. This decrease is associated with a reduced cost of raw materials and increased volumes which improved the absorption of manufacturing overhead costs.

##### *Research and Development*

Research and development expense increased \$720,000, or 40.8%, to \$2.5 million for the three months ended March 31, 2007 from \$1.8 million for the three months ended March 31, 2006. The increase in research and development expense was primarily attributable to an increase of \$364,000 in employee related expenses associated with the hiring of additional employees, \$226,000 in prototype expenses \$93,000 in temporary employees, and \$37,000 in tools and supplies.

##### *General and Administrative*

General and administrative expenses increased \$1.1 million, or 71.3%, to \$2.7 million for the three months ended March 31, 2007 from \$1.6 million for the three months ended March 31, 2006. The increase in expenses was primarily due to an increase of \$553,000 in employee compensation and benefit costs associated with the hiring of additional employees, \$313,000 in consulting and legal expenses, \$111,000 in bad debt expense and \$86,000 in increased depreciation expense.

##### *Sales and Marketing*

Sales and marketing expenses increased \$2.0 million, or 189.7%, to \$3.1 million for the three months ended March 31 2007, from \$1.1 million for the same period in 2006. The increase in expenses was primarily due to an

increase of \$1.0 million in demonstration kit units, \$498,000 in employee compensation and benefit costs resulting from the hiring of additional employees in our sales and marketing department, \$268,000 in travel, printing and tradeshow expenses used to support our selling efforts and \$217,000 in marketing consultants which include our external trainers.

*Other Income (Expense)*

Interest income was \$304,000 and \$235,000 during the three months ended March 31, 2007 and 2006, respectively. This represents an increase of \$69,000. Interest income was earned from investments in cash and cash equivalents. Interest expense was \$982,000 and \$269,000 during the three months ended March 31, 2007 and 2006, respectively. This represents an increase of \$714,000. The increase in interest expense was attributable to the interest expense on the \$30.0 million term loan from a group of lenders led by Merrill Lynch Capital that we entered into in December 2006. In addition, we recorded \$84,000 of other expense for the three months ended March 31, 2007 to reflect any increases in the estimated fair value of the warrants, which resulted from our adoption of Financial Accounting Standards Board Staff Position 150-5.

**Liquidity and Capital Resources**

We commenced operations in 2000 and have financed our operations through the private placement of equity securities and secured indebtedness. As of March 31, 2007, we had \$30.0 million of secured debt outstanding. Since inception, we have received net proceeds of \$119.5 million from the issuance of redeemable convertible preferred stock. As of March 31, 2007, we had \$19.1 million in cash and cash equivalents. We believe that our current cash and cash equivalents, including the net proceeds from our public offering, together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next twelve months.

On May 18, 2007, we issued and sold 7,700,000 shares of common stock at a price to the public of \$15.00 per share. On June 12, 2007, we issued and sold an additional 665,000 shares of common stock at a price to the public of \$15.00 per share pursuant to the underwriters' partial exercise of their over-allotment option. In connection with the IPO, we received total gross proceeds of \$125.5 million, or approximately \$113.8 million in net proceeds after deducting underwriting discounts and offering commissions.

We intend to use the proceeds from our offering for general corporate purposes, which may include the completion and improvement of our existing automated manufacturing line and the construction of a second automated line to increase our manufacturing capacity, the expansion of our sales and marketing activities, and the funding of research and development.

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

	<u>Three Months Ended March 31,</u>	
	<u>2007</u>	<u>2006</u>
	(Unaudited)	
	(In thousands)	
Cash used in operating activities	\$(11,865)	\$(4,899)
Net loss	\$(11,560)	\$(6,940)

For each of the periods above, net cash used in operating activities was attributable primarily to net losses after adjustment for non-cash charges, such as depreciation, amortization and stock-based compensation expense. Significant uses of cash from operations include increases in accounts receivable and increased inventory requirements for production, offset by increases in accounts payable, accrued expenses and deferred revenue.

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

	Three Months Ended March 31,	
	2007	2006
	(Unaudited) (In thousands)	
Cash used in investing activities	\$(2,331)	\$ (3,992)
Cash provided by financing activities	\$ 41	\$49,821

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. Cash provided by financing activities in 2006 was primarily generated from the issuance of preferred stock.

In February 2006, we sold 13,738,661 shares of Series E preferred stock for net proceeds of \$49.8 million. In February 2004, we sold 14,669,421 shares of Series D preferred stock for net proceeds of \$35.4 million. All of these shares will convert into shares of common stock on a 1-for-2.6267 basis upon the closing of our initial public offering.

