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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**Form 10-Q**

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

For the quarterly period ended September 30, 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 November 12, 2007, the registrant had 26,430,244 shares of common stock outstanding.

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**INSULET CORPORATION**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED SEPTEMBER 30, 2007**

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PART I — FINANCIAL INFORMATION

Item 1. *Financial Statements*

INSULET CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of September 30, 2007	As of December 31, 2006
	(In thousands, except share data) (Unaudited)	
<b>ASSETS</b>		
<b>Currents Assets</b>		
Cash	\$ 104,213	\$ 33,231
Accounts receivable, net	3,343	1,417
Inventories	4,572	3,390
Prepaid expenses and other current assets	1,763	1,827
Total current assets	113,891	39,865
Property and equipment, net	20,960	16,999
Other assets	754	276
Total assets	<u>\$ 135,605</u>	<u>\$ 57,140</u>
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>Currents Liabilities</b>		
Accounts payable	\$ 4,152	\$ 3,450
Accrued expenses	3,772	4,193
Deferred revenue	711	284
Current portion of long-term debt	10,671	29,222
Preferred stock warrant liability	—	1,931
Total current liabilities	19,306	39,080
Long-term debt, net of current portion	18,673	—
Other long-term liabilities	1,328	316
Total liabilities	39,307	39,396
<b>Redeemable convertible preferred stock, \$0.001 par value:</b>		
Authorized: zero and 46,408,050 shares at September 30, 2007 and December 31, 2006, respectively		
Issued and outstanding Series A: zero and 1,000,000 shares stated at liquidation and redemption value at September 30, 2007 and December 31, 2006, respectively	—	1,000
Issued and outstanding Series B: zero and 5,945,946 shares stated at liquidation and redemption value at September 30, 2007 and December 31, 2006, respectively	—	11,000
Issued and outstanding Series C: zero and 10,476,191 shares stated at liquidation and redemption value at September 30, 2007 and December 31, 2006, respectively	—	22,000
Issued and outstanding Series D: zero and 14,669,421 shares stated at liquidation and redemption value at September 30, 2007 and December 31, 2006, respectively	—	35,500
Issued and outstanding Series E: zero and 13,738,661 shares stated at liquidation and redemption value at September 30, 2007 and December 31, 2006, respectively	—	50,009
<b>Stockholders' equity (deficit)</b>		
Preferred stock, \$.001 par value: Authorized 5,000,000 and zero shares at September 30, 2007 and December 31, 2006, respectively. Issued and outstanding zero shares at September 30, 2007 and December 31, 2006.		
	—	—
Common stock, \$.001 par value:		
Authorized: 100,000,000 and 65,000,000 shares authorized at September 30, 2007 and December 31, 2006, respectively		
Issued: 26,427,641 and 457,076 shares at September 30, 2007 and December 31, 2006, respectively	27	1
Additional paid-in capital	236,182	293
Accumulated deficit	(139,911)	(102,040)
Subscription receivable	—	(19)
Total stockholders' equity (deficit)	96,298	(101,765)
Total liabilities and stockholders' equity (deficit)	<u>\$ 135,605</u>	<u>\$ 57,140</u>

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

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2007	2006	2007	2006
	(In thousands, except share and per share data)			
	(Unaudited)			
Revenue	\$ 3,791	\$ 920	\$ 9,011	\$ 2,022
Cost of revenue	7,583	4,379	19,054	11,718
Gross loss	(3,792)	(3,459)	(10,043)	(9,696)
Operating expenses:				
Research and development	2,231	2,083	7,221	5,891
General and administrative	3,388	2,250	8,845	5,574
Sales and marketing	4,144	1,741	10,652	4,286
Impairment of assets	1,027	—	1,027	—
Total operating expenses	10,790	6,074	27,745	15,751
Operating loss	(14,582)	(9,533)	(37,788)	(25,447)
Interest income	1,418	371	2,435	1,169
Interest expense	(475)	(255)	(2,444)	(792)
Change in value of preferred stock warrant liability	—	—	(74)	—
Net loss	(13,639)	(9,417)	(37,871)	(25,070)
Accretion of redeemable convertible preferred stock	—	—	—	(222)
Net loss attributable to common shareholders	\$ (13,639)	\$ (9,417)	\$ (37,871)	\$ (25,292)
Net loss per share basic and diluted	\$ (0.52)	\$ (26.48)	\$ (2.85)	\$ (72.43)
Weighted-average number of shares used in calculating net loss per share	26,322,763	355,574	13,294,107	349,199

