

INSULET CORP  
Form 10-Q  
November 06, 2015  
Table of Contents

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, 2015

OR

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

Commission File Number 001-33462

---

INSULET CORPORATION  
(Exact name of Registrant as specified in its charter)

---

Delaware (State or Other Jurisdiction of Incorporation or Organization)	04-3523891 (I.R.S. Employer Identification No.)
---	---

---

600 Technology Park Drive, Suite 200 Billerica, Massachusetts (Address of Principal Executive Offices)	01821 (Zip Code)
--	---------------------

Registrant's Telephone Number, Including Area Code: (978) 600-7000

---

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

As of November 5, 2015, the registrant had 56,928,573 shares of common stock outstanding.

---

Table of Contents

INSULET CORPORATION  
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED  
September 30, 2015  
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements (Unaudited) 3

Consolidated Balance Sheets as of September 30, 2015 (Unaudited) and December 31, 2014

Consolidated Statements of Operations for the three and nine months ended September 30, 2015  
and 2014 (Unaudited)

Consolidated Statements of Comprehensive Loss for the three and nine months ended September  
30, 2015 and 2014 (Unaudited)

Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014  
(Unaudited)

Condensed Notes to Consolidated Financial Statements (Unaudited) 7

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 25

Item 3. Quantitative and Qualitative Disclosures About Market Risk 37

Item 4. Controls and Procedures 37

PART II. OTHER INFORMATION

Item 1. Legal Proceedings 38

Item 1A. Risk Factors 38

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 38

Item 3. Defaults Upon Senior Securities 38

Item 4. Mine Safety Disclosures 38

Item 5. Other Information 38

Item 6. Exhibits 39

Signatures 40

---

Table of Contents

## PART I - FINANCIAL INFORMATION

## Item 1. Consolidated Financial Statements (Unaudited)

## INSULET CORPORATION

## CONSOLIDATED BALANCE SHEETS

	September 30, 2015	December 31, 2014
	(Unaudited)	
(In thousands, except share and per share data)		
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$145,467	\$151,193
Accounts receivable, net	31,803	39,882
Inventories, net	13,019	13,099
Prepaid expenses and other current assets	4,049	4,022
Total current assets	194,338	208,196
Property and equipment, net	41,536	37,069
Intangible assets, net	13,039	14,064
Goodwill	39,823	37,536
Other assets	4,384	5,291
Total assets	\$293,120	\$302,156
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities		
Accounts payable	\$15,614	\$14,659
Accrued expenses and other current liabilities	35,547	24,703
Deferred revenue	2,256	1,554
Current portion of capital lease obligations	6,020	3,380
Total current liabilities	59,437	44,296
Capital lease obligations	1,061	2,263
Long-term debt, net of discount	173,870	168,994
Other long-term liabilities	3,619	2,774
Total liabilities	237,987	218,327
Commitments and contingencies (Note 12)		
Stockholders' Equity		
Preferred stock, \$.001 par value:		
Authorized: 5,000,000 shares at September 30, 2015 and December 31, 2014.	—	—
Issued and outstanding: zero shares at September 30, 2015 and December 31, 2014.		
Common stock, \$.001 par value:		
Authorized: 100,000,000 shares at September 30, 2015 and December 31, 2014.		
Issued and outstanding: 56,914,557 and 56,299,022 shares at September 30, 2015 and 57 December 31, 2014, respectively.		56
Additional paid-in capital	679,761	661,811
Accumulated other comprehensive loss	(467	) (13
Accumulated deficit	(624,218	) (578,025
Total stockholders' equity	55,133	83,829
Total liabilities and stockholders' equity	\$293,120	\$302,156

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

Table of ContentsINSULET CORPORATION  
CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

(In thousands, except share and per share data)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Revenue	\$87,303	\$74,985	\$224,106	\$216,159
Cost of revenue	51,652	36,943	121,273	109,544
Gross profit	35,651	38,042	102,833	106,615
Operating expenses:				
Research and development	10,035	7,158	30,311	20,614
General and administrative	17,156	18,890	45,841	52,661
Sales and marketing	24,194	14,870	63,406	43,382
Total operating expenses	51,385	40,918	139,558	116,657
Operating loss	(15,734)	(2,876)	(36,725)	(10,042)
Interest income	46	32	123	92
Interest expense	(3,167)	(3,043)	(9,435)	(11,507)
Other expense, net	(10)	(677)	(5)	(1,302)
Loss on extinguishment of long-term debt	—	(4,260)	—	(23,203)
Interest and other expense, net	(3,131)	(7,948)	(9,317)	(35,920)
Loss before income taxes	(18,865)	(10,824)	(46,042)	(45,962)
Income tax expense	(62)	(21)	(151)	(138)
Net loss	\$(18,927)	\$(10,845)	\$(46,193)	\$(46,100)
Net loss per share basic and diluted	\$(0.33)	\$(0.19)	\$(0.81)	\$(0.83)
Weighted-average number of shares used in calculating net loss per share	56,898,281	55,819,242	56,735,944	55,447,414

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

Table of Contents

## INSULET CORPORATION

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

(In thousands)	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net loss	\$ (18,927	) \$ (10,845	) \$ (46,193	) \$ (46,100
Other comprehensive loss, net of tax				
Foreign currency translation adjustment, net of tax	(457	) 1	(454	) —
Total other comprehensive loss, net of tax	(457	) 1	(454	) —
Total comprehensive loss	\$ (19,384	) \$ (10,844	) \$ (46,647	) \$ (46,100

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

Table of Contents

INSULET CORPORATION  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

	Nine Months Ended September	
	30,	2014
(In thousands)	2015	2014
Cash flows from operating activities		
Net loss	\$(46,193	) \$(46,100
Adjustments to reconcile net loss to net cash used in operating activities		)
Depreciation and amortization	11,406	9,168
Non-cash interest and other expense	5,721	8,397
Stock-based compensation expense	13,852	18,247
Loss on extinguishment of debt	—	23,203
Provision for bad debts	2,762	2,669
Changes in operating assets and liabilities:		
Accounts receivable	5,286	(16,747
Inventories	312	(198
Deferred revenue	703	(66
Prepaid expenses and other assets	42	1,242
Accounts payable, accrued expenses and other current liabilities	11,782	3,861
Other long-term liabilities	370	637
Net cash provided operating activities	6,043	4,313
Cash flows from investing activities		
Purchases of property and equipment	(7,126	) (8,853
Acquisition of Canadian distribution business	(4,715	) —
Net cash used in investing activities	(11,841	) (8,853
Cash flows from financing activities		
Principal payments of capital lease obligations	(4,283	) (2,174
Proceeds from issuance of long-term debt, net of issuance costs	—	194,576
Repayment of long-term debt	—	(189,521
Proceeds from issuance of common stock, net of offering costs	7,043	6,877
Payment of withholding taxes in connection with vesting of restricted stock units	(2,468	) (8,573
Net cash provided by financing activities	292	1,185
Effect of exchange rate changes on cash	(220	) —
Net (decrease) in cash and cash equivalents	(5,726	) (3,355
Cash and cash equivalents, beginning of period	151,193	149,727
Cash and cash equivalents, end of period	\$145,467	\$146,372
Non-cash investing and financing activities		
Allocation to equity for conversion feature for the 2% Notes	\$—	\$35,638
Common stock issued in exchange for 3.75% Convertible Senior Notes	\$—	\$12,564
Purchases of property and equipment under capital lease	\$5,721	\$1,474

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

Table of Contents

INSULET CORPORATION  
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

Note 1. Nature of the Business

Insulet Corporation, the "Company," is primarily engaged in the development, manufacturing and sale of its proprietary OmniPod Insulin Management System (the "OmniPod System"), an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. The OmniPod System features a unique disposable tubeless OmniPod which is worn on the body for approximately three days at a time and the handheld, wireless Personal Diabetes Manager ("PDM"). Conventional insulin pumps require people with insulin-dependent diabetes to learn to use, manage and wear a number of cumbersome components, including up to 42 inches of tubing. In contrast, the OmniPod System features two discreet, easy-to-use devices that eliminate the need for a bulky pump, tubing and separate blood glucose meter, provides for virtually pain-free automated cannula insertion, communicates wirelessly and integrates a blood glucose meter.

The Company acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, "Neighborhood Diabetes") in June 2011, in order to expand the Company's full-suite diabetes management product offerings and obtain access to a larger number of insulin dependent patients. Through Neighborhood Diabetes, the Company is able to provide customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and has the ability to process claims as either durable medical equipment or through pharmacy benefits.

Commercial sales of the OmniPod System began in the United States in 2005. The Company sells the OmniPod System and other diabetes management supplies in the United States through direct sales to customers or through its distribution partners. The OmniPod System is currently available in multiple countries in Europe and in Canada.

On July 7, 2015, the Company executed an asset purchase agreement whereby it acquired the Canadian OmniPod distribution operations from GlaxoSmithKline (GSK). With the acquisition, the Company assumed all distribution, sales, marketing, training and support activities for the OmniPod system in Canada. Additional information regarding this acquisition is provided in note 3 to the consolidated financial statements included in this Form 10-Q.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited consolidated financial statements in this Quarterly Report on Form 10-Q have been prepared in accordance with generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these unaudited consolidated financial statements do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three and nine month periods ended September 30, 2015 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2015, or for any other subsequent interim period.

The unaudited consolidated financial statements in this Quarterly Report on Form 10-Q should be read in conjunction with the Company's consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

Foreign Currency Translation

For foreign operations, asset and liability accounts are translated at current exchange rates; income and expenses are translated using weighted average exchange rates for the reporting period. Resulting translation adjustments are reported in accumulated other comprehensive loss, a separate component of stockholders' equity. Gains and losses arising from transactions and translation of period-end balances denominated in currencies other than the functional currency are included in other expense, net, and were not material for fiscal years 2015 and 2014.

## Table of Contents

### Use of Estimates in Preparation of Financial Statements

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expense during the reporting periods. The most significant estimates used in these financial statements include the valuation of; stock-based compensation expense, acquired businesses, accounts receivable, inventories, goodwill, deferred revenue, and equity instruments, the lives of property and equipment and intangible assets, as well as warranty and doubtful accounts allowance reserve calculations. Actual results may differ from those estimates.

### Principles of Consolidation

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

### Cash and Cash Equivalents

For the purpose of the financial statement classification, the Company considers all highly liquid investment instruments with original maturities of 90 days or less, when purchased, to be cash equivalents. Cash equivalents include money market accounts, which are carried at cost which approximates their fair value. Outstanding letters of credit, related to security deposits for lease obligations, totaled \$1.2 million as of September 30, 2015 and December 31, 2014.

### Property and Equipment

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

### Business Combinations

The Company recognizes the assets and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets, including intangible assets, using a variety of methods and each asset is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant's use of the asset and the appropriate discount rates for a market participant. Assets recorded from the perspective of a market participant that are determined to not have economic use for the Company are expensed immediately. Any excess purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

### Goodwill

Goodwill represents the excess of the cost of acquired businesses over the fair value of identifiable net assets acquired. The Company follows the provisions of FASB ASC 350-20, Intangibles - Goodwill and Other ("ASC 350-20"). The Company performs an assessment of its goodwill for impairment on at least an annual basis or whenever events or changes in circumstances indicate there might be impairment.