On June 2, 2005, we entered into a term loan and security agreement with Lighthouse Capital Partners V, L.P. pursuant to which we borrowed \$10.0 million. This term loan was secured by all of our assets other than our intellectual property. Our borrowings under the term loan bore interest at a rate of 8% per annum. Interest was payable on a monthly basis during the term of the loan and, beginning on June 1, 2006, we were required to repay the principal in 42 equal monthly installments until the loan matured in December 2009. Upon the prepayment or final maturity of the term loan, we were required to pay the lender an additional amount equal to \$1.0 million of the original loan amount. In connection with the term loan, we issued a warrant to the lender to purchase up to 330,579 shares of Series D preferred stock at a purchase price of \$2.42 per share. The warrant automatically converts into a warrant to purchase common stock on a 1-for-2.6267 basis at a purchase price of \$6.36 per share upon the closing of our initial public offering. The cost of the warrant is being amortized to interest expense over the 54 month life of this term loan. The fair value of the warrant was calculated using the Black-Scholes option pricing model with the following assumptions: seven year expected life risk-free, interest rate of 3.89% and no dividend yield. At March 31, 2006, there were 330,579 shares of common stock reserved for the exercise of the warrant. Accordingly, the discount on the long-term debt is being accreted over the repayment term of 42 months.

On December 27, 2006, we entered into a credit and security agreement with a group of lenders led by Merrill Lynch Capital pursuant to which we borrowed \$30.0 million in a term loan. We used \$9.5 million of the proceeds from this term loan to repay all remaining amounts owed under the loan with Lighthouse Capital Partners V, L.P. that we had entered into in June 2005. This term loan is secured by all of our assets other than our intellectual property. Our borrowings under the term loan bear interest at a floating rate equal to the LIBOR rate plus 6% per annum. Interest is payable on a monthly basis during the term of the loan and, beginning on October 1, 2007, we will be required to repay the principal in 33 equal monthly installments of \$909,091. In addition, we are subject to loan origination fees amounting to \$900,000 for the costs incurred by the lenders in making the funds available. We have capitalized these costs as deferred financing costs. The deferred financing cost will be amortized to interest expense over the entire 42-month life of this term loan. This term loan also is subject to acceleration upon the occurrence of any fact, event or circumstance that has resulted or could reasonably be expected to result in a material adverse effect. Consequently, such debt has been classified as a current liability at December 31, 2006 in accordance with the provisions set forth by *FASB Technical Bulletin No. 79-3 Subjective Acceleration Clauses in Long-Term Debt Agreements*. In connection with the term loan, we issued seven-year warrants expiring in December 2013 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 convert into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of \$9.56 per share upon the closing of our initial public offering.

The credit and security agreement contains limitations, subject to certain exceptions, on, among other things, our ability to incur additional indebtedness or liens, make dividends or distributions to our stockholders, repurchase shares of our stock, acquire or dispose of any assets other than in the ordinary course of business, make investments in other entities, merge or consolidate with another entity or engage in a change of control, a new business or a non-arms' length transaction with one of our affiliates. Additionally, under the agreement, we are obligated to complete construction of a second OmniPod manufacturing line by March 31, 2009, which deadline may be extended to June 30, 2009 in specified circumstances. If we are not in compliance with these covenants, breach any representation or warranty in the credit and security agreement, default in any payment due under the credit and security agreement or related promissory notes or any other indebtedness above a specified amount, fail to

discharge a judgment against us above a specified amount, cease to be solvent or experience other insolvency related events, then the administrative agent may declare all of the amounts owed under the term loan immediately due and payable.

We lease our facilities, which are accounted for as operating leases. The lease generally provides for a base rent plus real estate taxes and certain operating expenses related to the lease. We entered into a new lease in 2004 which contains renewal options, escalating payments and leasehold allowances over the life of the lease. As of March 31, 2007, we had an outstanding letter of credit which totaled \$200,000 to cover our security deposits for lease obligations. This letter of credit will expire October 30, 2009.

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

As of March 31, 2007, 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 revenue from the sale of its OmniPod Insulin Management System to diabetes patients. The initial sale to a new customer typically includes OmniPods and a Starter Kit, which include the Personal Diabetes Manager (“PDM”), two OmniPods, the OmniPod System User Guide and the OmniPod System Interactive Training CD. We offer a 30-day right of return for our Starter Kits sales (we changed prospectively to a 45-day right of return effective for shipments subsequent to December 1, 2006). Subsequent sales to existing customers typically consist of OmniPods sales. Revenues are recognized in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements* (“SAB 104”), which requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

- The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval.
- Transfer of title and risk and rewards of ownership are passed to the patient upon shipment from us.
- The selling prices for all sales are fixed and agreed with the patient, and if applicable, the patient’s third-party insurance provider(s) prior to shipment and are based on established list prices or, in the case of certain third-party insurers, contractually agreed upon prices.

We have considered the requirements of Emerging Issues Task Force (“EITF”) No. 00-21, *Revenue Arrangements with Multiple Deliverables*, when accounting for the OmniPods and Starter Kits. EITF 00-21 requires that we assess whether the different elements qualify for separate accounting. We recognize revenue for the Starter Kits once all elements have been delivered and the right of return has expired.

We have applied Statement of Financial Accounting Standards (“SFAS”) No. 48, *Revenue Recognition When the Right of Return Exists*. In accordance with SFAS No. 48, we defer the revenue and, to the extent allowed, all related costs of all initial shipments until the right of return has lapsed. We have deferred revenue of \$679,000 and \$284,000 as of March 31, 2007 and December 31, 2006, respectively.