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

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

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
	<b>(Unaudited)</b>	
<b>Cash flows from operating activities</b>		
Net loss	\$ (37,871)	\$(25,070)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	3,352	1,835
Amortization of debt discount	179	43
Redeemable convertible preferred stock warrant expense	74	—
Stock compensation expense	939	400
Provision for bad debts	682	109
Gain/ loss on disposal of assets	—	344
Loss on impairment of assets	1,027	—
Non cash interest expense	(57)	—
Changes in operating assets and liabilities:		
Accounts receivable	(2,608)	(971)
Inventory	(1,182)	(1,381)
Prepays and other current assets	64	185
Other assets	(478)	1
Accounts payable and accrued expenses	276	3,481
Other long term liabilities	1,012	172
Deferred revenue	427	72
Net cash used in operating activities	<u>(34,164)</u>	<u>(20,780)</u>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	<u>(8,340)</u>	<u>(10,807)</u>
Net cash used in investing activities	<u>(8,340)</u>	<u>(10,807)</u>
<b>Cash flows from financing activities</b>		
Proceeds from sale of Series E preferred stock, net of issuance cost	—	49,787
Principal payments of long term debt	—	(837)
Proceeds from issuance of common stock, net of offering expenses	<u>113,486</u>	<u>66</u>
Net cash provided by financing activities	<u>113,486</u>	<u>49,016</u>
Net increase in cash and cash equivalents	70,982	17,429
Cash and cash equivalents, beginning of year	<u>33,231</u>	<u>7,660</u>
Cash and cash equivalents, end of period	<u>\$104,213</u>	<u>\$ 25,089</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 2,368	\$ 336
<b>Non-cash financing activities</b>		
Accretion of redeemable convertible preferred stock	\$ —	\$ 222
Conversion of preferred stock to common stock upon initial public offering	\$119,509	\$ —

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

**INSULET CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**1. Nature of Business**

Insulet Corporation (the “Company”) is principally engaged in the development, manufacture and marketing of an insulin infusion system for people with insulin-dependent diabetes. The Company was incorporated in Delaware in 2000 and has its corporate headquarters in Bedford, Massachusetts. Since inception, the Company has devoted substantially all of its efforts to designing, developing and marketing the OmniPod Insulin Management System. 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. In May 2007, the Company completed an initial public offering of its common stock.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying unaudited condensed 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 and nine month periods ended September 30, 2007 are not necessarily indicative of the results that may be expected for the full fiscal year ending December 31, 2007, or for any other subsequent interim period.

The condensed 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 notes required by generally accepted accounting principles for complete financial statements.

The condensed consolidated financial statements should be read in conjunction with the Company’s consolidated financial statements and notes thereto contained 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 generally accepted accounting principles in the United States 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 may 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.

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

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

Bad debt expense for the three and nine months ended September 30, 2007 amounted to \$293,000 and \$682,000, respectively. There were zero and \$51,000 in write-offs or other adjustments to the allowance for doubtful accounts during the three and nine months ended September 30, 2007, respectively. There were no write-offs during 2006.

### ***Inventories***

Inventories are stated at the lower of cost or market, determined under the first-in, first-out (“FIFO”) method. Inventory has been written down to market value for all periods presented as the Company currently manufactures the OmniPod 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 Personal Diabetes Managers (“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.

### ***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. In the three months ended September 30, 2007, the Company recorded an impairment charge of approximately \$1.0 million for certain manufacturing equipment.

### ***Revenue Recognition***

The Company generates revenue from sales 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 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 additional OmniPods. Revenue is recognized in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements* (“SAB 104”), which requires that persuasive evidence of a sales arrangement exists, delivery of goods occurs through transfer of title and risk and rewards of ownership, the selling price is fixed or determinable and collectibility is reasonably assured. With respect to these criteria:

- The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval.
- 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 the Company to assess whether the different elements qualify for separate accounting. The Company

recognizes revenue for the initial shipment to a patient or other third party once all elements have been delivered 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 \$711,000 and \$284,000 as of September 30, 2007 and December 31, 2006, respectively.

#### ***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 September 30, 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 estimated interest and penalties for uncertain tax positions in income tax expense. Upon adoption and as of September 30, 2007, the Company had no interest and penalty accrual or expense.

#### ***Recent Accounting Pronouncements***

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (“SFAS 157”). This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company 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, if any, 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 the requirements of SFAS 159 and has not yet determined the impact, if any, on its financial statements.

### **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. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options and warrants (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method). Because the Company reported a net loss for the three and nine months ended September 30, 2007 and 2006, respectively, all

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

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	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 and ESPP	2,866,928	2,358,444	2,866,928	2,358,444
Outstanding warrants	78,440	125,853	78,440	125,853
Total	<u>2,945,368</u>	<u>19,932,088</u>	<u>2,945,368</u>	<u>19,932,088</u>

#### 4. Inventories

Inventories consist of the following:

	As of September 30, 2007	As of December 31, 2006
	(In thousands)	
Raw materials	\$ 1,928	\$ 1,177
Work-in-process	887	367
Finished goods	1,757	1,846
	<u>\$ 4,572</u>	<u>\$ 3,390</u>

Inventories of finished goods were adjusted by \$458,000 and \$1.5 million as of September 30, 2007 and December 31, 2006, respectively, to reflect values at the lower of cost or market. At September 30, 2007 and December 31, 2006, 38% and 54%, respectively, of the reported finished goods inventory was valued below the Company's cost. The Company's production process has a high degree of fixed costs due to the early stage of capacity build-up and market penetration of its products. 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. 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 set 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

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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 repaid 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 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 term loan was 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*. At September 30, 2007, the term loan principal has been presented in the Company's consolidated balance sheet with its current and non-current components stated separately, based on its stated repayment schedule, as a result of the significant increase in the Company's cash reserves following initial public offering of the Company's common stock in May 2007.