The Company continues to operate in one segment, which is considered to be the sole reporting unit and therefore, goodwill was tested for impairment at the enterprise level. The Company performs an annual goodwill impairment test unless interim indicators of impairment exist. The Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of its sole reporting unit is less than its carrying amount. This qualitative analysis is used as a basis for determining whether it is necessary to perform the two-step goodwill impairment analysis. If the Company determines that it is more likely than not that its fair value is less than its carrying amount, then the two-step goodwill impairment test will be performed. The first step compares the carrying value of the reporting unit to its fair value using a discounted cash flow analysis. If the reporting unit's carrying value exceeds its fair value, the Company would record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. There were no indicators of goodwill impairment during the three and nine months ended September 30, 2015 or 2014.





## Table of Contents

### Revenue Recognition

The Company generates nearly all of its revenue from sales of its OmniPod System and other diabetes related products including blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals to customers and third-party distributors who resell the products to patients with diabetes.

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

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

Transfer of title and risk and rewards of ownership are passed to the patient or third-party distributor upon shipment of the products.

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

The Company offers a 45-day right of return for sales of its OmniPod System in the United States, and a 90-day right of return for sales of its OmniPod System in Canada to new patients and defers revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of the Company's historical return data to its related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. When doubt exists about reasonable assuredness of collectability from specific customers, the Company defers revenue from sales of products to those customers until payment is received. In June 2011, the Company entered into a development agreement with a U.S. based pharmaceutical company (the "Development Agreement"). Under the Development Agreement, the Company was required to perform design, development, regulatory, and other services to support the pharmaceutical company as it worked to obtain regulatory approval to use the Company's drug delivery technology as a delivery method for its pharmaceutical. Over the term of the Development Agreement, the Company has invoiced amounts based upon meeting certain deliverable milestones. Revenue on the Development Agreement was recognized using a proportional performance methodology based on efforts incurred and total payments under the agreement. The impact of changes in the expected total effort or contract payments was recognized as a change in estimate using the cumulative catch-up method. The pharmaceutical company received regulatory approval and now purchases product from the Company for use with its pharmaceutical under a supply agreement. Product revenue under this arrangement is recognized at the time that all of the revenue recognition criteria are met, typically upon shipment.

The Company deferred revenue of \$2.4 million and \$1.6 million as of September 30, 2015 and December 31, 2014, respectively. Deferred revenue as of September 30, 2015 included \$0.2 million classified in other long term liabilities. International OmniPod revenue accounted for approximately 16% and 11% of total revenue in the third quarter and first nine months of 2015, respectively, compared to approximately 17% for the same periods in 2014.

### Shipping and Handling Costs

The Company does not typically charge its customers for shipping and handling costs associated with shipping its product to its customers. These shipping and handling costs are included in general and administrative expenses.

### Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents. The Company maintains the majority of its cash with two financial institutions.

The Company purchases complete OmniPods from Flextronics International Ltd., its single source supplier. As of September 30, 2015 and December 31, 2014, liabilities from this vendor represented approximately 26% and 24% of the combined balance of accounts payable, accrued expenses and other current liabilities, respectively.

## Table of Contents

In the three months ended September 30, 2015 and 2014, two customers represented 12% and 11%, and 15% and 10% of total revenue, respectively. In the nine months ended September 30, 2015, one customer represented 11% of total revenue. In the nine months ended September 30, 2014, two customers represented 15% and 12% of total revenue, respectively.

### Segment Reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company's current product offering primarily consists of diabetes supplies, including the OmniPod System as well as other diabetes related products and supplies such as blood glucose testing supplies, traditional insulin pumps, pump supplies, and pharmaceuticals. The Company's current product offering is marketed to a single customer type. As the Company sells a single product type, management operates the business as a single entity.

### Reclassification of Prior Period Balance

Certain reclassifications have been made to prior periods amounts to conform to the current period financial statement presentation. These reclassifications have no effect on previously reported net income.

### Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 requires that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. Under this guidance, a company may make additional estimates regarding performance conditions and the allocation of variable consideration. The guidance is effective in fiscal years beginning after January 1, 2018, with early adoption permitted. The Company is currently evaluating the impact of ASU 2014-09. The Company has not yet selected a transition method nor has it determined the effect of the standard on our consolidated financial position and results of operations.

In June 2014, the FASB issued ASU No. 2014-12, Compensation - Stock Compensation (Topic 718), Accounting for Share-Based Payments when the terms of an award provide that a performance target could be achieved after the requisite service period ("ASU 2014-12"). ASU 2014-12 clarifies the period over which compensation cost would be recognized in awards with a performance target that affects vesting and that could be achieved after the requisite service period. Compensation cost would be recognized over the required service period, if it is probable that the performance condition will be achieved. The guidance is effective in fiscal years beginning after January 1, 2016, with early adoption permitted. The Company is currently evaluating the impact of ASU 2014-12.

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs ("ASU 2015-03"). ASU 2015-03 amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. The guidance is effective for annual reporting periods beginning after December 15, 2015, and must be applied retrospectively. Early adoption is permitted. Had the Company adopted ASU 2015-03, other noncurrent assets and long-term debt would both have been \$4.1 million and \$5.0 million lower as of September 30, 2015 and December 31, 2014, respectively.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory ("ASU 2015-11"). ASU 2015-11 amends existing guidance and requires entities to measure most inventory at the lower of cost and net realizable value. The guidance is effective prospectively for annual reporting periods beginning after December 15, 2016. Early adoption is permitted. Upon adoption, entities must disclose the nature of and reason for the accounting change. The Company is currently evaluating the impact of ASU 2015-11.

In September 2015, the FASB issued ASU No. 2015-16, Simplifying the Accounting for Measurement Period Adjustments ("ASU 2015-16"). ASU 2015-16 eliminates the requirement that an acquirer in a business combination account for measurement-period adjustments retrospectively. Instead, an acquirer will recognize a measurement period adjustment during the period in which it determines the amount of the adjustment, including the effect on earnings of any amounts it would have recorded in previous periods if the accounting had been completed at the acquisition date. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2015-16.



Table of Contents

## Other Significant Policies:

The following table identifies the Company's other significant accounting policies and the note and page where a detailed description of each policy can be found.

<u>Fair Value Measurements</u>	Note	4	Page	<u>12</u>
<u>Accounts Receivable and Allowance for Doubtful Accounts</u>	Note	8	Page	<u>17</u>
<u>Inventories</u>	Note	9	Page	<u>17</u>
<u>Intangibles and Other Long-Lived Assets</u>	Note	10	Page	<u>18</u>
<u>Warranty</u>	Note	11	Page	<u>19</u>
<u>Stock-Based Compensation</u>	Note	13	Page	<u>20</u>
<u>Income Taxes</u>	Note	14	Page	<u>23</u>

Table of Contents

## Note 3. Business Combinations

On July 7, 2015, the Company executed an asset purchase agreement with GlaxoSmithKline (GSK) whereby the Company acquired GSK's assets associated with the Canadian distribution of the Company's products. With the acquisition, the Company assumed all distribution, sales, marketing, training and support activities for the OmniPod system in Canada through its wholly-owned subsidiary, Insulet Canada Corporation.

The acquisition allows the Company to establish a local presence in Canada that enables it to engage directly with healthcare providers and OmniPod users. The aggregate purchase price of approximately \$4.7 million consisted of cash paid at closing, subject to certain adjustments.

The Company has accounted for the acquisition as a business combination. Under business combination accounting, the assets and liabilities were recorded as of the acquisition date, at their respective fair values, and consolidated with the Company. The excess of the purchase price over the fair value of net assets acquired was recorded as goodwill.

The operating results of GSK Canada have been included in the consolidated financial statements since July 7, 2015, the date the acquisition was completed. These results are not material to our revenues or operating results.

Prior to the acquisition the Company had a pre-existing relationship with GSK. As a result of the acquisition, the pre-existing relationship was settled by Insulet, with Insulet repurchasing the \$0.5 million of inventory held by GSK at the date of the asset purchase. The inventory repurchased had been sold to GSK during the second quarter of 2015, however no revenue was recognized by Insulet on these sales given the expectation to repurchase. As the inventory was repurchased at cost, there were no gains or losses associated with this transaction. This transaction was accounted for separately from the business combination.

The table below details the consideration transferred to acquire GSK (in thousands):

Cash	\$5,000
Employment liability transfer fee	(285 )
Total consideration	\$4,715

The fair value of the assets acquired and liabilities assumed was determined based on information that was available to management at the time the financial statements were prepared and are preliminary, subject to the completion of an independent third party valuation.

The preliminary fair value of the assets acquired and liabilities assumed was:

Goodwill	\$2,403
Contractual relationships	2,100
Inventory	230
Assumed liabilities	(18 )
	\$4,715

During the three and nine months ended September 30, 2015, the Company incurred transaction costs of \$0.1 million, consisting primarily of legal fees, which have been recorded as general and administrative expenses. The Company determined that there was no value to the reacquisition of the Canada exclusivity contract due to the contribution charges of the contractual relationships.

## Note 4. Fair Value Measurements

The Company adopted the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures ("ASC 820") related to the fair value measurement of certain of its assets and liabilities. ASC 820 defines fair value as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. A single estimate of fair value results from a complex series of judgments about future events and uncertainties and relies heavily on estimates and assumptions. When estimating fair value, depending on the nature and complexity of the asset or liability, the Company may use one or all of the following approaches:

- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.



Table of Contents

• Cost approach, which is based on the cost to acquire or construct comparable assets less an allowance for functional and/or economic obsolescence.

¶ Income approach, which is based on the present value of the future stream of net cash flows.

To measure fair value, the Company uses the following fair value hierarchy based on three levels of inputs, as described in ASC 820, of which the first two are considered observable and the last unobservable:

Level 1 — quoted prices in active markets for identical assets or liabilities

Level 2 — observable inputs other than quoted prices in active markets for identical assets or liabilities

Level 3 — unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

The assets and liabilities subject to fair value measurement standards at September 30, 2015 and December 31, 2014 are cash equivalents, consisting of money market funds, and long-term debt which are both based on Level 1 inputs.

Certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and other liabilities are carried at cost, which approximates their fair value because of the short-term maturity of these financial instruments.

The following table provides a summary of financial assets that are measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014, aggregated by the level in the fair value hierarchy within which those measurements fall (in thousands):

	Fair Value Measurements			
	Total	Level 1	Level 2	Level 3
September 30, 2015				
Cash Equivalents - Money Market Funds	\$ 108,196	\$ 108,196	\$—	\$—
December 31, 2014				
Cash Equivalents - Money Market Funds	\$ 123,141	\$ 123,141	\$—	\$—

**Debt**

The estimated fair value of debt is based on the Level 1 quoted market prices for the same or similar issues and included the impact of the conversion features.

The carrying amounts and the estimated fair values of financial instruments as of September 30, 2015 and December 31, 2014, are as follows (in thousands):

	September 30, 2015		December 31, 2014	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
2% Convertible Senior Notes	\$ 173,870	\$ 185,504	\$ 168,994	\$ 237,475

The Company issued \$201.3 million in principal amount of 2% Notes (as defined below) in June 2014. The carrying value of the 2% Notes at September 30, 2015 includes a debt discount of \$27.4 million which is being amortized as non-cash interest expense over the term of the 2% Notes. The decrease in the estimated fair values of these liabilities from December 31, 2014 to September 30, 2015 represents the impact of the quoted bond prices at those dates.