We recognize subsequent sales of OmniPods upon shipment in accordance with the provisions set forth by SAB 104.

#### **Product Warranty Costs**

We provide a four-year warranty on the PDM and we replace any OmniPods that do not function in accordance with product specifications. Warranty expense is recorded in the period the shipment occurs. The expense is based on historical experience, and the estimated cost to service the claims. While we engage in extensive product quality programs and processes, our warranty obligation is affected by product failure rates, user error, variability in physiology and anatomy of our customers, material usage and delivery costs. Should actual product failure and user error rates, material usage or delivery costs differ from our estimates, the amount of actual warranty costs could materially differ from our estimates.

#### **Inventories**

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. Costs for the OmniPod System include raw material, labor and manufacturing overhead. Market value is determined as the lower of replacement cost or net realizable value. Currently, the value of inventories is below the cost of manufacturing the OmniPod System; therefore, all labor, overhead and excess materials costs are expensed as incurred and inventory is valued at net realizable value.

#### **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. Accounts receivable consist of amounts due from third-party payors and patients. We account for bad debts using the allowance method. The bad debt allowances are recorded in the period when the revenue is recorded. Due to our limited operational history, the allowance is based upon competitive benchmarks and is adjusted currently for any changes in estimated collections. Should current market and economic conditions deteriorate, our actual bad debt experience could exceed our estimate. Fixed property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. We review long-lived assets, including property and equipment and intangibles, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value. We consider various valuation factors, principally discounted cash flows, to assess the fair values of long-lived assets

#### **Income Taxes**

In June 2006, the FASB issued FASB Interpretation (“FIN”) No. 48, *Accounting for Uncertainty in Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in an entity’s financial statements in accordance with SFAS No. 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on our financial position or results of operations. Upon adoption and as of March 31, 2007, we have no unrecognized tax benefits recorded.

## Stock Based Compensation

Effective January 1, 2006, we adopted SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R, which is a revision of Statement No. 123, *Accounting for Stock Based Compensation*. SFAS 123R supersedes Accounting Principles Board No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and amends Financial Accounting Standards Board, or FASB, Statement No. 95 *Statement of Cash Flows*. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Prior to January 1, 2006, we accounted for employee stock based compensation in accordance with the provisions of APB 25 and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation — an Interpretation of APB No. 25*, and complied with the disclosure provisions of SFAS 123, and related SFAS No. 148, *Accounting for Stock-Based Compensation — Transaction and Disclosure*. Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the stock and the exercise price of the option. The stock based compensation is amortized using the straight-line method over the vesting period.

SFAS 123R requires nonpublic companies that used the minimum value method in SFAS 123R for either recognition or pro forma disclosures to apply SFAS 123R using the prospective-transition method. As such, we will continue to apply APB 25 in future periods to equity awards outstanding at the date of SFAS 123R's adoption that were measured using the minimum value method. In accordance with the requirements of SFAS 123R, we will not present pro forma disclosures for periods prior to the adoption of SFAS 123R, as the estimated fair value of our stock options granted through December 31, 2005 was determined using the minimum value method.

Effective January 1, 2006 with the adoption of SFAS 123R, we elected to use the Black-Scholes option pricing model to determine the weighted-average fair value of options granted. In accordance with SFAS 123R, we will recognize the compensation expense of share-based awards on a straight-line basis over the vesting period of the award. Stock based compensation expense recognized under SFAS 123R for the three months ended March 31, 2007 was \$209,000.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. We do not have a history of market prices of our common stock as we are not a public company, and as such, we estimate volatility in accordance with Securities and Exchange Commission's Staff Accounting Bulletin No. 107, *Share-Based Payment*, or SAB 107, using historical volatilities of similar public entities. The expected life of the awards is estimated based on the "SEC Shortcut Approach" as defined in SAB 107, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of the awards. The dividend yield assumption is based on company history and expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock based compensation expense recognized in the financial statements in 2006 and thereafter is based on awards that are ultimately expected to vest. We evaluate the assumptions used to value the awards on a quarterly basis and if factors change and different assumptions are utilized, stock based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock based compensation expense.

The assumptions used in the Black-Scholes option-pricing model are as follows:

	<b>Year Ended December 31, 2006</b>
Dividend yield	0.00%
Expected volatility	67.00%
Risk-free interest rate	4.81%
Expected life (in years)	6.25

Prior to April 1, 2006, the exercise prices for options granted were set by our board of directors based upon guidance set forth by the American Institute of Certified Public Accountants, or the AICPA, in the AICPA Technical Practice Aid, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation," or the AICPA Practice Aid. To that end, our board of directors considered a number of factors in determining the option price, including the following factors: (1) prices for our preferred stock, which we had sold to outside investors in arms-length transactions, and the rights, preferences and privileges of our preferred stock and common stock in the Series A through Series E financing, (2) obtaining FDA 510(k) clearance, (3) launching the OmniPod System and (4) achievement of budgeted revenue and results.