In connection with this term loan, the Company issued warrants to the lenders to purchase up to 247,252 shares of Series E preferred stock. 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. Prior to the Company's initial public offering, these warrants were recorded as "warrants to purchase shares subject to redemption" 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* ("FSP-150").

Upon the closing of the Company's initial public offering, all warrants converted 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.

Significant terms and fair values of warrants to purchase common stock are as follows (in thousands except share and per share data), and reflect the conversion ratio of 2.6267 redeemable convertible preferred shares for each common share:

Stock	Expiration Date	Exercise Price Per Share	Common Shares as of		Fair Value as of December 31, 2006
			September 30, 2007	December 31, 2006	
Series D preferred	June 2, 2012	\$ 6.36	—	125,853	\$ 1,096
Series E preferred	December 27, 2013	9.56	78,440	94,128	835
<b>Total</b>			<b>78,440</b>	<b>219,981</b>	<b>\$ 1,931</b>

In the three months ended September 30, 2007, Lighthouse Capital Partners V, L.P. exercised their right to exercise 125,853 warrants, resulting in the issuance of 89,821 common shares.

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The Company recorded \$835,000 as the fair value of the warrants for Series E preferred stock as a discount to the term loan. The fair value of the warrants is being amortized to interest expense over the 42-month life of this term loan.

Upon the closing of the Company's initial public offering on May 18, 2007, all outstanding warrants to purchase shares of the Company's preferred stock were converted into warrants to purchase shares of common stock and, as a result, are no longer 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, determined to be \$2,005,000, was reclassified from liabilities to additional paid-in capital, a component of stockholders' equity. No periodic fair value adjustments will be made in future periods.

### **6. 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 currently not 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.

### **7. Equity**

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

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 initial public offering, the Company received total gross proceeds of \$125.5 million, or approximately \$113.4 million in net proceeds after deducting underwriting discounts and offering expenses.

In the three and nine months ended September 30, 2007, 125,853 and 141,541 warrants to purchase common stock issued in relation to the Company's term loan were exercised,

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resulting in the issuance of 89,821 and 95,509 common shares, respectively. In addition, 25,009 and 62,265 common shares were issued related to exercises of employee stock options in the three and nine months ended September 30, 2007, respectively.

### ***Redeemable Convertible Preferred Stock Conversion***

Upon the closing of the initial public offering of the Company's common stock, all redeemable convertible preferred stock converted to common stock.

### ***Stock Option Plans***

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 Company's 2000 Stock Option and Incentive 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 the lesser of 3% of the number of shares of common stock of the Company outstanding as of the immediately preceding December 31, or 725,000 shares. At September 30, 2007, 284,932 options were available for future grant.

Under the Company's 2000 Stock Option and Incentive Plan (the "2000 Plan"), options could be granted to persons who were, at the time of grant, employees, officers, or directors of, or consultants or advisors to, the Company. The 2000 Plan provided for the granting of non-statutory stock options, incentive stock options, stock bonuses, and rights to acquire restricted stock. The option price at the date of grant was determined by the Board of Directors and, in the case of incentive stock options, could 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 granted under the 2000 Plan 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.

Activity under the Company's Stock Option Plans:

	<b>Number of Options(#)</b>	<b>Weighted Average Exercise Price(\$)</b>	<b>Aggregate Intrinsic Value(\$)</b>
Balance, December 31, 2006	2,318,250	3.15	
Granted	647,906	11.7	
Exercised	(62,265)	1.33	857,544(1)
Canceled	(38,204)	7.94	
Balance, September 30, 2007	<u>2,865,687</u>	5.54	46,456,430(2)
Vested, September 30, 2007	<u>1,683,228</u>	2.52	32,369,316(2)
Vested and expected to vest, September 30, 2007(3)	<u>2,578,545</u>		

- (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 September 30, 2007, and the exercise price of the underlying options.

- (3) Represents the number of vested options as of September 30, 2007, plus the number of unvested options expected to vest as of September 30, 2007, based on the unvested options outstanding at September 30, 2007, adjusted for an 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 \$9.49 and \$6.41 per share for the three months ended September 30, 2007 and 2006, respectively. The weighted average estimated fair value of the employee stock options granted was \$8.74 and \$5.17 per share for the nine months ended September 30, 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 the Company's 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 and nine months ended September 30, 2007 and 2006, respectively:

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Risk-free interest rate	4.66%	4.80%	4.78%	4.88%
Expected term (in years)	6.25	6.25	6.25	6.25
Dividend yield	0	0	0	0
Expected volatility	67.00%	71.36%	67.00%	71.36%

*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-

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based compensation expense could be significantly different from what the Company has recorded in the current period.

In the three months ended September 30, 2007 and 2006, 1,241 and zero shares, respectively, were contingently issued under the employee stock purchase plan ("ESPP"). In the nine months ended September 30, 2007 and 2006, 1,241 and zero shares, respectively, were contingently issued under the ESPP. In the three months ended September 30, 2007 and 2006, the Company recorded compensation charges of approximately \$4,800 and zero, respectively, of stock compensation charges related to the ESPP. In the nine months ended September 30, 2007 and 2006, the Company recorded compensation charges of approximately \$4,800 and zero, respectively, of stock compensation charges related to the ESPP.