Table of Contents

## Note 5. Debt

The Company had outstanding convertible debt and related deferred financing costs on its consolidated balance sheet as follows (in thousands):

	As of	
	September 30, 2015	December 31, 2014
Principal amount of the 2% Convertible Senior Notes	\$201,250	\$201,250
Unamortized debt discount	(27,380	) (32,256
Long-term debt, net of discount	\$173,870	\$168,994
Deferred financing costs	\$4,130	\$4,974

Interest expense related to the 3.75% Notes (as defined below) and the 2% Notes was included in interest and other expense on the consolidated statements of operations as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Contractual coupon interest	\$1,007	\$962	\$3,019	\$3,583
Accretion of debt discount	1,650	1,548	4,876	6,431
Amortization of debt issuance costs	281	277	844	615
Loss on extinguishment of long-term debt	—	4,260	—	23,203
Total interest and other expense	\$2,938	\$7,047	\$8,739	\$33,832

**3.75% Convertible Senior Notes**

In June 2011, the Company sold \$143.8 million in principal amount of 3.75% Convertible Senior Notes due June 15, 2016 (the "3.75% Notes"). The interest rate on the notes was 3.75% per annum, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 3.75% Notes were convertible into the Company's common stock at an initial conversion rate of 38.1749 shares of common stock per \$1,000 principal amount of the 3.75% Notes, which was equivalent to a conversion price of approximately \$26.20 per share.

In connection with the issuance of the 3.75% Notes, the Company repurchased \$70 million in principal amount of its 5.375% Convertible Senior Notes due June 15, 2013 (the "5.375% Notes") for \$85.1 million, a 21.5% premium on the principal amount. The investors that held the \$70 million in principal amount of repurchased 5.375% Notes purchased \$59.5 million in principal amount of the 3.75% Notes and retained approximately \$13.5 million in principal amount of the remaining 5.375% Notes. These investors' combined \$73.0 million in principal amount of convertible debt (\$13.5 million of 5.375% Notes and \$59.5 million of 3.75% Notes) was considered to be a modification of a portion of the 5.375% Notes and was accounted for separately from the issuance of the remainder of the 3.75% Notes.

The Company recorded a total debt discount of \$25.8 million related to the modified debt. This discount consisted of \$10.5 million related to the remaining debt discount on the \$70 million in principal amount of 5.375% Notes repurchased, \$15.1 million related to the premium payment in connection with the repurchase and \$0.2 million related to the increase in the value of the conversion feature. The total debt discount was being amortized as non-cash interest expense at the effective rate of 16.5% over the five year term of the modified debt. Additionally, the Company paid transaction fees of approximately \$2.0 million related to the modification, which were recorded as interest and other expense at the time of the modification.

As of December 31, 2013, the 5.375% Notes were repaid in full and no amounts remained on the Company's balance sheet related to these notes.

Table of Contents

Of the \$143.8 million in principal amount of 3.75% Notes issued in June 2011, \$84.3 million in principal amount was considered to be an issuance of new debt. The Company recorded a debt discount of \$26.6 million related to the \$84.3 million in principal amount of 3.75% Notes. The debt discount was recorded as additional paid-in capital to reflect the value of its nonconvertible debt borrowing rate of 12.4% per annum and was being amortized as non-cash interest expense over the five year term of the 3.75% Notes. The Company incurred deferred financing costs related to this offering of approximately \$2.8 million, of which \$0.9 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder was recorded as other assets in the consolidated balance sheet and was being amortized as non-cash interest expense over the five year term of the 3.75% Notes.

In June 2014, in connection with the issuance of \$201.3 million in principal amount of 2% Convertible Senior Notes due June 15, 2019 (the "2% Notes"), the Company repurchased approximately \$114.9 million in principal amount of the 3.75% Notes for \$160.7 million, a premium of \$45.8 million over the principal amount. Investors that held approximately \$80.0 million of 3.75% Notes purchased approximately \$98.2 million in principal amount of the 2% Notes. The repurchase of the 3.75% Notes was treated as an extinguishment of debt since the fair value of the conversion feature changed by more than 10%. The extinguishment of the 3.75% Notes was accounted for separately from the issuance of the 2% Notes. The \$160.7 million paid to extinguish the debt was allocated to debt and equity based on their respective fair values immediately prior to the transaction. The Company allocated \$112.4 million of the payment to the debt and \$48.3 million to equity.

The 3.75% Notes were convertible at the option of the holder during the quarter ended June 30, 2014 since the last reported sales price per share of the Company's common stock was equal to or greater than 130% of the conversion price for at least 20 of the 30 trading days ended on March 31, 2014. The 3.75% Notes and any unpaid interest were convertible at the Company's option for cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock.

Beginning on June 20, 2014, the Company had the right to redeem the 3.75% Notes, at its option, in whole or in part, if the last reported sale price per share of the Company's common stock was at least 130% of the conversion price then in effect for at least 20 trading days during a period of 30 consecutive trading days. In June 2014, the Company met the redemption requirements and notified holders of its intent to redeem the outstanding \$28.8 million in principal amount of 3.75% Notes in July 2014. Prior to the redemption date, holders of \$28.5 million in principal amount of 3.75% Notes exercised their right to convert their outstanding 3.75% Notes. The Company settled this conversion of the 3.75% Notes in July 2014 by providing cash of \$28.5 million for the principal amount of the outstanding 3.75% Notes converted and issuing 348,535 shares of common stock for the conversion premium totaling \$12.6 million, for a total consideration paid of \$41.1 million. The Company settled the redemption of the remaining \$0.3 million in principal amount in exchange for a cash payment of \$0.3 million representing principal and accrued and unpaid interest. The Company allocated \$27.9 million of the total consideration paid to the debt and \$13.5 million to equity. The Company recorded a loss on extinguishment of debt of \$23.2 million in connection with the repurchase and redemption of the 3.75% Notes during the year ended December 31, 2014, representing the excess of the \$140.3 million allocated to the debt over its carrying value, net of deferred financing costs.

Certain features related to a portion of the 3.75% Notes, including the holders' ability to require the Company to repurchase their notes and the higher interest payments required in an event of default, were considered embedded derivatives and were required to be bifurcated and accounted for at fair value. The Company assessed the value of these embedded derivatives at each balance sheet date.

No cash interest expense was recorded related to the 3.75% Notes in the three and nine months ended September 30, 2015 and the three months ended September 30, 2014. Cash interest expense related to the 3.75% Notes outstanding was \$2.4 million in the nine months ended September 30, 2014. There was no non-cash interest expense recorded in the three and nine months ended September 30, 2015 and the three months ended September 30, 2014 related to the 3.75% Notes, compared to \$4.9 million in the nine months ended September 30, 2014.

As of December 31, 2014, no amounts remain outstanding related to the 3.75% Notes.

**2% Convertible Senior Notes**

In June 2014, the Company sold \$201.3 million in principal amount of the 2% Notes due June 15, 2019. The interest rate on the notes is 2% per annum, payable semi-annually in arrears in cash on December 15 and June 15 of each year.

The 2% Notes are convertible into the Company's common stock at an initial conversion rate of 21.5019 shares of common stock per \$1,000 principal amount of the 2% Notes, which is equivalent to a conversion price of approximately \$46.51 per share, subject to adjustment under certain circumstances.

Table of Contents

The Company recorded a debt discount of \$35.6 million related to the 2% Notes. The debt discount was recorded as additional paid-in capital to reflect the value of the Company's nonconvertible debt borrowing rate of 6.2% per annum. This debt discount is being amortized as non-cash interest expense over the five year term of the 2% Notes. The Company incurred deferred financing costs related to this offering of approximately \$6.7 million, of which \$1.2 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as non-cash interest expense over the five year term of the 2% Notes.

The Company determined that the higher interest and tax payments required in certain circumstances are considered embedded derivatives and should be bifurcated and accounted for at fair value. The Company assesses the value of the embedded derivatives at each balance sheet date. The derivatives had de minimis value at the balance sheet date.

Cash interest expense related to the 2% Notes was \$1.0 million in both the three months ended September 30, 2015 and 2014, and \$3.0 million and \$1.2 million in the nine months ended September 30, 2015 and 2014, respectively. Non-cash interest expense related to the 2% Notes was \$1.9 million and \$1.8 million in the three months ended September 30, 2015 and 2014, respectively, and \$5.7 million and \$2.1 million in the nine months ended September 30, 2015 and 2014, respectively.

As of September 30, 2015, the Company included \$173.9 million on its balance sheet in long-term debt related to the 2% Notes.

**Note 6. Capital Lease Obligations**

As of September 30, 2015 and December 31, 2014, the Company has approximately \$13.7 million and \$8.0 million of manufacturing equipment acquired under capital leases, respectively. The obligations under the capital leases are being repaid in equal monthly installments over 24 to 36 month terms and include principal and interest payments with an effective interest rate of 13% to 17%.

The assets have been recorded at \$13.7 million and are included in property and equipment on the Company's balance sheet as of September 30, 2015. The assets acquired under capital leases are being amortized on a straight-line basis over 5 years in accordance with the Company's policy for depreciation of manufacturing equipment. Amortization expense on assets acquired under capital leases is included with depreciation expense. Amortization expense related to these capital leased assets was \$0.6 million and \$0.3 million in the three months ended September 30, 2015 and 2014, respectively, and \$1.7 million and \$1.0 million in the nine months ended September 30, 2015 and 2014, respectively. Assets held under capital leases consist of the following (in thousands):

	As of	
	September 30, 2015	December 31, 2014
Manufacturing equipment	\$13,705	\$7,984
Less: Accumulated amortization	(3,623)	(1,885)
Total	\$10,082	\$6,099

The aggregate future minimum lease payments related to these capital leases as of September 30, 2015, are as follows (in thousands):

Years Ending December 31,	Minimum Lease Payments
2015 (remaining)	\$1,762
2016	5,639
2017	269
Total future minimum lease payments	\$7,670
Interest expense	(589)
Total capital lease obligations	\$7,081

Table of Contents

The Company recorded \$0.3 million and \$0.4 million of interest expense on the capital leases in the three months ended September 30, 2015 and 2014, respectively. The Company recorded \$1.0 million in both the nine month periods ended September 30, 2015 and 2014.

## Note 7. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options, restricted stock units 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, 2015 and 2014, all potential dilutive common shares have been excluded from the computation of the diluted net loss per share for all periods presented, as the effect would have been anti-dilutive.

Potential dilutive common share equivalents consist of the following:

	Three and Nine Months Ended September 30,	
	2015	2014
2.00% Convertible Senior Notes	4,327,257	4,327,257
Unvested restricted stock units	862,044	786,850
Outstanding options	2,959,320	1,549,211
Total dilutive common shares	8,148,621	6,663,318

## Note 8. Accounts Receivable

Accounts receivable consist of amounts due from third-party payors, patients, third-party distributors and government agencies. The Company records an allowance for doubtful accounts at the time potential collection risk is identified. The Company estimates its allowance based on historical experience, assessment of specific risk, discussions with individual customers or various assumptions and estimates that are believed to be reasonable under the circumstances. The Company believes the reserve is adequate to mitigate current collection risk.

Accounts receivable from one customer represented approximately 13% of gross accounts receivable as of September 30, 2015. As of December 31, 2014 accounts receivable from two customers represented approximately 19% and 10% of gross accounts receivable, respectively.