In connection with the preparation of the financial statements for our initial public offering, we retrospectively estimated the fair value of our common stock based upon several factors, including the following factors: (1) operating and financial performance, (2) progress and milestones attained in the business, (3) past sales of convertible preferred stock, (4) the results of retrospective independent valuations, and (5) the expected valuation obtained in an initial public offering. We believe this to have been a reasonable methodology based on the factors above and based on several arm's-length transactions involving our stock supportive of the results produced by this valuation methodology.

See note 8 to our consolidated financial statements included in this Quarterly Report on Form 10-Q for a summary of the stock option activity under our employee stock based compensation plan.

## Warrants

In connection with the term loans with Lighthouse Capital Partners and a group of lenders led by Merrill Lynch Capital, we issued warrants to the lenders to purchase shares of its redeemable convertible preferred stock. These warrants have been recorded as "preferred stock warrant liability" in current liabilities in accordance with FASB Statement No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity* and FASB Staff Position No. 150-5 *Issuer's Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable*.

Significant terms and fair values of warrants to purchase redeemable convertible preferred stock are as follows (in thousands except share and per share data):

Stock	Expiration Date	Exercise Price Per Share	Shares as of		Fair Value as of	
			March 31, 2007	December 31, 2006	March 31, 2007	December 31, 2006
Series D preferred	June 2, 2012	\$ 2.42	330,579	330,579	\$ 1,150	\$ 1,096
Series E preferred	December 27, 2013	3.64	247,252	247,252	865	835
<b>Total</b>			<b>577,831</b>	<b>577,831</b>	<b>\$ 2,015</b>	<b>\$ 1,931</b>

All warrants automatically converted upon the closing our initial public offering into warrants to purchase shares of common stock on a 1-for-2.6267 basis at an exercise price of \$6.36 per share in the case of the Series D warrant and an exercise price of \$9.56 per share in the case of the Series E warrants.

We recorded the \$251,000 and \$835,000 fair value of the warrants for Series D and Series E preferred stock, respectively as a discount to the term loans.

The fair value of the Series D and Series E warrants was calculated as of March 31, 2007, using the Black-Scholes option-pricing model with the following assumptions: 5.25 (Series D) and 6.75 year (Series E) expected lives, risk-free interest rate of 4.54% (Series D) and 4.58% (Series E), expected volatility of 67.00%, and no dividend yield. The fair value of the Series D and Series E warrants was calculated as of December 31, 2006, using the Black-Scholes option-pricing model with the following assumptions: 5.5 (Series D) and 7 year (Series E) expected lives, risk-free interest rate of 4.70%, expected volatility of 71.36%, and no dividend yield.

We recorded \$84,000 of other expense for the three months ended March 31, 2007 to reflect increases in the estimated fair value of the warrants during the period.

Upon the closing of our initial public offering on May 18, 2007, all outstanding warrants to purchase shares of our preferred stock automatically converted into warrants to purchase shares of our common stock and, as a result, will no longer be subject to FSP 150-5 for periods ended or ending on or after that date. The aggregate fair value of these warrants as of May 18, 2007, after a final remeasurement of fair value, will be reclassified from liabilities to additional paid-in capital, a component of stockholders' equity, and we will cease to record any related periodic fair value adjustments.

### **Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. We will be required to adopt SFAS 157 in the first quarter of 2008. We are currently evaluating the requirements of SFAS 157 and have not yet determined the impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *Fair Value Option for Financial Assets and Financial Liabilities – Including an amendment of FASB Statement 115* ("SFAS 159"), which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. We are currently evaluating if we will elect the fair value option for any of our eligible financial instruments and other items.

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

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

### **Item 4T. Controls and Procedures**

#### **Disclosure Controls and Procedures**

Management conducted an evaluation, as of March 31, 2007, 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) under the supervision and with the participation of our chief executive officer and chief financial officer. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. Based upon that evaluation, our chief executive officer and chief financial officer have concluded that they believe that as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2007 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.

We are not currently subject to any material pending legal proceedings.

### Item 1A. Risk Factors

*You should carefully consider the risk factors set forth below as well as the other information contained in this Quarterly Report on Form 10-Q. Any of the following risks could materially and adversely affect our business, financial condition or results of operations. In such a case, you may lose all or part of your investment. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial may also materially adversely affect our business, financial condition or results of operations.*

#### Risks Relating to Our Business

***We have incurred significant operating losses since inception, our independent registered public accounting firm has issued an opinion expressing substantial doubt about our ability to continue as going concern and we are currently selling the OmniPod System at a loss 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 and we are currently not able to manufacture and sell the OmniPod System at a cost and in volumes sufficient to allow us to achieve profitability. For the quarter ended March 31, 2006 and 2007, our gross losses from the manufacture and sale of the OmniPod System were \$2.5 million and \$2.6 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, including a net loss of \$11.6 million for the quarter ended March 31, 2007. As of March 31, 2007, we had an accumulated deficit of \$113.6 million. As we have grown our business, our net loss has increased each quarter and we expect our rate of loss to continue to increase on a quarterly basis at least into 2008.