The amount of stock-based compensation expense that is expected to be recognized for outstanding, unvested options as of September 30, 2007 is as follows (in thousands):

2007	\$ 460
2008	1,803
2009	1,805
2010	1,474
2011	447
	<u>\$ 5,989</u>

Employee stock-based compensation expense under SFAS 123R recognized in the three and nine months ended September 30, 2007, was \$432,000 and \$939,000, respectively. For the same periods in 2006, employee stock-based compensation recognized was \$246,000 and \$400,000, respectively.

At September 30, 2007, the Company had \$5,995,000, which includes \$6,000 related to the ESPP, 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.

### **8. Impairment of Property and Equipment**

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

### **9. Income Taxes**

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

### **10. Subsequent Events**

#### ***Contract Manufacturing Agreement***

On October 4, 2007, the Company entered into a first addendum to that certain non-exclusive contract manufacturing agreement, dated January 3, 2007, between the Company and a subsidiary of Flextronics

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International Ltd. (“Flextronics”). Pursuant to the original manufacturing agreement, Flextronics has been providing a sub-assembly of components to the Company’s OmniPod disposable insulin infusion device. This first addendum expands the scope of the services to be provided by Flextronics under this manufacturing agreement to include the production of the OmniPod device itself towards the end of 2008.

***Common Stock Offering***

On October 29, 2007, the Company filed a registration statement on Form S-1 relating to the sale by certain of the Company’s stockholders of 4,898,398 shares of the Company’s common stock, as well as the issuance and sale by the Company of up to 734,759 shares of its common stock, which are purchasable by the underwriters upon their exercise of a 30-day over-allotment option granted to the underwriters by the Company. The Company did not receive any of the proceeds of the sale of shares of its common stock by the selling stockholders. On November 13, 2007, the underwriters notified the Company of the partial exercise of the over-allotment option with respect to 459,759 shares of common stock. Upon the closing of the sale of these shares, the Company will receive net proceeds of approximately \$9.2 million. The Company expects to use these net proceeds for general corporate purposes.

## **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. These forward-looking statements are based on our current expectations and beliefs concerning future developments and their potential effects on it. There can be no assurance that future developments affecting it will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with our dependence on the OmniPod System; our ability to achieve and maintain market acceptance of the OmniPod System; potential manufacturing problems, including damage, destruction or loss of any of our automated assembly units or difficulties in implementing our automated manufacturing strategy; our ability to anticipate and effectively manage risks associated with doing business internationally, particularly in China; potential problems with sole source or other third-party suppliers on which we are dependent; our ability to obtain favorable reimbursement from third-party payors for the OmniPod System and potential adverse changes in reimbursement rates or policies relating to the OmniPod; potential adverse effects resulting from competition with competitors; technological innovations adversely affecting our business; potential termination of our license to incorporate a blood glucose meter into the OmniPod System; our ability to protect our intellectual property and other proprietary rights; conflicts with the intellectual property of third parties; adverse regulatory or legal actions relating to the OmniPod System; the potential violation of federal or state laws prohibiting "kickbacks" and false and fraudulent claims or adverse affects of challenges to or investigations into our practices under these laws; product liability lawsuits that may be brought against us; unfavorable results of clinical studies relating to the OmniPod System or the products of our competitors; potential future publication of articles or announcement of positions by physician associations or other organizations that are unfavorable to our products; our ability to attract and retain key personnel; our ability to manage our growth; risks associated with potential future acquisitions; our ability to maintain compliance with the restrictions and covenants contained in our existing credit and security agreement; our ability to successfully maintain effective internal controls; and other risks and uncertainties described in our Quarterly Report on Form 10-Q for the three months ended March 31, 2007, which was filed with the Securities and Exchange Commission on June 28, 2007 as updated by Part II, Item 2A., "Risk Factors" of this Quarterly Report on Form 10-Q. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements.

### **Overview**

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

Since inception and until 2005, we devoted substantially all of our efforts to designing and developing the OmniPod System, raising capital and recruiting personnel. 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 and Midwestern United States and with some key diabetes practitioners, academic centers and clinics elsewhere in the United States. Our total revenues were \$3.8 million and \$9.0 million for the three and nine months ended September 30, 2007, respectively. As of September 30, 2007, approximately 3,200 patients were using the OmniPod System in the United States. Historically, the growth in our quarterly revenue has not been consistent with our quarterly patient growth due to a number of factors, including the deferral of revenue received from new patients within 45 days prior to the end of a quarter and the timing and average size of reorders from existing patients.

At present, the expansion of our business is primarily constrained by our current capacity to manufacture the OmniPod insulin infusion device, and our primary near-term goal is to expand the production of OmniPods. Currently, the sale price of the OmniPod is not sufficient to cover our direct manufacturing costs. Increasing our production capacity for OmniPods will allow for volume purchase discounts to reduce our raw material costs and improve absorption of manufacturing overhead costs.