The components of accounts receivable are as follows (in thousands):

	As of	
	September 30, 2015	December 31, 2014
Trade receivables	\$37,709	\$45,719
Allowance for doubtful accounts	(5,906	) (5,837
Total accounts receivable	\$31,803	\$39,882

## Note 9. Inventories

Inventories are held at the lower of cost or market, determined under the first-in, first-out method. Inventory has been recorded at cost as of September 30, 2015 and December 31, 2014. Work in process is calculated based upon a buildup in the stage of completion using estimated labor inputs for each stage in production. The Company periodically reviews inventories for net realizable value based on quantities on hand and expectations of future use.

Inventories consist of the following (in thousands):

	As of	
	September 30, 2015	December 31, 2014
Raw materials	\$967	\$853
Work-in-process	200	254
Finished goods, net	11,852	11,992
Total inventories	\$13,019	\$13,099



Table of Contents

## Note 10. Other Intangible Assets

The Company's finite-lived intangible assets are stated at cost less accumulated amortization. The Company assesses its intangible and other long-lived assets for impairment whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company recognizes an impairment loss for intangibles and other finite-lived assets if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. Any such impairment loss is measured as the difference between the carrying amount and the fair value of the asset. The estimation of useful lives and expected cash flows requires the Company to make significant judgments regarding future periods that are subject to some factors outside its control. Changes in these estimates can result in significant revisions to the carrying value of these assets and may result in material charges to the results of operations. The Company recorded \$32.9 million of other intangible assets as a result of the acquisition of Neighborhood Diabetes. The estimated life of the acquired tradename asset is 15 years. The estimated useful life of the acquired customer relationship asset is 10 years. Intangible assets with determinable estimated lives are amortized over these lives.

The Company recorded \$2.1 million of other intangible assets in the nine months ended September 30, 2015 as a result of the acquisition of its Canadian distribution business (see Footnote 3 for further description). The Company determined that the estimated useful life of the contractual relationship asset is 5 years and is amortizing the asset over the estimated lives, based on the expected cash flows of the assets, accordingly. The amortization of other intangible assets was approximately \$0.5 million for the three and nine months ended September 30, 2015. Amortization expense for the year ending December 31, 2015 is expected to be approximately \$1.0 million.

Other intangible assets consist of the following (in thousands):

	As of September 30, 2015			December 31, 2014		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Customer and contractual relationships, net <sup>(1)</sup>	\$32,099	\$(21,051)	) \$11,048	\$30,100	\$(18,167)	) \$11,933
Tradename	2,800	(809)	) 1,991	2,800	(669)	) 2,131
Total intangible assets	\$34,899	\$(21,860)	) \$13,039	\$32,900	\$(18,836)	) \$14,064

<sup>(1)</sup> Includes foreign currency translation loss of approximately \$0.1 million.

Amortization expense related to other intangible assets was approximately \$1.2 million and \$0.9 million for the three months ended September 30, 2015 and 2014, respectively. Amortization expense was approximately \$3.0 million and \$3.1 million for the nine months ended September 30, 2015 and 2014, respectively.

Amortization expense expected for the next five years and thereafter is as follows (in thousands):

Years Ending December 31,	Amortization Expense		
	Customer and Contractual Relationships	Tradename	Total
2015 (remaining)	\$1,214	\$47	\$1,261
2016	2,914	187	3,101
2017	2,184	187	2,371
2018	1,774	187	1,961
2019	1,438	187	1,625
Thereafter	1,524	1,196	2,720
Total	\$11,048	\$1,991	\$13,039

As of September 30, 2015, the weighted average amortization period of the Company's intangible assets is approximately 6.3 years.





Table of Contents

## Note 11. Product Warranty Costs

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

A reconciliation of the changes in the Company's product warranty liability is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Balance at the beginning of the period	\$3,167	\$2,505	\$2,614	\$3,090
Warranty expense <sup>(1)</sup>	1,579	596	3,300	1,139
Warranty claims settled	(992)	(566)	(2,160)	(1,694)
Balance at the end of the period	\$3,754	\$2,535	\$3,754	\$2,535

(1) Includes \$0.5 million of warranty expense related to product that was shipped during the three months ending September 30, 2015 that did not meet the Company's quality expectations.

	As of September 30, 2015	December 31, 2014
Composition of balance:		
Short-term	\$1,925	\$981
Long-term	1,829	1,633
	\$3,754	\$2,614

## Note 12. Commitments and Contingencies

## Operating Leases

The Company leases its facilities in Massachusetts, New York, Florida, Canada and Singapore. The Company's leases are accounted for as operating leases. The leases generally provide for a base rent plus real estate taxes and certain operating expenses related to the leases.

In 2013, the Company entered into a new lease agreement for approximately 90,000 square feet of laboratory and office space for its corporate headquarters in Billerica, Massachusetts. The lease term began in August 2014 and expires in October 2022 and contains escalating payments over the life of the lease. In 2015, the Company extended its Singapore lease which now expires in July 2016. In 2014, the Company amended its existing lease for warehouse space in Billerica, Massachusetts which extended the term and increased the approximate square footage under the lease. The lease now expires in September 2019. Additionally, in 2014, the Company amended its existing lease for office space in New York which now expires in January 2019. The Company's Florida lease expires in December 2015. In the second quarter of 2015, the Company entered into a new lease agreement of office space in Ontario, Canada. The lease term began in June 2015 and expires in May 2018.

Certain of the Company's operating lease agreements contain scheduled rent increases. Rent expense is recorded using the straight-line method and deferred rent is included in other liabilities in the accompanying balance sheets. The Company has considered FASB ASC 840-20, Leases in accounting for these lease provisions.

The aggregate future minimum lease payments related to these leases as of September 30, 2015, are as follows (in thousands):

Table of Contents

Years Ending December 31,	Minimum Lease Payments
2015 (remaining)	\$573
2016	2,290
2017	2,327
2018	2,308
2019	2,181
Thereafter	6,080
Total	\$15,759

## Legal Proceedings

In October 2013, the Company received a letter from the Office of the Massachusetts Attorney General contending that prior to September 2012 Neighborhood Diabetes engaged in improper sales practices by automatically refilling certain prescriptions for MassHealth patients. The Company responded to this letter, stating that Neighborhood Diabetes' refill practices during the period in question were appropriate and consistent with applicable laws. The Company entered into a Settlement and Release Agreement and paid approximately \$1.5 million in connection with the settlement of this matter in the first quarter of 2015.

The Company is in the process of responding to a revised audit report received in November 2015 on behalf of the Centers for Medicare and Medicaid Services and the State of New York alleging overpayment of certain Medicaid claims to Neighborhood Diabetes. Due in part to the preliminary nature of this matter, the Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this matter.

The Company is in the process of responding to a draft audit report received in June 2015 from the Connecticut Department of Social Services Office of Quality Assurance alleging overpayment of certain Medicaid claims to Neighborhood Diabetes. Due in part to the preliminary nature of this matter, the Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this matter.

The Company received a warning letter from the FDA in June 2015 that related to the release of certain lots of OmniPods that did not conform to final acceptance criteria. A voluntary recall of the identified lots was issued and the Company incurred \$0.1 million as warranty expense. The Company has replied to the FDA's letter, and received a response indicating that its corrective actions appear to have adequately addressed the issue outlined in the letter.

The Company has reached a settlement agreement with the Massachusetts Department of Revenue for sales and use tax audits related to Neighborhood Diabetes. Based on the settlement agreement, the Company recorded a liability of \$0.8 million, which was a reduction of its previously recorded liability of \$3.7 million in connection with the settlement of this matter at June 30, 2015.

Between May 5, 2015 and June 16, 2015, three class action lawsuits were filed by shareholders in the U.S. District Court, Massachusetts, against the Company and certain individual current and former executives of the Company. Two suits subsequently were voluntarily dismissed. *Arkansas Teacher Retirement System v. Insulet, et al.*, 1:15-cv-12345, which remains outstanding, alleges violations of Sections 10(b) and 20(a) and Rule 10b-5 of the Securities Exchange Act of 1934 by making allegedly false and misleading statements about the Company's business, operations, and prospects. The lawsuit seeks, among other things, compensatory damages in connection with the Company's allegedly inflated stock price between May 7, 2013 and April 30, 2015, as well as attorneys' fees and costs. Due in part to the preliminary nature of this matter, the Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this matter.

The Company is, from time to time, involved in the normal course of business in various legal proceedings, including intellectual property, contract employment and product liability suits. Although the Company is unable to quantify the exact financial impact of any of these matters, the Company believes that none of these currently pending matters will have an outcome material to its financial condition or business.

## Note 13. Equity

The Company accounts for stock-based compensation under the provisions of FASB ASC 718-10, Compensation — Stock Compensation ("ASC 718-10"), which requires all share-based payments to employees, including grants of employee stock options and restricted stock units, to be recognized in the income statement based on their fair values.

Share-based payments that contain performance conditions are recognized when such conditions are probable of being achieved.

20

---

Table of Contents

The Company uses the Black-Scholes option pricing model to determine the weighted-average fair value of options granted. The Company determines the intrinsic value of restricted stock and restricted stock units based on the closing price of its common stock on the date of grant. The Company recognizes the compensation expense of share-based awards on a straight-line basis for awards with only service conditions and on an accelerated method for awards with performance conditions. Compensation expense is recognized over the vesting period of the awards.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is computed over expected terms based upon the historical volatility of the Company's stock. The expected life of the awards is estimated based on the midpoint scenario, which combines historical exercise data with hypothetical exercise data for outstanding options. 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 is based on awards that are ultimately expected to vest. The Company evaluates the assumptions used to value the awards on a quarterly basis and if factors change and different assumptions are utilized, stock-based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

In July 2014, in connection with the extinguishment of \$28.5 million in principal amount of 3.75% Notes, the Company issued 348,535 shares of its common stock to the holders representing the conversion premium.

The Company grants share-based awards to employees in the form of options to purchase the Company's common stock, the ability to purchase stock at a discounted price under the employee stock purchase plan and restricted stock units. Stock-based compensation expense related to share-based awards recognized in the three month periods ended September 30, 2015 and 2014 was \$4.2 million and \$9.6 million, respectively, and was calculated based on awards ultimately expected to vest. Stock-based compensation expense related to share-based awards recognized in the nine month periods ended September 30, 2015 and 2014 was \$13.8 million and \$18.2 million, respectively, and was calculated on awards ultimately expected to vest.

At September 30, 2015, the Company had \$41.7 million of total unrecognized compensation expense related to unvested stock options and restricted stock units.

**Stock Options**

In May 2007, in conjunction with the Company's initial public offering, the Company adopted its 2007 Stock Option and Incentive Plan (the "2007 Plan"). The 2007 Plan was amended and restated in November 2008, May 2012 and May 2015 to provide for the issuance of additional shares and to amend certain other provisions. As of September 30, 2015, 912,917 shares remain available for future issuance under the 2007 Plan.

In the nine months ended September 30, 2015, the Company awarded 194,500 shares of performance-based incentive stock options. The stock options were granted under the 2007 Plan and vest over a four year period from the grant date with the potential of an accelerated vesting period pursuant to the achievement of certain performance conditions.

Table of Contents

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

	Number of Options (#)	Weighted Average Exercise Price (\$)	Aggregate Intrinsic Value (\$) (In thousands)
Balance, December 31, 2014	1,847,669	\$26.99	
Granted	1,838,876	32.62	
Exercised <sup>(1)</sup>	(432,525 )	15.79	\$8,386
Canceled	(294,700 )	34.15	
Balance, September 30, 2015	2,959,320	\$31.41	\$4,284
Vested, September 30, 2015 <sup>(2)</sup>	883,047	\$27.31	\$4,060
Vested and expected to vest, September 30, 2015 <sup>(2)(3)</sup>	2,669,160		\$4,275

(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, 2015, and the exercise price of the underlying options.