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

Our sole product is the OmniPod System, which we introduced to the market in October 2005. We expect to derive substantially all of our revenue from the sale of this product. Accordingly, our ability to generate revenues 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 acceptance among opinion leaders in the diabetes treatment community, insulin-prescribing physicians, third-party payors and people with insulin-dependent diabetes;
- manufacturing 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;

- 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 revenues could be significantly reduced.

***Our ability to achieve profitability from a current net loss level will depend on our ability to reduce the per unit cost of manufacturing the OmniPod through the successful implementation of our automated manufacturing strategy or otherwise.***

Currently, the sale price of the OmniPod System is not sufficient to cover our direct manufacturing costs. We are in the process of completing the construction, testing and installation of automated manufacturing equipment to be used in the assembly of the OmniPod in order to increase our manufacturing volume. Increased volumes will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs. During 2008, we expect to complete the planned automation of our existing manufacturing line, which is designed exclusively for the manufacture of the OmniPod, and begin construction of a second manufacturing line. Pending construction and installation of the remaining automated manufacturing equipment that we plan to use, we are manually performing these steps in the manufacturing process, which limits our ability to increase our manufacturing capacity and decrease our per unit cost of goods sold, thereby causing us to incur negative gross margins. We are also exploring alternative site manufacturing capabilities in Asia. We cannot assure you that we will successfully complete the planned automation of our existing manufacturing line or subsequent lines in the future or otherwise reduce the per unit cost of manufacturing the OmniPod. Failure to do so would limit our production capacity and our ability to reduce raw material and manufacturing overhead costs. 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.

***Our manufacturing operations 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. Each of these suppliers is a sole-source supplier. In addition, we have entered into a contract manufacturing agreement with a subsidiary of Flextronics International Ltd. in China for the supply of a sub-assembly of some of the OmniPod's components. We do not have long-term supply agreements with the suppliers of most of our components, and, in most cases, we purchase these components 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. 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 components 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 components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or replacement suppliers, particularly for our sole-source components, in part because of the FDA approval process and because of the custom nature of various parts we require. Any interruption or delay in the supply of components, or our inability to obtain components 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.

***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. As of March 31, 2007, we had entered into contracts establishing reimbursement for the OmniPod System with national and regional third-party payors covering an estimated 92 million lives. These contracts provide reimbursement in each of the 26 states in which we currently sell the OmniPod System. While we anticipate entering into additional contracts with other third-party payors doing business in these states, 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 are in the process of seeking appropriate coding verification for Medicare reimbursement of the OmniPod System. As a result, we have decided to focus our initial efforts in establishing reimbursement for the OmniPod System by negotiating contracts with private insurers. Failure to secure or retain adequate coverage or reimbursement for the OmniPod System by third-party payors could have a material adverse effect on our business, financial condition and results of operations.

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

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The OmniPod System competes with a number of existing insulin delivery devices as well as other methods for the treatment of diabetes. Medtronic MiniMed, a division of Medtronic, Inc., has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States are Animas Corporation, a division of Johnson & Johnson, and Deltec, a division of Smiths Medical MD, Inc. In October 2006, following the lifting of an FDA ban on the import of Disetronic insulin pumps, Roche Disetronic, a division of Roche Diagnostics, announced its re-entry into the conventional insulin pump market in the United States.

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

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage;
- 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.

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

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

The diabetes treatment market is subject to rapid technological change and product innovation. The OmniPod System is based on our proprietary technology, but a number of companies, medical researchers and existing pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and/or prevention of insulin-dependent diabetes. For example, FDA approval of a commercially viable "closed-loop" system that combines continuous "real-time" glucose sensing or monitoring and automatic continuous subcutaneous insulin infusion in a manner that delivers appropriate amounts of insulin on a timely basis without patient direction could have a material adverse effect on our revenues and future profitability. We have an agreement with Abbott Diabetes Care, Inc., a global healthcare company that develops continuous glucose monitoring technology, to develop a product that will integrate the receiver portion of Abbott's continuous glucose monitor, the FreeStyle Navigator, with the OmniPod System PDM. The FreeStyle Navigator is currently pending FDA approval and is not available on the market. Medtronic, Inc. has developed an FDA-approved product combining continuous glucose sensing and CSII therapy and if we fail to do so, we may be at a significant competitive disadvantage, which could negatively impact our business. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve the treatment of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could render the OmniPod System obsolete, which may have a material adverse effect on our business, financial condition and results of operations.

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

Our rights to incorporate the FreeStyle blood glucose meter into the OmniPod System are governed by a development and license agreement with Abbott Diabetes Care, Inc., as the successor to TheraSense, Inc. This agreement provides us with a non-exclusive, fully paid, non-transferable and non-sublicensable license in the United States under patents and other relevant technical information relating to the FreeStyle blood glucose meter during the term of the agreement. The term of the agreement is for seven years, with automatic renewals for subsequent three-year periods unless either party provides written notice of termination at least 90 days prior to the scheduled expiration of the then-current term. The current term is scheduled to expire in January 2009. The agreement may also 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.