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During 2008, we expect to complete the planned automation of our existing manufacturing line in Bedford, Massachusetts. 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. In addition, we expect that during 2008, construction of a partially automated manufacturing line will be completed at a facility in China operated by a subsidiary of Flextronics International Ltd. By the end of 2008, we intend to purchase complete OmniPods from Flextronics. No assurances can be given that we will successfully complete the planned automation of our existing manufacturing line, successfully implement our Asian manufacturing strategy 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. ("Flextronics") for the supply of a sub-assembly of some of the OmniPod's components. In the second quarter of 2007, we received the initial shipments of OmniPod sub-assemblies from Flextronics under the agreement. On October 4, 2007, we entered into a first addendum to the contract manufacturing agreement with Flextronics. This first addendum expands the scope of the services to be provided by Flextronics under this manufacturing agreement to include the production of the OmniPod device itself.

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. We continue to negotiate contracts establishing reimbursement for the OmniPod System with national and regional third-party payors, and we believe that substantially all of the units sold have been reimbursed by third-party payors, subject to applicable deductible and co-payment amounts. As we expand our sales and marketing coverage area and increase our manufacturing capacity, we will need to maintain and expand available reimbursement for the OmniPod System.

Since our inception in 2000, we have incurred losses every quarter. In the three and nine months ended September 30, 2007, we incurred a net loss of \$13.6 million and \$37.9 million, respectively. As of September 30, 2007, we had an accumulated deficit of \$139.9 million. We have financed our operations through the private placement of equity securities, secured indebtedness and an initial public offering of our common stock. As of September 30, 2007, we had \$30.0 million of secured debt outstanding. Since inception, we have received net proceeds of \$232.9 million from the issuance of redeemable convertible preferred stock and common stock.

In May 2007, in our initial public offering, we issued and sold 7,700,000 shares of common stock at a price to the public of \$15.00 per share. In June 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 initial public offering, including the partial exercise of the over-allotment option, we received total gross proceeds of \$125.5 million, or approximately \$113.4 million in net proceeds after deducting underwriting discounts and offering expenses.

On October 29, 2007, we filed a registration statement on Form S-1 relating to the sale by certain of our stockholders of 4,898,398 shares of our common stock, as well as the issuance and sale by us of up to 734,759 shares of our common stock, which are purchasable by the underwriters upon their exercise of a 30-day over-allotment option that we granted to the underwriters. We did not receive any of the proceeds of the sale of shares of our common stock by the selling stockholders. On November 13, 2007, the underwriters notified us of the partial exercise of the over-allotment option with respect to 459,759 shares of common stock. Upon the closing of the sale of these shares, we will receive net proceeds of approximately \$9.2 million. We expect to use these net proceeds for general corporate purposes.

During the three months ended September 30, 2007, we recorded an impairment charge related to certain production machinery and equipment in the amount of approximately \$1.0 million. The expected impairment charge was a result of the ongoing improvements to our product design and associated manufacturing processes, which were aimed at achieving lower per-unit costs, and the ongoing upgrades to our manufacturing process, which rendered certain equipment obsolete.

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 production 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 (“SAB 104”) and Statement of Financial Accounting Standards No. 48, *Revenue Recognition when the Right of Return Exists* (“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 (“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). As of September 30, 2007, the balance of deferred revenue was \$711,000.

For the remainder of 2007, we expect our quarterly revenues to increase. We expect our OmniPod production capacity to expand as we receive increased supplies from Flextronics and continue the process of automating our OmniPod manufacturing process. Our current OmniPod manufacturing capacity is approximately 45,000 OmniPods per month. By completing the planned automation of our existing manufacturing line in Bedford, Massachusetts and by purchasing complete OmniPods from Flextronics, we expect to increase our production capacity to in excess of 200,000 OmniPods per month toward the end of 2008.

*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, inventories of finished goods have 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 the supply of subassemblies from Flextronics increases, and 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 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, as well as the costs of market studies and product development projects. We expense all research and development costs as incurred. For the remainder of 2007, we expect overall research and development spending to remain significant and consistent with previous periods 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.

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*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, as 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 our use of external services.

*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* ("SFAS 123"). Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS Statement No. 123 (revised 2004), *Share-Based Payment* ("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 and nine months ended September 30, 2007 and 2006:

	Three months ended			Nine months ended		
	September 30,			September 30,		
	2007	2006	% Change	2007	2006	% Change
	(In thousands)					
Revenue	\$ 3,791	\$ 920	312%	\$ 9,011	\$ 2,022	346%
Cost of revenue	7,583	4,379	73%	19,054	11,718	63%
Gross loss	(3,792)	(3,459)	10%	(10,043)	(9,696)	4%
Operating expenses:						
Research and development	2,231	2,083	7%	7,221	5,891	23%
General and administrative	3,388	2,250	51%	8,845	5,574	59%
Sales and marketing	4,144	1,741	138%	10,652	4,286	149%
Impairment of assets	1,027	—	—	1,027	—	—
Total operating expenses	10,790	6,074	78%	27,745	15,751	76%
Operating loss	(14,582)	(9,533)	53%	(37,788)	(25,447)	48%
Other income (expense), net	943	116	713%	(83)	377	122%
Net loss	<u>\$(13,639)</u>	<u>\$(9,417)</u>	45%	<u>\$(37,871)</u>	<u>\$(25,070)</u>	51%

### Comparison of the Three and Nine Months Ended September 30, 2007 and 2006

#### Revenues

Our total revenues were \$3.8 million for the three months ended September 30, 2007 and \$9.0 million for the nine months ended September 30, 2007, compared to \$0.9 million and \$2.0 million for the same periods in 2006. The increase in revenues is due to the increase in customers from approximately 800 at September 30, 2006 to

approximately 3,200 at September 30, 2007. As we continue our sales and marketing efforts, we expect our revenues to increase.