Represents the number of vested options as of September 30, 2015, plus the number of unvested options expected to vest as of September 30, 2015, based on the unvested options outstanding at September 30, 2015, adjusted for the estimated forfeiture.

At September 30, 2015 there were 2,959,320 options outstanding with a weighted average exercise price of \$31.41 and a weighted average remaining contractual life of 8.6 years. At September 30, 2015 there were 883,047 options exercisable with a weighted average exercise price of \$27.31 and a weighted average remaining contractual life of 6.9 years.

Employee stock-based compensation expense related to stock options in the three month periods ended September 30, 2015 and 2014 was \$2.0 million and \$2.3 million, respectively, and was based on awards ultimately expected to vest. Employee stock-based compensation expense related to stock options in the nine months ended September 30, 2015 and 2014 was \$7.0 million and \$5.2 million, respectively, and was based on awards ultimately expected to vest. At September 30, 2015, the Company had \$22.1 million of total unrecognized compensation expense related to stock options that will be recognized over a weighted average period of 1.5 years.

#### Employee Stock Purchase Plan

As of September 30, 2015 and September 30, 2014, the Company had no shares contingently issued under the employee stock purchase plan ("ESPP"). In the three and nine months ended September 30, 2015 and 2014, the Company recorded no significant stock-based compensation charges related to the ESPP.

#### Restricted Stock Units

In the nine months ended September 30, 2015, the Company awarded 696,926 restricted stock units to certain employees, which included 114,287 restricted stock units subject to the achievement of performance conditions (performance-based restricted stock units). The number of performance-based restricted stock units granted during the nine months ended September 30, 2015 that are expected to vest may vary based on the Company's quarterly evaluation of the probability of the performance criteria being achieved. The Company recognized stock compensation expense of \$0.4 million in the nine months ended 2015 as it expects a portion of the performance-based restricted stock units granted will be earned based on its evaluation of the performance criteria at September 30, 2015. The restricted stock units were granted under the 2007 Plan and vest annually over a three year period from the grant date.

The restricted stock units granted have a weighted average fair value of \$30.68 per share based on the closing price of the Company's common stock on the date of grant. The restricted stock units granted during the nine months ended September 30, 2015 were valued at approximately \$21.4 million on their grant date, and the Company is recognizing the compensation expense over the vesting period. Approximately \$1.7 million and \$7.3 million of stock compensation expense related to the vesting of restricted stock units was recognized in the three months ended

Edgar Filing: INSULET CORP - Form 10-Q

September 30, 2015 and 2014, respectively. Approximately \$6.3 million and \$13.0 million of stock-based compensation expense related to the vesting of restricted stock units was recognized in the nine months ended September 30, 2015 and 2014, respectively. Approximately \$19.6 million of the fair value of the restricted stock units remained unrecognized as of September 30, 2015 and will be recognized over a weighted average

Table of Contents

period of 1.3 years. Under the terms of the awards, the Company will issue shares of common stock on each of the vesting dates.

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

	Number of Shares (#)	Weighted Average Fair Value (\$)
Balance, December 31, 2014	746,612	\$31.40
Granted	696,926	30.68
Vested	(253,870	) 28.23
Forfeited	(327,624	) 33.34
Balance, September 30, 2015	862,044	\$31.01

## Note 14. Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect in the years in which the differences are expected to reverse. A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company reviews its deferred tax assets for recoverability considering historical profitability, projected future taxable income, and the expected timing of the reversals of existing temporary differences and tax planning strategies. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company follows the provisions of FASB ASC 740-10, Income Taxes ("ASC 740-10") on accounting for uncertainty in income taxes recognized in its financial statements. ASC 740-10 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, ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense.

The Company files federal, state and foreign tax returns. These returns are generally open to examination by the relevant tax authorities from three to four years from the date they are filed. The tax filings relating to the Company's federal and state tax returns are currently open to examination for tax years 2011 through 2013 and 2010 through 2013, respectively. In addition, the Company has generated tax losses since its inception in 2000. These years may be subject to examination if the losses are carried forward and utilized in future years.

At September 30, 2015 and December 31, 2014, the Company provided a valuation allowance for the full amount of its net deferred tax asset because it is not more likely than not that the future tax benefit will be realized.

Income tax expense consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Current	\$44	\$6	\$84	\$59
Deferred	18	15	67	79
Total	\$62	\$21	\$151	\$138

In the three and nine months ended September 30, 2015 and 2014, the current portion of income tax expense primarily related to state and foreign taxes, and the deferred portion primarily related to U.S. Federal and State amounts.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes as well as federal and state net operating losses and tax credit carryforwards.





Table of Contents

In the future, the Company will generate additional deferred tax assets and liabilities related to its amortization of acquired intangible assets for tax purposes because these long-lived intangible assets are not amortized for financial reporting purposes. The tax amortization in future years will give rise to a temporary difference and a tax liability, which will only reverse at the time of ultimate sale or further impairment of the underlying intangible assets. Due to the uncertain timing of this reversal, the temporary difference cannot be considered as a source of future taxable income for purposes of determining a valuation allowance; therefore, the tax liability cannot be used to offset the deferred tax asset related to the net operating loss carryforward for tax purposes that will be generated by the same amortization.

The Company had no unrecognized tax benefits at September 30, 2015.

Note 15. Change in Accounting Estimate

The Company capitalizes eligible software development costs, including salaries and payroll-related costs of employees who devote time to the development. Capitalization begins when a detail program design is completed and technological feasibility has been established. These costs are amortized on a straight-line basis over the estimated useful life. In the second quarter of 2015, based on changes in one of the Company's ongoing projects, the Company determined that the detailed program designs were no longer sufficiently complete to establish technological feasibility of this project. As such, all costs previously capitalized for this project, approximately \$1.3 million, and all subsequent costs incurred through September 30, 2015, have been recorded to research and development expense. This change in estimate increased research and development expense in the three and nine months ended September 30, 2015 by approximately \$2.6 million and \$7.3 million, respectively.

The Company records inventory at cost according to ASU No. 330, Inventory ("ASU 330"). In the third quarter of 2015, the Company identified that certain lots of OmniPods had increased complaints relating to the deployment of the needle mechanism. The Company believes that all goods produced with the specific tooling changes of needle mechanism components are subject to replacement, including certain OmniPod lots held as inventory at September 30, 2015. As such, the Company has determined that it will not recover any amounts related to this inventory. Accordingly, this change in estimate increased our cost of revenue in the three and nine months ended September 30, 2015 by approximately \$6.4 million.

Table of Contents

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

FORWARD-LOOKING STATEMENTS

You should read the following discussion of our financial condition and results of operations in conjunction with our consolidated financial statements and the accompanying condensed notes to those financial statements included in this Quarterly Report on Form 10-Q. This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933 and of Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements.

These risks and uncertainties include, but are not limited to:

- risks associated with our dependence on our principal product, the OmniPod System;
- our ability to sustain or reduce production costs and increase customer orders and manufacturing volumes;
- adverse changes in general economic conditions;
- impact of healthcare reform laws;
- our inability to raise additional funds in the future on acceptable terms or at all;
- potential supply problems or price fluctuations with sole source or third-party suppliers on which we are dependent;
- the potential establishment of a competitive bid program;
- failure to retain supplier pricing discounts and achieve satisfactory gross margins;
- failure to retain key supplier and payor partners;
- international business risks;
- our inability to secure and retain adequate coverage or reimbursement for the OmniPod System by third-party payors and potential adverse changes in reimbursement rates or policies relating to the OmniPod System;
- failure to retain key payor partners and their members;
- failure to retain and manage successfully our Medicare and Medicaid business;
- potential adverse effects resulting from competition;
- reliance on information technology systems and our ability to control related risks, including a cyber-attack or other breach or disruption of these systems;
- technological breakthroughs and innovations adversely affecting our business, and our own new product development initiatives may prove to be ineffective or not commercially successful;
- potential termination of our license to incorporate a blood glucose meter into the OmniPod System, or our inability to enter into new license agreements;
- challenges to the further development of our non-insulin drug delivery business;
- our ability to protect our intellectual property and other proprietary rights; conflicts with the intellectual property of third-parties, including claims that our current or future products infringe or misappropriate the proprietary rights of others;
- adverse regulatory or legal actions relating to the OmniPod System;
- failure of our contract manufacturers or component suppliers to comply with the FDA's quality system regulations;
- the potential violation of federal or state laws prohibiting "kickbacks" or protecting the confidentiality of patient health information, or any challenge to or investigation into our practices under these laws;

Table of Contents

product liability lawsuits that may be brought against us;  
reduced retention rates of our customer base;  
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 diabetes associations or other organizations that are unfavorable to the OmniPod System;  
the concentration of substantially all of our operations at a single location in China and substantially all of our inventory at a single location in Massachusetts;  
our ability to attract and retain personnel;  
our ability to manage our growth;  
fluctuations in quarterly results of operations;  
risks associated with potential future acquisitions or investments in new businesses;  
our ability to generate sufficient cash to service all of our indebtedness;  
the expansion of our distribution network;  
our ability to successfully maintain effective internal control over financial reporting;  
the volatility of the price of our common stock;  
risks related to future sales of our common stock or the conversion of any of our 2% Convertible Senior Notes due June 15, 2019;  
potential limitations on our ability to use our net operating loss carryforwards; and  
anti-takeover provisions in our organizational documents.

The factors discussed above are not intended to be a complete statement of all risks and uncertainties and should be evaluated with all other risks described in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on February 26, 2015 in the section entitled “Risk Factors,” and in our other filings from time to time with the Securities and Exchange Commission. 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 primarily engaged in the development, manufacturing and sale of our proprietary OmniPod Insulin Management System (the “OmniPod System”), an innovative, discreet and easy-to-use insulin infusion system for people with insulin-dependent diabetes. The OmniPod System features a unique disposable tubeless OmniPod which is worn on the body for approximately three days at a time and the handheld, wireless Personal Diabetes Manager (“PDM”). Conventional insulin pumps require people with insulin-dependent diabetes to learn to use, manage and wear a number of cumbersome components, including up to 42 inches of tubing. In contrast, the OmniPod System features two discreet, easy-to-use devices that eliminate the need for a bulky pump, tubing and separate blood glucose meter, provides for virtually pain-free automated cannula insertion, communicates wirelessly and integrates a blood glucose meter. We believe that the OmniPod System’s unique proprietary design offers significant lifestyle benefits to people with insulin-dependent diabetes.

We acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, “Neighborhood Diabetes”) in June 2011. Through Neighborhood Diabetes, we are able to provide customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and have the ability to process claims as either durable medical equipment or through pharmacy benefits.

We executed an asset purchase agreement with GlaxoSmithKline (GSK) whereby we acquired assets associated with the Canadian distribution of the Company's products. With the acquisition, we assumed all distribution, sales, marketing, training and support activities for the OmniPod system in Canada. Additional information regarding this acquisition is provided in note 3 to the consolidated financial statements included in this Form 10-Q.



Table of Contents

We began commercial sale of the OmniPod System in the United States in 2005. We sell the OmniPod System and other diabetes management supplies in the United States through direct sales to customers or through our distribution partners. The OmniPod System is currently available in multiple countries in Europe and in Canada.