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

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

Our success will depend in part on our continued ability to develop or acquire commercially-valuable patent rights and to protect these rights adequately. Our patent position is generally uncertain and involves complex legal and factual questions. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

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

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

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

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

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

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

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

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

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

Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

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

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that we could be increasingly subject to third-party infringement claims as our revenues increase, the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe. For example, we are aware of certain patents and patent applications owned by our

competitors that cover different aspects of insulin infusion and the related devices. Any of these third parties might make a claim of infringement against us. In particular, Medtronic, Inc., in a letter dated March 13, 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. While we believe that the OmniPod System does not infringe these patents, we would consider resolving the matter on reasonable terms. If we are unable to reach agreement with Medtronic, Inc. on this matter, they may sue us for infringement. We believe we would have meritorious defenses to any such suit. Any litigation, regardless of its outcome, would likely result in the expenditure of significant financial resources and the diversion of management’s time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition or results of operations.

***We are subject to extensive regulation by the U.S. Food and Drug Administration, which could restrict the sales and marketing of the OmniPod System and could cause us to incur significant costs.***

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement or refunds

- voluntary or mandatory recall or seizure of our current or future products;
- administrative detention by the FDA of medical devices believed to be adulterated or misbranded;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses or modifications to the OmniPod System;
- rescinding 510(k) clearance or suspending or withdrawing pre-market approvals that have already been granted; and
- criminal prosecution.

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

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

We 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 component suppliers' facilities would pass any future quality system inspection. If our or any of our component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our devices could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our packaging and labeling operations or the manufacturing operations of our contract manufacturers, or a recall of our devices. If any of these events occurs, we may not be able to provide our customers with the quantity of OmniPods they require on a timely basis, our reputation could be harmed and we could lose customers, any or all of which may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales

programs, we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Because we may provide some coding and billing information to purchasers of the OmniPod System, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. In addition, these laws are potentially applicable to us because we provide reimbursement to healthcare professionals for training patients on the use of the OmniPod System. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

A key to driving our revenue growth is the retention of a high percentage of our customers. We have developed retention programs aimed at both the healthcare professionals and the patients, which include appeals assistance, patient training, 24/7 customer support and an automatic re-order program for patients. Since we began shipping the OmniPod System in October 2005, we have had a very high customer retention rate; however, we cannot assure you that we will maintain this retention rate in the future. 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 intend 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 intend to sponsor market studies to assess various aspects of its functionality and its relative efficacy. The data obtained from the studies may be unfavorable to the OmniPod System or may be inadequate to support satisfactory conclusions. In addition, in the future we may sponsor clinical trials to assess certain aspects of the efficacy of the OmniPod System. If future clinical trials fail to support the efficacy of our current or future products, our sales may be adversely affected and we may lose an opportunity to secure clinical preference from prescribing clinicians, which may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

- failure to fulfill foreign regulatory requirements on a timely basis or at all to market the OmniPod System or other future products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- adapting to the differing laws and regulations, business and clinical practices, and patient preferences in foreign countries;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign distributors or sales or marketing agents;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in economies outside of the United States;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences.

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

***All of our operations are currently conducted at a single location and any disruption at our facility could increase our expenses.***

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

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

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

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

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

To date, we have focused our sales and marketing efforts in the Eastern United States. As we expand our sales into the balance of the United States and internationally, we will need to obtain coverage contracts with additional third-party payors in those areas. Failure to obtain such contracts would limit our ability to successfully penetrate those areas. In addition, the geographic expansion of our business will require additional manufacturing capacity to supply those markets as well as additional sales and marketing resources.

We expect to significantly increase our manufacturing capacity, our personnel and the scope of our sales and marketing efforts on a phased basis into the rest of the United States and internationally. This growth, as well as any other growth that we may experience in the future, will provide challenges to our organization and may strain our management and operations. In order to manage future growth, we will be required to improve existing, and implement new, management systems, sales and marketing efforts and distribution channels. We may also need to partner with additional third-party suppliers to manufacture certain components of the OmniPod System and complete the planned automation of our existing line as well as subsequent lines in the future. A transition to new suppliers may result in additional costs or delays. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to

manufacture sufficient inventory or attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver the OmniPod System in a timely manner and our results of operations may be adversely affected.

***Our future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.***

We believe that our current cash and cash equivalents, including the proceeds from our initial public offering in May 2007, together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 12 months. However, we may seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. Our capital requirements will depend on many factors, including:

- revenues generated by sales of the OmniPod System and any other future products that we may develop;
- costs associated with adding further manufacturing capacity;
- costs associated with expanding our sales and marketing efforts;
- 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.

As a result of these factors, we may need to raise additional funds, and these funds may not be available on favorable terms, or at all. Furthermore, 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. If we cannot raise funds on acceptable terms, we may not be able to enhance the OmniPod System or 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 may experience significant fluctuations in our quarterly results of operations.***

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

- delays in shipping due to capacity constraints;
- practices of health insurance companies and other third-party payors with respect to reimbursement for our current or future products;

- market acceptance of the OmniPod System;
- our ability to manufacture the OmniPod efficiently;
- timing of regulatory approvals and clearances;
- new product introductions;
- competition; and
- timing of research and development expenditures.