*Cost of Revenues*

Cost of revenues was \$7.6 million for the three months ended September 30, 2007 and \$19.1 million for the nine months ended September 30, 2007, compared to \$4.4 million and \$11.7 million for the same periods in 2006. The increase is due to increased sales volume. Cost of revenues includes adjustment of inventory to lower of cost or market and indirect costs. The per-unit cost to manufacture the OmniPod decreased in the three and nine months ended September 30, 2007, compared to the same period in 2006, resulting in improvements in our gross margin. This decrease is a result of reduced cost of raw materials and increased volumes which improved the absorption of manufacturing overhead costs.

*Research and Development*

Research and development expense increased \$148,000, or 7%, to \$2.2 million for the three months ended September 30, 2007 and \$1.3 million, or 23%, to \$7.2 million for the nine months ended September 30, 2007. For the three months ended September 30, 2007 the increase in expense was primarily attributable to an increase of \$275,000 in consulting services partially offset by a reduction in prototype expenses. For the nine months ended September 30, 2007, the increase in expense was primarily attributable to an increase of \$700,000 in employee related expenses, \$439,000 in consulting services, \$137,000 in travel expenses, and \$53,000 in tools and other expenses.

*General and Administrative*

General and administrative expenses increased \$1.1 million, or 47%, to \$3.4 million for the three months ended September 30, 2007 and increased \$3.3 million, or 59%, to \$8.8 million for the nine months ended September 30, 2007. For the three months ended September 30, 2007, the increase in expenses was primarily due to an increase of \$484,000 in employee compensation and benefit costs associated with the hiring of additional employees, \$324,000 in consulting and legal expenses, \$158,000 in increased travel expenses, \$236,000 in bad debt expense, \$92,000 in increased insurance expense, \$89,000 in distribution expenses, \$53,000 in increased depreciation expense and \$49,000 in other expense. For the three months ended September 30, 2006, we incurred an expense of \$345,000 related to the disposal of assets, whereas there was no such expense incurred in the same period in 2007. For the nine months ended September 30, 2007, the increase in expense was primarily due to an increase of \$1.3 million in employee compensation and benefit costs associated with the hiring of additional employees, \$929,000 in consulting and legal expenses, \$573,000 in bad debt expense, reflecting increased sales volume, \$242,000 in increased travel, \$200,000 in increased depreciation expense, \$186,000 in increased insurance expense, and \$144,000 in other expenses. For the nine months ended September 30, 2006, we incurred an expense of \$345,000 for the disposal of assets, whereas there was no such expense incurred in the same period in 2007.

*Sales and Marketing*

Sales and marketing expenses increased \$2.4 million, or 138%, to \$4.1 million for the three months ended September 30, 2007, and increased \$6.4 million, or 149%, to \$10.7 million for the nine months ended September 30, 2007. The increase in expenses for the three months ended September 30, 2007, was primarily due to an increase of \$1.3 million in employee compensation and benefit costs resulting from the hiring of additional employees in our sales and marketing department, \$510,000 in travel, printing and tradeshow expenses used to support our selling efforts, \$338,000 in patient demonstration kits, \$187,000 in marketing consultants which include our external trainers and \$86,000 in other expenses. For the nine months ended September 30, 2007, the increase in expenses was primarily due to an increase of \$2.5 million in employee compensation and benefit costs resulting from the hiring of additional employees in our sales and marketing department, \$1.7 million in patient demonstration kits \$1.4 million in travel, printing and tradeshow expenses used to support our selling efforts, \$604,000 in marketing consultants which include our external trainers and \$214,000 in other marketing expenses.

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### *Asset Impairment*

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

### *Other Income (Expense)*

Interest income was \$1.4 million and \$2.4 million during the three and nine months ended September 30, 2007, respectively. This represents an increase of \$1.0 million and \$1.3 million compared to the same periods in 2006, caused primarily by higher cash balances. Interest income was earned from cash deposits and short-term interest bearing instruments. Interest expense was \$475,000 and \$2.4 million during the three and nine months ended September 30, 2007, respectively, representing an increase of \$220,000 and \$1.7 million compared to the same periods in 2006. The increase in interest expense was attributable to the interest expense for the \$30.0 million term loan obtained in December 2006.

### **Liquidity and Capital Resources**

We commenced operations in 2000 and have to date financed our operations primarily through private placement of common and preferred stock, secured indebtedness and an initial public offering of our common stock. As of September 30, 2007, we had \$30 million of secured debt outstanding. Since inception, we have received net proceeds of \$232.9 million from the issuance of redeemable convertible preferred stock and common stock. As of September 30, 2007, we had \$104.2 million in cash and cash equivalents. We believe that our current cash and cash equivalents, including the net proceeds from our initial 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 and debt service requirements for at least the next twelve months.