We sell our proprietary OmniPod System as well as blood glucose testing supplies, traditional insulin pumps, pump supplies, pharmaceuticals and other products for the management and treatment of diabetes to people with diabetes. Through our infrastructure in the reimbursement, billing and collection areas, we are able to provide for adjudication of claims as either durable medical equipment or through pharmacy benefits. Claims are adjudicated under private insurers, Medicaid or Medicare. As we expand our sales and marketing focus, increase our manufacturing capacity and expand to additional international markets, we will need to maintain and expand available reimbursement for our product offerings.

Our sales and marketing effort is focused on generating demand and acceptance of the OmniPod System among key diabetes practitioners, academic medical centers, clinics, people with insulin-dependent diabetes, third-party payors, government agencies, and third-party distributors. Our marketing strategy is to build awareness for the benefits of the OmniPod System through a wide range of education programs, social networking, patient demonstration programs, support materials, media advertisements and events at the national, regional and local levels. We are using third-party distributors to improve our access to managed care and government reimbursement programs, expand our commercial presence and provide access to additional potential patients. Our total revenue was \$87.3 million and \$224.1 million for the three and nine months ended September 30, 2015, compared to \$75.0 million and \$216.2 million, respectively, in the corresponding 2014 periods.

We currently produce the OmniPod System on partially automated manufacturing lines at a facility in China operated by a subsidiary of Flextronics International Ltd. ("Flextronics"). We purchase complete OmniPods pursuant to our agreement with Flextronics. Under the agreement, Flextronics has agreed to supply us, as a non-exclusive supplier, with OmniPods at agreed upon prices per unit pursuant to a rolling forecast that we provide. The current term of the agreement expires in December 2017 and is automatically renewed for one-year terms subsequently. It may be terminated upon prior written notice given no less than a specified number of days prior to the date of termination. The specified number of days is intended to provide the parties with sufficient time to make alternative arrangements in the event of termination.

We seek to increase manufacturing volumes and reduce the per-unit production cost for the OmniPod. By increasing production volumes of the OmniPod, we expect to reduce our per-unit raw material costs and improve absorption of manufacturing overhead costs. We continue to seek to sustain or reduce our cost per OmniPod through reductions in the bill of material as well as through manufacturing efficiencies. We believe our current manufacturing capacity is sufficient to meet our expected 2015 demand for OmniPods.

We purchase certain other diabetes management supplies from manufacturers at contracted rates and supply these products to our customers. Based on market penetration, payor plans and other factors, certain manufacturers provide rebates based on product sold. We record these rebates as a reduction to cost of goods sold as they are earned. Since our inception in 2000, we have incurred losses every quarter. In the three and nine months ended September 30, 2015, we incurred net losses of \$18.9 million and \$46.2 million, respectively. As of September 30, 2015, we had an accumulated deficit of \$624.2 million. We have financed our operations through private placements of debt and equity securities, public offerings of our common stock, issuances of convertible debt and borrowings under certain other debt agreements. As of September 30, 2015, we had \$201.3 million of convertible debt outstanding which matures in June 2019.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts in 2015 will be focused primarily on the expansion of our customer base in the United States and internationally. Achieving these objectives is expected to require additional investments in certain personnel and initiatives. We believe that we will continue to incur net losses in the near term in order to achieve these objectives. However, we believe that the accomplishment of our near term objectives will have a positive impact on our financial condition in the future.

At September 30, 2015, we had cash and cash equivalents totaling \$145.5 million. We believe that our cash and cash equivalents, together with the cash expected to be generated from product sales, will be sufficient to meet our projected operating and debt service requirements for the next twelve months.



## Table of Contents

### Financial Operations Overview

**Revenue.** We derive most of our revenue from the sale of the OmniPod System and other diabetes related products including blood glucose testing supplies, traditional insulin pumps, pump supplies and other pharmaceuticals to customers and third-party distributors who resell the product to customers. 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 PDM, a handheld device much like a personal digital assistant that wirelessly programs the OmniPod with insulin delivery instructions, assists the patient with diabetes management and incorporates a blood glucose meter. Revenue with respect to the OmniPod system is primarily attributable to stand-alone OmniPod sales.

In June 2011, we entered into a development agreement with a U.S. based pharmaceutical company (the "Development Agreement"). Under the Development Agreement, we were required to perform design, development, regulatory, and other services to support the pharmaceutical company as it worked to obtain regulatory approval to use our drug delivery technology as a delivery method for its pharmaceutical. The pharmaceutical company received regulatory approval in December 2014 and now purchases product from us for use with its pharmaceutical under a supply agreement. Product revenue under this arrangement is recognized at the time that all of the revenue recognition criteria are met, typically upon shipment.

As of September 30, 2015 and December 31, 2014, we had deferred revenue of \$2.4 million and \$1.6 million, respectively. Total deferred revenue as of September 30, 2015 included \$0.2 million classified in long term liabilities. For the year ending December 31, 2015, we expect our revenue to continue to increase as we gain new customers in the United States; continue expansion in Europe, Canada, and certain other international markets and increase commercial sales with our drug delivery partners. In the three months ended September 30, 2015, new patient starts in the United States increased by 24%. New patient starts in any given quarter generally represent less than 10% of revenue in that three month period and therefore are an early indicator of future growth in our recurring revenue model rather than an explanation of growth for a given quarter. Increased revenue is dependent upon the success of our sales efforts, our customer retention and our ability to produce OmniPods in sufficient volumes as our patient base grows and is subject to other risks and uncertainties, including the potential for a reduction in on-hand inventory levels amongst our distributors.

**Cost of revenue.** Cost of revenue consists primarily of raw material, labor, warranty, inventory reserve and overhead costs such as freight and depreciation related to the OmniPod System and the cost of products we acquire from third party suppliers. Cost of revenue will continue to increase as our revenue increases.

**Research and development.** Research and development expenses consist primarily of personnel costs and outside services within our product development, regulatory and clinical functions, and product development projects. We expense all research and development costs as incurred, unless these costs meet the criteria to be capitalized as internal use software or software to be sold, leased or marketed. For the year ending December 31, 2015, we expect overall research and development spending to increase from our 2014 spend as we increase development efforts on our on-going projects including continued improvements to the manufacturing process of the OmniPod System, the development of a new PDM, the integration with continuous glucose monitoring technology, a development effort with Eli Lilly and Company to further address the needs of Type 2 diabetes patients with OmniPod technology and the ability to use our technology as a delivery platform for other pharmaceuticals.

**General and administrative.** General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, finance, legal, information technology and human resource functions, as well as legal fees, accounting fees, insurance costs, bad debt expenses, shipping, handling and facilities-related costs. For the year ending December 31, 2015, we incurred significant nonrecurring costs including those related to the transition of our management team, however overall we expect general and administrative expenses to decrease as compared to our 2014 spending because we incurred significant costs in 2014 to resolve our then outstanding litigation with Becton, Dickinson and Company.

**Sales and marketing.** Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support, customer support and training functions, sales commissions paid to our sales representatives and costs associated with participation in medical conferences, physician symposia and promotional activities, including distribution of units used in our demonstration kit programs. We expect sales and marketing expenses in the

year ending December 31, 2015 to increase compared to 2014 as we expand our

28

---



Table of Contents

commercial team and invest in initiatives that will enhance awareness and drive increased adoption of the OmniPod System as well as increased adoption of our technology as a delivery platform for other pharmaceuticals.

## Results of Operations

This section discusses our consolidated results of operations for the third quarter and first nine months of 2015 compared to the same periods in 2014, and should be read in conjunction with the consolidated financial statements and accompanying condensed notes included in this Form 10-Q.

TABLE 1: RESULTS OF OPERATIONS

(In Thousands)	Three Months Ended September 30,				Nine Months Ended September 30,				
	2015	2014	\$ Change	% Change	2015	2014	\$ Change	% Change	
Revenue	\$87,303	\$74,985	\$12,318	16 %	\$224,106	\$216,159	\$7,947	4 %	
Cost of revenue	51,652	36,943	14,709	40 %	121,273	109,544	11,729	11 %	
Gross profit	35,651	38,042	(2,391 )	(6 )%	102,833	106,615	(3,782 )	(4 )%	
Gross margin	40.8 %	50.7 %			45.9 %	49.3 %			
Operating expenses:									
Research and development	10,035	7,158	2,877	40 %	30,311	20,614	9,697	47 %	
General and administrative	17,156	18,890	(1,734 )	(9 )%	45,841	52,661	(6,820 )	(13 )%	
Sales and marketing	24,194	14,870	9,324	63 %	63,406	43,382	20,024	46 %	
Total operating expenses	51,385	40,918	10,467	26 %	139,558	116,657	22,901	20 %	
Operating loss	(15,734 )	(2,876 )	12,858	447 %	(36,725 )	(10,042 )	26,683	266 %	
Interest and other expense, net	(3,131 )	(7,948 )	(4,817 )	(61 )%	(9,317 )	(35,920 )	(26,603 )	(74 )%	
Income tax expense	(62 )	(21 )	41	195 %	(151 )	(138 )	13	9 %	
Net loss	\$(18,927 )	\$(10,845 )	\$8,082	75 %	\$(46,193 )	\$(46,100 )	\$93	— %	

## Revenue

Our total revenue increased to \$87.3 million, up \$12.3 million, or 16%, in the third quarter of 2015 compared to the third quarter of 2014, due to growth across all of our product lines, led by growth in U.S. OmniPod revenue and our on-body injection devices for drug delivery. Our U.S. OmniPod revenue increased to \$50.0 million, up \$5.2 million, or 12%, reflecting growth in our installed base of OmniPod users. Our international OmniPod revenue increased to \$13.5 million, up \$1.1 million, or 9%, primarily reflecting growth in our direct business following the acquisition of our Canadian distributor in July 2015. Our drug delivery revenue increased to \$7.1 million, up \$4.8 million, due to growth in demand for our on-body injection devices following regulatory approval of our primary device in December 2014. Our Neighborhood Diabetes revenue increased to \$16.7 million, up \$1.2 million, or 8%, reflecting growth in patient demand.

Total revenue increased \$7.9 million in the first nine months of 2015 compared to the same period in 2014, primarily the result of an increase in our on-body injection devices for drug delivery and an increase in U.S. OmniPod revenue, offset by lower international OmniPod revenue. Our U.S. OmniPod revenue increased to \$133.9 million, up \$3.9 million, or 3%, reflecting growth in our installed base of OmniPod users, offset by lower distributor shipments in the first half of 2015 as compared to 2014. Our international OmniPod revenue decreased to \$24.9 million, down \$11.8 million, or 32%, primarily reflecting lower distributor revenues due to changes in distributor ordering patterns and a lower transfer price to our distributor in 2015. Our drug delivery revenue increased to \$19.3 million, up \$14.7 million, due to growth in demand for our on-body injection devices following regulatory approval of our primary device in December 2014. Our Neighborhood Diabetes revenue increased to \$46.0 million, up \$1.1 million, or 2%, reflecting growth in patient demand.

Table of Contents**Cost of Revenue**

Cost of revenue increased \$14.7 million in the third quarter of 2015 compared to the third quarter of 2014 primarily due to approximately \$7.7 million of costs incurred during the third quarter of 2015 associated with certain product which ultimately did not meet our quality expectations, these costs include a specific reserve of \$6.4 million for certain product in inventories at September 30, 2015 and approximately \$1.3 million from inefficiencies related to reduced production levels and increased warranty reserve during the third quarter. We expect to record an additional specific reserve of \$1.0 million for certain product produced in this configuration in the fourth quarter of 2015. In the first nine months of 2015, cost of revenue increased \$11.7 million compared to the same period in 2014, due primarily to the specific inventory reserve incurred during the third quarter of 2015.