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

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

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

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

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

- dilutive issuances of equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;

- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which in future periods may result in significant charges to earnings.

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

***Our credit and security agreement contains restrictions and covenants that may limit our operating flexibility and which, if violated, could result in the acceleration of the amounts due under this agreement.***

On December 27, 2006, we entered into a credit and security agreement with a group of lenders led by Merrill Lynch Capital pursuant to which we borrowed \$30.0 million in a term loan. This term loan is secured by all of our assets other than our intellectual property. The credit and security agreement imposes certain limitations on us, including limitations on our ability to do the following, subject to certain exceptions:

- transfer all or any part of our businesses or properties, other than transfers done in the ordinary course of business;
- engage in any business other than the business of designing, manufacturing, distributing and selling drug delivery devices and providing associated services or a reasonably related business;
- merge or consolidate with or into any other business organization;
- suffer or permit a change of control;
- incur additional indebtedness;
- incur liens with respect to any of our properties;
- pay dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock;
- directly or indirectly acquire or own, or make any investment in, any entity;
- directly or indirectly enter into or permit to exist any transaction with any of our affiliates except transactions that are on terms that are no less favorable to us than would be obtained in an arm's length transaction with a non-affiliate;
- acquire any assets other than in the ordinary course of business;
- incur any liability for rental payments except in the ordinary course of business; or
- enter into any sale and leaseback transaction.

Additionally, under the agreement, we must complete construction of a second manufacturing line for the OmniPods by March 31, 2009, which deadline may be extended to June 30, 2009 in specified circumstances.

Complying with these restrictions and covenants may make it more difficult for us to successfully execute our business strategy and compete against companies who are not subject to similar restrictions and covenants. Additionally, if we violate any of these restrictions or covenants, our lenders under this agreement may accelerate all

of our outstanding indebtedness and other amounts due under the credit and security agreement and, if we do not pay these amounts, proceed against the collateral securing these obligations.

***We will incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.***

The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted thereunder by the Securities and Exchange Commission, or SEC, will result in increased costs to us as we become a publicly-traded company. As a public company, we will be required to comply with many of these rules and regulations, and may be required to comply with additional rules and regulations in the future. For example, we are evaluating our internal controls systems in order to allow us to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. In addition, these efforts will divert management's time and attention away from our business in order to ensure compliance with these regulatory requirements. This diversion of management's time and attention may have a material adverse effect on our business, financial condition and results of operations. These new rules and regulations may also make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

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

As a public company, after an initial transition period, we will be required to maintain internal control over financial reporting and our management will be required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Additionally, we will be required to disclose in our annual reports on Form 10-K our management's assessment of the effectiveness of our internal control over financial reporting and a registered public accounting firm's attestation report on this assessment. As a public company, we will also be required to maintain disclosure controls and procedures, which encompass most of our internal control over financial reporting. Our principal executive officer and principal financial officer will be required to evaluate our disclosure controls and procedures as of the end of each quarter and disclose in our annual reports on Form 10-K and our quarterly reports on Form 10-Q their conclusions regarding the effectiveness of these controls and procedures. If we are not successful in establishing effective internal control over financial reporting or disclosure controls and procedures, there could be inaccuracies or omissions in the information we are required to file with the Securities and Exchange Commission, including our consolidated financial information. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets or cause our stock to be delisted from the Nasdaq Global Market or any other securities exchange on which it is then listed.

***Our common stock has not been publicly traded and we expect that the price of our common stock will fluctuate substantially.***

Prior to our initial public offering in May 2007, there was no public market for shares of our common stock. An active public trading market for shares of our common stock may not develop or, if developed, may not be sustained. The market price of our common stock will be affected by a number of factors, including:

- failure to maintain and increase manufacturing capacity and reduce per unit production costs;
- changes in the availability of third-party reimbursement in the United States or other countries;

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

***Sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and make it difficult for you to recover the full value of your investment in our shares.***

If our existing stockholders sell substantial amounts of our common stock in the public market following this offering, or if there is a perception that these sales may occur, the market price of our common stock could decline. In connection with our initial public offering in May 2007, we obtained lock-up agreements from our current stockholders representing over 99% of our outstanding common stock preventing, with limited exceptions, those stockholders from selling their stock for a period of 180 days from May 14, 2007. At various times after such lock-up agreements pertaining to this offering expire, approximately 17,787,580 additional shares will be eligible for sale in the public market at various times, subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended. Holders of substantially all of such shares of our common stock have the right to require us to register such shares for sale under the Securities Act in certain circumstances and also have the right to include those shares in a registration initiated by us. If we are required to include the shares of our common stock of these stockholders pursuant to these registration rights in a registration initiated by us, sales made by such stockholders may adversely affect the price of our common stock and our ability to raise needed capital. In addition, if these stockholders exercise their demand registration rights and cause a large number of shares to be registered and sold in the public market or demand that we register their shares on a shelf registration statement, such sales or shelf registration may have an adverse effect on the market price of our common stock.