In May 2007, in our initial public offering, we issued and sold 7,700,000 shares of common stock at a price to the public of \$15.00 per share. In June 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 our initial public offering, including the partial exercise of the over-allotment option, we received total net proceeds of \$113.4 million. We intend to use the proceeds from our offerings to expend funds in connection with our efforts to expand our manufacturing capacity, expand our sales and marketing activities and fund our research and development, among other general corporate purposes.

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

	<b>Nine months ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
Cash used in operating activities	\$ (34,164)	\$ (20,780)
Net loss	\$ (37,871)	\$ (25,070)

For each of the periods above, the increase in net cash used in operating activities was attributable primarily to the growth of our operations after adjustment for non-cash charges, such as depreciation, amortization

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and stock-based compensation expense as well as changes to working capital. Significant uses of cash from operations include increases in accounts receivable and increased inventory requirements for production, partly 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:

	September 30,	
	2007	2006
	(In thousands)	
Cash used in investing activities	\$ (8,340)	\$(10,807)
Cash provided by financing activities	\$113,486	\$ 49,016

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. All of these preferred shares converted 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 converted into a warrant to purchase common stock on a 1-for-2.6267 basis at a purchase price of \$6.36 per share at the closing of our initial public offering. The cost of the warrant was 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.

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 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, due to our low cash resources, relative to our operating losses, prior to our initial public offering, all of such debt was 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 converted into warrants to purchase common stock on a 1-for-2.6267 basis at a purchase price of \$9.56 per share at the closing of our initial public offering. At September 30, 2007, the term loan principal

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was presented in our consolidated balance sheet with its current and non-current components stated separately, based on its stated repayment schedule, as a result of the significant increase in our cash reserves following our initial public offering in May 2007.

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 of our facility in Bedford, Massachusetts generally provides for a base rent plus real estate taxes and certain operating expenses related to the lease. We entered into a new lease for our Bedford facility in 2004 which contains renewal options, escalating payments and leasehold allowances over the life of the lease. As of September 30, 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.

During the remainder of 2007, we will be expending funds in connection with, among other things, our efforts to expand our automated manufacturing process and increase our production capacity, and expand our sales and marketing activities. We expect total capital expenditure purchases during 2007 to be at least \$10.0 million in connection with our efforts to expand our automated manufacturing process and increase our manufacturing capacity.

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

As of September 30, 2007, we did not have any off-balance sheet financing arrangements.

### **Contractual Obligations**

The disclosure of payments we have committed to make under our contractual obligations is set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our registration statement on Form S-1 for the fiscal year ended December 31, 2006. There have been no material changes to our contractual obligations since June 30, 2007.

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

- The evidence of an arrangement generally consists of a physician order form, a patient information form, and if applicable, third-party insurance approval.
- 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 initial shipment to a patient or other third party once all elements have been delivered and the right of return has expired.

### ***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. We perform ongoing evaluations of customers and continuously monitor collections and payments and estimates an allowance for doubtful accounts based on the aging of the underlying receivables, experience to date and any specific collection issues that have been identified. Actual results may differ materially from our estimates. Fixed property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. We review long-lived assets, including property and equipment and intangibles, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. 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. During the three months ended September 30, 2007, we performed a review of certain production equipment. The review resulted in a non-cash charge of \$1.0 million for the write-down of certain impaired assets. The impaired assets, which have no future use, consist of manufacturing equipment. The impairment charges were recorded following determination of the fair value of cash flows resulting from use of the affected assets, and the carrying value of the assets has been reduced to reflect their fair value.

### ***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 September 30, 2007, we have no unrecognized tax benefits recorded.

### ***Stock Based Compensation***

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Share Based Payment (“SFAS 123R”), which is a revision of Statement No. 123, or SFAS 123, Accounting for Stock Based Compensation. SFAS 123R supersedes Accounting Principles Board 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.

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 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.

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. Because our initial public offering was completed in May 2007, we do not have sufficient history of market prices of our common stock, and as such we estimate volatility in accordance with Securities and Exchange Commission’s Staff Accounting Bulletin No. 107, Share-Based Payment (“SAB 107”), using historical volatilities of comparable 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.

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 in the AICPA Technical Practice Aid, “Valuation of Privately-Held-Company Equity Securities Issued as Compensation”. To that end, the board considered a number of factors in determining the option price, including the following factors: (1) prices for our

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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: (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. 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.

### **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. Until the completion of our initial public offering, these warrants were recorded as "warrants to purchase shares subject to redemption" 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* ("FSP 150-5").

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	Common Shares as of		Fair Value as of December 31, 2006
			September 30, 2007	December 31, 2006	
Series D preferred	June 2, 2012	\$ 6.36	—	125,853	\$ 1,096
Series E preferred	December 27, 2013	9.56	78,440	94,128	835
<b>Total</b>			<b>78,440</b>	<b>219,981</b>	<b>\$ 1,931</b>

In the three months ended September 30, 2007, Lighthouse Capital Partners V, L.P. exercised their right to convert 125,853 warrants into common stock, resulting in the issuance of 89,821 shares of common stock.

We recorded \$835,000 as the fair value of the warrants for Series E preferred stock 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.