**Gross Margin**

Gross margin in the third quarter and first nine months of 2015 decreased by approximately 10 and 3 points, respectively, compared to the same periods in 2014. The decreases for both comparisons primarily resulted from approximately \$7.7 million of costs incurred during the third quarter of 2015 associated with certain product which did not meet our quality expectations, as well as lower royalty revenues in 2015 as compared to 2014 and a decrease in the transfer price to our international OmniPod distributor in 2015 as compared to 2014.

**Research and Development**

Research and development expenses increased \$2.9 million to \$10.0 million for the three months ended September 30, 2015, compared to \$7.2 million for the same period in 2014. The increase was primarily the result of expenses related to our development projects and ongoing efforts to improve our current product.

Research and development expenses increased \$9.7 million to \$30.3 million for the nine months ended September 30, 2015, compared to \$20.6 million for the same period in 2014. The increase was primarily the result of an \$8.9 million increase in expenses related to our development projects. Additionally, there was a \$1.1 million increase in employee related expenses, including costs related to the addition of employees and higher management transition costs.

**General and Administrative**

General and administrative expenses decreased \$1.7 million to \$17.2 million for the three months ended September 30, 2015, compared to \$18.9 million for the same period in 2014, primarily the result of a \$4.9 million decrease in employee related expenses including stock compensation and severance payments. This decrease was offset by an increase in legal, audit, professional services fees and consulting fees of approximately \$1.9 million, as well as an increase in shipping costs of \$0.4 million. The higher legal, audit, and professional fees were primarily a result of the Company's review of historic revenue transactions.

General and administrative expenses decreased \$6.8 million to \$45.8 million for the nine months ended September 30, 2015, compared to \$52.7 million for the same period in 2014. The decrease was primarily the result of the Becton Dickinson patent litigation settlement and other legal fees of approximately \$8.4 million included in 2014 and a \$1.1 million decrease in employee related expenses. The decrease was partially offset by an increase in consulting fees and information technology spending of approximately \$1.5 million and \$0.4 million, respectively.

**Sales and Marketing**

Sales and marketing expenses increased \$9.3 million to \$24.2 million for the three months ended September 30, 2015, compared to \$14.9 million for the same period in 2014. The increase was mainly the result of a \$5.4 million increase in employee related expenses due to the addition of employees in our sales force and customer support areas in 2015 as compared to 2014 and a \$2.7 million increase in costs associated with marketing campaigns, new market opportunities and other strategic initiatives as we continue to expand awareness of the OmniPod System and our on-body injection devices for drug delivery. Additionally, we incurred increases in advertising and other selling costs as well as in travel and entertainment costs of approximately \$0.7 million and \$0.5 million, respectively. We also incurred additional sales and marketing expenses following our acquisition of our Canadian distributor in July 2015, including \$0.5 million of amortization of acquired intangibles.

Table of Contents

Sales and marketing expenses increased \$20.0 million to \$63.4 million for the nine months ended September 30, 2015, compared to \$43.4 million for the same period in 2014. The increase was mainly the result of a \$12.5 million increase in employee related expenses due to the addition of employees in our sales force and customer support areas in 2015 as compared to 2014. Additionally, we incurred a \$5.9 million increase in costs associated with marketing campaigns as we continue to expand awareness of the OmniPod System and our on-body injection devices for drug delivery and an additional \$1.2 million increase in travel and entertainment costs. We also incurred additional sales and marketing expenses following our acquisition of our Canadian distributor towards in July 2015, including \$0.5 million of amortization of acquired intangibles.

**Interest and Other Expense, Net**

Interest and other expense, net was \$3.1 million and \$9.3 million for the three and nine months ended September 30, 2015, compared to \$7.9 million and \$35.9 million for three and nine months ended September 30, 2014. Decreases in interest and other expense, net in the third quarter and first nine months of 2015 compared to the third quarter and first nine months of 2014 was primarily related to the loss from extinguishment of long-term debt of \$4.3 million and \$23.2 million, respectively. The decrease also resulted from a 2% interest rate on our long-term debt in 2015 compared to a 3.75% interest rate in the prior period.

**Income Tax Expense**

Income tax expense was \$0.1 million and de minimis in the three months ended September 30, 2015 and 2014, respectively, and \$0.2 million and \$0.1 million for the nine months ended September 30, 2015 and 2014, respectively. Income tax expense is comprised of a current and deferred portion. The current portion primarily related to state and foreign taxes and the deferred portion primarily related to federal and state tax amounts. Additional information regarding income tax expenses is provided in note 14 to the consolidated financial statements included in this Form 10-Q.

**Liquidity and Capital Resources**

We commenced operations in 2000 and to date we have financed our operations primarily through private placements of common and preferred stock, secured indebtedness, public offerings of our common stock and issuances of convertible debt.

As of September 30, 2015, we had \$145.5 million in cash and cash equivalents. We believe that our current cash and cash equivalents, together with the cash expected to be generated from sales, will be sufficient to meet our projected operating and debt service requirements for at least the next twelve months.

**Equity**

In July 2014, in connection with the extinguishment of \$28.5 million in principal amount of 3.75% Notes (as defined below), we issued 348,535 shares of common stock to the holders representing the conversion value in excess of the principal amount.

Additional information about our common stock issuances is provided in note 13 to the consolidated financial statements included in this Form 10-Q.

Table of Contents

## Debt

We had outstanding convertible debt and related deferred financing costs on our consolidated balance sheet as follows (in thousands):

	As of	
	September 30, 2015	December 31, 2014
Principal amount of the 2% Convertible Senior Notes	\$201,250	\$201,250
Unamortized debt discount	(27,380	) (32,256
Long-term debt, net of discount	\$173,870	\$168,994
Deferred financing costs	\$4,130	\$4,974

Interest expense related to the 3.75% Notes and the 2% Notes was included in interest and other expense on the consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Contractual coupon interest	\$1,007	\$962	\$3,019	\$3,583
Accretion of debt discount	1,650	1,548	4,876	6,431
Amortization of debt issuance costs	281	277	844	615
Loss on extinguishment of long-term debt	—	4,260	—	23,203
Total interest and other expense	\$2,938	\$7,047	\$8,739	\$33,832

## 3.75% Convertible Senior Notes

In June 2011, we sold \$143.8 million in principal amount of 3.75% Convertible Senior Notes due June 15, 2016 (the "3.75% Notes"). The interest rate on the notes was 3.75% per annum, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 3.75% Notes were convertible into our common stock at an initial conversion rate of 38.1749 shares of common stock per \$1,000 principal amount of the 3.75% Notes, which was equivalent to a conversion price of approximately \$26.20 per share.

In connection with the issuance of the 3.75% Notes, we repurchased \$70 million in principal amount of the 5.375% Convertible Senior Notes due June 15, 2013 (the "5.375% Notes") for \$85.1 million. The investors that held the \$70 million in principal amount of repurchased 5.375% Notes purchased \$59.5 million in principal amount of the 3.75% Notes and retained approximately \$13.5 million in principal amount of the remaining 5.375% Notes. These investors' combined \$73.0 million in principal amount of convertible debt (\$13.5 million of 5.375% Notes and \$59.5 million of 3.75% Notes) was considered to be a modification of a portion of the 5.375% Notes.

We recorded a total debt discount of \$25.8 million related to the modified debt. This discount consisted of \$10.5 million related to the remaining debt discount on the \$70 million in principal amount of 5.375% Notes repurchased, \$15.1 million related to the premium payment in connection with the repurchase and \$0.2 million related to the increase in the value of the conversion feature. The total debt discount was being amortized as non-cash interest expense at the effective rate of 16.5% over the five year term of the modified debt. Additionally, we paid transaction fees of approximately \$2.0 million related to the modification, which were recorded as interest expense and other expense at the time of the modification.

As of December 31, 2013, the 5.375% Notes were repaid in full and no amounts remained on our balance sheet related to these notes.

In June 2014, in connection with the issuance of \$201.3 million in principal amount of 2% Convertible Senior Notes due June 15, 2019 (the "2% Notes"), we repurchased approximately \$114.9 million in principal amount of the 3.75% Notes for \$160.7 million. Investors that held approximately \$80.0 million of 3.75% Notes purchased approximately \$98.2 million in principal amount of the 2% Notes. The repurchase of the 3.75% Notes was treated as an extinguishment of debt accounted for separately from the issuance of the 2% Notes and allocated to debt and equity based on their respective fair values immediately prior to the transaction.

In June 2014, we met the redemption requirements of the 3.75% Notes and notified holders of our intent to redeem the outstanding \$28.8 million principal amount in July 2014. Prior to the redemption date, holders of \$28.5 million in

principal amount of 3.75% Notes notified us that they exercised their right to convert their outstanding 3.75% Notes. We settled this conversion of the 3.75% Notes in July 2014 by providing cash of \$28.5 million for the

Table of Contents

principal amount of the outstanding 3.75% Notes converted and issuing 348,535 shares of common stock for the conversion premium totaling \$12.6 million, for a total consideration paid of \$41.1 million. We settled the redemption of the remaining \$0.3 million in principal amount in exchange for a cash payment of \$0.3 million representing principal and accrued and unpaid interest. We allocated \$27.9 million of the total consideration paid to the debt and \$13.5 million to equity, and recorded a loss on extinguishment of debt of \$23.2 million in connection with the repurchase and redemption of the 3.75% Notes during the year ended December 31, 2014.

No cash interest expense was recorded related to the 3.75% Notes in both the three and nine months ended September 30, 2015 and the three months ended September 30, 2014. Cash interest expense related to the outstanding 3.75% Notes was \$2.4 million in the nine months ended September 30, 2014.

As of December 31, 2014, no amounts remained outstanding related to the 3.75% Notes.

2% Convertible Senior Notes

In June 2014 we sold \$201.3 million in principal amount of the 2% Notes due June 15, 2019. The interest rate on the notes is 2% per annum, payable semi-annually in arrears in cash on December 15 and June 15 of each year. The 2% Notes are convertible into our common stock at an initial conversion rate of 21.5019 shares of common stock per \$1,000 principal amount of the 2% Notes, which is equivalent to a conversion price of approximately \$46.51 per share, subject to adjustment under certain circumstances.

We recorded a debt discount of \$35.6 million related to the 2% Notes. The debt discount was recorded as additional paid-in capital to reflect the value of our nonconvertible debt borrowing rate of 6.2% per annum. This debt discount is being amortized as non-cash interest expense over the five year term of the 2% Notes. We incurred deferred financing costs related to this offering of approximately \$6.7 million, of which \$1.2 million has been reclassified as an offset to the value of the amount allocated to equity. The remainder is recorded as other assets in the consolidated balance sheet and is being amortized as non-cash interest expense over the five year term of the 2% Notes.

We determined that the higher interest and tax payments required in certain circumstances are considered embedded derivatives and should be bifurcated and accounted for at fair value. We assess the value of the embedded derivatives at each balance sheet date. The derivatives had de minimis value at the balance sheet date.

Cash interest expense related to the 2% Notes was \$1.0 million in both the three months ended September 30, 2015 and 2014, and \$3.0 million and \$1.2 million in the nine months ended September 30, 2015 and 2014, respectively.