We also intend to file one or more registration statements with the SEC covering, as of April 15, 2007: 2,685,941 shares of our common stock issuable upon the exercise of outstanding stock options granted under our 2000 Stock Option and Incentive Plan; 4,160,000 shares of our common stock available for future issuance under our 2007 Stock Option and Incentive Plan (which includes 3,625,000 shares, representing the maximum aggregate increases of 725,000 shares per year through 2012 provided for by this Plan); and 380,000 shares of our common stock available for future issuance under our 2007 Employee Stock Purchase Plan. Upon effectiveness of such registration statements, any shares subsequently issued under such plans will be eligible for sale in the public market, except to the extent that they are restricted by the lock-up agreements referred to above and subject to compliance with Rule 144 in the case of our affiliates. Sales of a large number of shares of our common stock issued under these plans in the public market may have an adverse effect on the market price of our common stock.

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

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

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

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

***We do not intend to pay cash dividends.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of our existing debt facility prohibits us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for the foreseeable future.

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

During the three month period ended March 31, 2007, we granted stock options to purchase 223,303 shares of our common stock at an exercise price of \$11.64 per share. We also issued 28,368 shares of our common stock upon the exercise of options for aggregate proceeds of \$22,476.70.

The securities issued in the foregoing transactions were offered and sold in reliance on exemptions from registration set forth in Section 4(2) of the Securities Act of 1933, as amended, or regulations promulgated thereunder, relating to sales by an issuer not involving any public offering, or an exemption from registration under Rule 701 promulgated under the Securities Act of 1933, as amended. No underwriters or placement agents were involved in the foregoing issuances and sales.

In June 2007, we completed the initial public offering of shares of our common stock. On May 14, 2007, a Registration Statement on Form S-1 (File No. 333-140694), as amended, relating to our initial public offering of common stock was declared effective by the Securities and Exchange Commission. On May 18, 2007, we issued and sold 7,700,000 shares of our common stock at a price to the public of \$15.00 per share. As part of the initial public offering, we granted the several underwriters an over-allotment option to purchase up to an additional 1,155,000 shares of our common stock from us. On June 12, 2007, we issued and sold an additional 665,000 shares

of common stock at a price to the public of \$15.00 per share pursuant to the underwriters' partial exercise of their over-allotment option. There were no selling stockholders in the offering. The offer and sale of all of the shares in the initial public offering were registered under the Securities Act of 1933, as amended, pursuant to an initial registration statement on Form S-1 (File No. 333-140694), which was declared effective by the Securities and Exchange Commission on May 14, 2007, and a second registration statement on Form S-1 (File No. 333-142952) filed pursuant to Rule 462(b) promulgated under the Securities Act of 1933, as amended, which was effective on May 14, 2007. J.P. Morgan Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated acted as joint book runners, and Thomas Weisel Partners LLC and Leerink Swann & Co., Inc. acted as co-managers for our initial public offering.

In connection with our initial public offering, we received total gross proceeds of \$125,475,000, or approximately \$113,791,750 in net proceeds after deducting underwriting discounts and offering commissions of \$8,783,250 and other offering costs of approximately \$2,900,000. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours. We intend to use the net proceeds for general corporate purposes, which may include: (i) the completion and improvement of its existing automated line and the construction of a second automated line to increase its manufacturing capacity; (ii) the expansion of its sales and marketing activities; and (iii) the funding of research and development.

### **Item 3. Defaults Upon Senior Securities**

None.

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

None.

### **Item 5. Other Information**

In a Press Release dated June 21, 2007, we previously reported a net loss per share for the three months ended March 31, 2007 at \$(24.02). In this Quarterly Report on Form 10-Q, we have revised the calculation of our net loss per share for the three months ended March 31, 2007 to \$(23.86). This revision reflects a correction to the calculation of the weighted shares outstanding in connection with stock options exercised in the three months ended March 31, 2007. This revision did not affect the previously reported net loss per share for the fiscal year and three months ended December 31, 2006.

### **Item 6. Exhibits**

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

**SIGNATURES**

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

INSULET CORPORATION  
(Registrant)

Date: June 27, 2007

/s/ Duane DeSisto

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

Date: June 27, 2007

/s/ Carsten Boess

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

## EXHIBIT INDEX

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**CERTIFICATION**

I, Duane DeSisto, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of Insulet Corporation;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release No. 34-47986];
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Duane DeSisto

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Duane DeSisto  
President and Chief Executive Officer  
June 27, 2007

## CERTIFICATION

I, Carsten Boess, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of Insulet Corporation;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release No. 34-47986];
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Carsten Boess

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Carsten Boess  
Chief Financial Officer  
June 27, 2007

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

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Insulet Corporation, a Delaware corporation (the "Company"), does hereby certify with respect to the Quarterly Report of the Company on Form 10-Q for the period ended March 31, 2007, as filed with the Securities and Exchange Commission (the "Report") that, to his knowledge:

- (1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Duane DeSisto

Name: Duane DeSisto  
Title: President and Chief Executive Officer  
Date: June 27, 2007

/s/ Carsten Boess

Name: Carsten Boess  
Title: Chief Financial Officer  
Date: June 27, 2007

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.