Upon the closing of our initial public offering on May 18, 2007, all outstanding warrants to purchase shares of our preferred stock were converted into warrants to purchase shares of our common stock and, as a result, are 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, determined to be \$2,005,000, was reclassified from liabilities to additional paid-in capital, a component of stockholders' equity, and we have ceased to record any related periodic fair value adjustments.

### **Recent Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States, and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007, and for interim periods within those fiscal years. We 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, if any, 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 the requirements of SFAS 159 and have not yet determined the impact, if any, on our consolidated financial statements.

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

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

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

**Disclosure Controls and Procedures**

Management conducted an evaluation, as of September 30, 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 September 30, 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.*

None.

### Item 1A. *Risk Factors*

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. “Risk Factors” in our Quarterly Report on Form 10-Q for the three months ended March 31, 2007, which could materially affect our business, financial condition or future results. The risk factors included in our Quarterly Report on Form 10-Q for the three months ended March 31, 2007 have not materially changed other than as set forth below. These risks are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

***Our ability to achieve profitability from a current net loss level will depend on our ability to reduce the per unit cost of producing the OmniPod through the successful implementation of our automated manufacturing strategy and our plan to purchase complete OmniPods manufactured in China.***

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 at our facility in Bedford, Massachusetts. 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. In addition, we expect that during 2008, construction of a partially automated manufacturing line will be completed at a facility in China operated by a subsidiary of Flextronics International Ltd. We cannot assure you that we will successfully complete the planned automation of our existing manufacturing line or subsequent lines in the future, complete construction of the partially automated line in China 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.

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

We rely on a number of suppliers who manufacture the components of the OmniPods and PDMs. For example, we rely on Phillips Plastic Corporation to manufacture and supply a number of injection molded components of the OmniPod, Freescale Semiconductor, Inc. to manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod and a subsidiary of Flextronics International Ltd. to manufacture a sub-assembly of some of the OmniPod’s components. Each of these suppliers is a sole-source supplier. In addition, we have recently expanded the scope of our existing contract manufacturing agreement with a subsidiary of Flextronics International Ltd. in China to cover the supply of complete OmniPods. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we make our purchases on a purchase order basis. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. 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:

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

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

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

In order to reduce our cost of goods sold and increase our production capacity, we increasingly rely on third party suppliers located outside of the United States. For example, 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. In the second quarter of 2007, we received initial shipments of OmniPod sub-assemblies from Flextronics under the agreement. On October 4, 2007, we expanded the scope of that agreement to cover the production of complete OmniPods. During 2008, we expect to complete the construction of a partially automated manufacturing line at a facility in China operated by Flextronics. As a result, our business will become increasingly subject to risks associated with doing business internationally, including:

- changes in foreign currency exchange rates;
- instability in the political or economic conditions;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulty in staffing and managing widespread operations;
- difficulties associated with foreign legal systems;
- differing protection of intellectual property; and
- unexpected changes in regulatory requirements.

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

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

We expect that sales of the OmniPod System will be limited unless a substantial portion of the sales price of the OmniPod System is paid for by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations and other managed care providers. As of September 30, 2007, we had entered into contracts establishing reimbursement for the OmniPod System with national and regional third-party payors covering an estimated 96 million lives. These contracts provide reimbursement in each of the 30 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 believe that the coding verification for Medicare reimbursement of the OmniPod System is inappropriate and we are therefore in the process of seeking appropriate coding verification. As a result, we have 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.

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

On May 14, 2007, our registration statements on Form S-1 (Registration Nos. 333-140694 and 333-142952), as amended, were declared effective for our initial public offering, pursuant to which we offered and sold 8,365,000 shares of common stock and received net proceeds of approximately \$113.4 million, after deducting underwriting discounts and offering commissions of approximately \$8.8 million and other offering costs of approximately \$3.3 million. None of the underwriting discounts and commissions or offering expenses were 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. All of the shares of common stock issued pursuant to the registration statements were sold at a price to the public of \$15.00 per share. The managing underwriters were J.P. Morgan Securities Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Thomas Weisel Partners LLC and Leerink Swann & Co., Inc.

As of September 30, 2007, we have used approximately \$9.2 million of the net proceeds we received from the offering for working capital and other general corporate purposes, including the financing our growth, the expansion of our OmniPod production capacity, the continued expansion of our sales and marketing activities and the funding of our research and development efforts. Pending such usage, we have invested the net proceeds in short-term, interest-bearing investment-grade securities. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b).

In September 2007, Lighthouse Capital Partners V, L.P. exercised their right to convert 125,853 warrants into common stock, resulting in the issuance of 89,821 shares of common stock. The securities issued in the foregoing transaction were offered and sold in reliance on an exemption from registration set forth in Section 3(a)(9) of the Securities Act relating to exchanges of securities. No underwriters or placement agents were involved in the foregoing issuance.

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**Item 3. Defaults Upon Senior Securities**

None.

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

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>
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)

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

Date: November 14, 2007

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

Date: November 14, 2007

**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  
Duane DeSisto  
President and  
Chief Executive Officer

November 14, 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

Carsten Boess  
Chief Financial Officer

November 14, 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 September 30, 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: November 14, 2007

/s/ Carsten Boess

Name: Carsten Boess

Title: Chief Financial Officer

Date: November 14, 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.