Non-cash interest expense related to the 2% Notes was \$1.9 million and \$1.8 million in the three months ended September 30, 2015 and 2014, respectively, and \$5.7 million and \$2.1 million in the nine months ended September 30, 2015 and 2014, respectively.

As of September 30, 2015, we included \$173.9 million on the balance sheet in long-term debt related to the 2% Notes. Additional information regarding our debt issuances is provided in note 5 to the consolidated financial statements included in this Form 10-Q.

Capital Leases

As of September 30, 2015 and December 31, 2014, we have approximately \$13.7 million and \$8.0 million of manufacturing equipment acquired under capital leases, respectively. The obligations under the capital leases are being repaid in equal monthly installments over 24 to 36 month terms and include principal and interest payments with an effective interest rate of 13% to 17%. The assets have been recorded at \$13.7 million and are included in property and equipment on our balance sheet as of September 30, 2015.

Table of Contents

At September 30, 2015, \$6.0 million was included in current liabilities and \$1.1 million was included in long-term liabilities on our balance sheet related to these capital leases. The aggregate future minimum lease payments related to these capital leases as of September 30, 2015, are as follows (in thousands):

Years Ending December 31,	Minimum Lease Payments
2015 (remaining)	\$1,762
2016	5,639
2017	269
Total future minimum lease payments	\$7,670
Interest expense	(589 )
Total capital lease obligations	\$7,081

We recorded \$0.3 million and \$0.4 million of interest expense on the capital leases in both the three months ended September 30, 2015 and 2014, respectively. We recorded \$1.0 million in both the nine months ended September 30, 2015 and 2014.

**Operating Activities**

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

	Nine Months Ended September 30,	
	2015	2014
Cash provided by operating activities	\$6,043	\$4,313
Net loss	\$(46,193 )	\$(46,100 )

In the nine months ended September 30, 2015, net cash provided by operating activities was primarily attributable to operations after adjustments for non-cash and other expenses of approximately \$33.7 million and changes in operating assets and liabilities of \$18.5 million. Non-cash and other items included depreciation and amortization of \$11.4 million, stock-based compensation of \$13.8 million, provision for bad debts of \$2.8 million and non-cash interest and other expense of \$5.7 million. Changes in operating assets and liabilities primarily consisted of an increase of \$11.8 million in accounts payable, accrued expenses, and other current liabilities and a decrease in accounts receivable of \$5.3 million.

Non-cash and other items provided by operating activities was \$61.7 million in the nine months ended September 30, 2014, and included a loss from the extinguishment of debt of \$23.2 million, depreciation and amortization of \$9.2 million, stock-based compensation of \$18.2 million, non-cash interest and other expense of \$8.4 million and provision for bad debts of \$2.7 million.

**Investing and Financing Activities**

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

	Nine Months Ended September 30,	
	2015	2014
Cash used in investing activities	\$(11,841 )	\$(8,853 )
Cash provided by financing activities	\$292	\$1,185

Cash used in investing activities in the nine months ended September 30, 2015 was primarily related to purchases of property and equipment, of which the majority related to the purchase of manufacturing equipment for use in the production of the OmniPod System, as well as the acquisition of our Canadian distributor in July 2015.

Cash used in investing activities in the nine months ended September 30, 2014 as primarily related to purchases of property and equipment, of which the majority related to the purchase of manufacturing equipment for use in the production of the OmniPod System.

Cash provided by financing activities in the nine months ended September 30, 2015 was mainly related to the net proceeds from the issuance of common stock related to exercises of employee stock options offset by our payment of

taxes in connection with the vesting of the restricted stock units in the period and payment of certain

34

---



Table of Contents

capital lease obligations. Cash provided by financing activities in the nine months ended September 30, 2014 mainly related to the net proceeds from the issuance of long-term debt and common stock related to exercises of employee stock options offset by our repayment of debt and payment of taxes in connection with the vesting of the restricted stock units in the period.

**Commitments and Contingencies**

We lease our facilities in Massachusetts, New York, Florida, Canada and Singapore. Our leases are accounted for as operating leases. The leases generally provide for a base rent plus real estate taxes and certain operating expenses related to the leases. In 2013, we entered into a new lease agreement for approximately 90,000 square feet of laboratory and office space for our corporate headquarters in Billerica, Massachusetts. The lease term began in August 2014 and expires in October 2022 and contains escalating payments over the life of the lease. In 2015, we extended our Singapore lease which now expires in July 2016. In 2014, we amended our existing lease for warehouse space in Billerica, Massachusetts which extended the term and increased the approximate square footage under the lease. The lease now expires in September 2019. Additionally, in 2014, we amended our existing lease for office space in New York which now expires in January 2019. Our Florida lease expires in December 2015. In the second quarter of 2015, we entered into a new lease agreement of office space in Ontario, Canada. The lease term began in June 2015 and expires in May 2018.

Certain of our operating lease agreements contain scheduled rent increases. Rent expense is recorded using the straight-line method and deferred rent is included in other liabilities in the accompanying balance sheets.

The following table summarizes our principal obligations as of September 30, 2015 (in thousands):

Contractual Obligations	Payments Due in						
	Total	2015 (remaining)	2016	2017	2018	2019	Later
Operating lease obligations	\$15,759	\$573	\$2,290	\$2,327	\$2,308	\$2,181	\$6,080
Debt obligations <sup>(1)</sup>	216,176	1,006	4,025	4,025	4,025	203,095	—
Capital lease obligations <sup>(2)</sup>	7,670	1,762	5,639	269	—	—	—
Purchase obligations	3,250	1,250	2,000	—	—	—	—
Total contractual obligations	\$242,855	\$4,591	\$13,954	\$6,621	\$6,333	\$205,276	\$6,080

(1) The interest rate on the convertible debt is 2% per annum. We have included future payments of interest on the long-term debt in our obligations.

(2) The effective interest rate on the capital lease obligations is 13-17%. We have included future payments of interest on the capital leases in our obligations.

We are in the process of responding to a revised audit report received in November 2015 on behalf of the Centers for Medicare and Medicaid Services and the State of New York alleging overpayment of certain Medicaid claims to Neighborhood Diabetes. Due in part to the preliminary nature of this matter, the Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this matter.

We are in the process of responding to a draft audit report received in June 2015 from the Connecticut Department of Social Services Office of Quality Assurance alleging overpayment of certain Medicaid claims to Neighborhood Diabetes. Due in part to the preliminary nature of this matter, the Company currently cannot reasonably estimate a possible loss, or range of loss, in connection with this matter.

We received a warning letter from the FDA in June 2015 that related to the release of certain lots of OmniPods that did not conform to final acceptance criteria. A voluntary recall of the identified lots was issued and the Company accrued \$0.1 million as warranty expense. The Company has replied to the FDA's letter, and received a response indicating that its corrective actions appear to have adequately addressed the issue outlined in the letter.

We have reached a settlement agreement with the Massachusetts Department of Revenue for sales and use tax audits related to Neighborhood Diabetes. Based on the settlement agreement, we recorded a liability of \$0.8 million, which was a reduction of our previously recorded liability of \$3.7 million in connection with the settlement of this matter at June 30, 2015.

Edgar Filing: INSULET CORP - Form 10-Q

Between May 5, 2015 and June 16, 2015, three class action lawsuits were filed by shareholders in the U.S. District Court, Massachusetts, against us and certain individual current and former executives of the Company. Two suits subsequently were voluntarily dismissed. Arkansas Teacher Retirement System v. Insulet, et al., 1:15-cv-12345, which remains outstanding, alleges violations of Sections 10(b) and 20(a) and Rule 10b-5 of the

35

---

## Table of Contents

Securities Exchange Act of 1934 by making allegedly false and misleading statements about our business, operations, and prospects. The lawsuit seeks, among other things, compensatory damages in connection with the our allegedly inflated stock price between May 7, 2013 and April 30, 2015, as well as attorneys' fees and costs. Due in part to the preliminary nature of this matter, we currently cannot reasonably estimate a possible loss, or range of loss, in connection with this matter.

### Off-Balance Sheet Arrangements

As of September 30, 2015, we did not have any off-balance sheet financing arrangements.

### Critical Accounting Policies and Estimates

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying condensed 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 have reviewed our policies and estimates to determine our critical accounting policies for the nine months ended September 30, 2015. We have made no material changes to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2014.

### Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 requires that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. Under this guidance, a company may make additional estimates regarding performance conditions and the allocation of variable consideration. The guidance is effective in fiscal years beginning after January 1, 2017, with early adoption permitted. We are currently evaluating the impact of ASU 2014-09. We have not yet selected a transition method nor have we determined the effect of the standard on our consolidated financial position and results of operations.

In June 2014, the FASB issued ASU No. 2014-12, Compensation - Stock Compensation (Topic 718), Accounting for Share-Based Payments when the terms of an award provide that a performance target could be achieved after the requisite service period ("ASU 2014-12"). ASU 2014-12 clarifies the period over which compensation cost would be recognized in awards with a performance target that affects vesting and that could be achieved after the requisite service period. Compensation cost would be recognized over the required service period, if it is probable that the performance condition will be achieved. The guidance is effective in fiscal years beginning after January 1, 2016, with early adoption permitted. We are currently evaluating the impact of ASU 2014-12.

In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs ("ASU 2015-03"). ASU 2015-03 amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. The guidance is effective for annual reporting periods beginning after December 15, 2015, and must be applied retrospectively.

Early adoption is permitted. Had we adopted ASU 2015-03, other noncurrent assets and long-term debt would both have been \$4.1 million and \$5.0 million lower as of September 30, 2015 and December 31, 2014, respectively.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory ("ASU 2015-11"). ASU 2015-11 amends existing guidance and requires entities to measure most inventory at the lower of cost and net realizable value. The guidance is effective prospectively for annual reporting periods beginning after December 15, 2016. Early adoption is permitted. Upon adoption, entities must disclose the nature of and reason for the accounting change. We are currently evaluating the impact of ASU 2015-11.

In September 2015, the FASB issued ASU No. 2015-16, Simplifying the Accounting for Measurement Period Adjustments ("ASU 2015-16"). ASU 2015-16 eliminates the requirement that an acquirer in a business combination account for measurement-period adjustments retrospectively. Instead, an acquirer will recognize a measurement period adjustment during the period in which it determines the amount of the adjustment, including the effect on earnings of any amounts it would have recorded in previous periods if the accounting had been completed at the acquisition date. Early adoption is permitted. We are currently evaluating the impact of ASU 2015-16.



Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

As of September 30, 2015, we had outstanding debt recorded on our consolidated balance sheet of \$201.3 million related to our 2% Notes and \$7.1 million related to capital lease obligations. As the interest rates are fixed, changes in interest rates do not affect the value of our debt or capital lease obligations.

**Foreign Currency Exchange Risk.** Our business is subject to risks, including, but not limited to: unique economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. Fluctuations in foreign currency rates could affect our sales, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluations can result in a loss if we hold deposits of that currency. A hypothetical 10% increase or decrease in foreign currencies that we transact in would not have a material adverse impact on our business, financial condition or results of operations.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

As of September 30, 2015, our management conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) under the supervision and with the participation of our chief executive officer and chief financial officer. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures.

Based upon that evaluation of our disclosure controls and procedures as of September 30, 2015, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, including ensuring that such material information is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

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, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Information regarding our legal proceedings is provided in note 12 to the consolidated financial statements in this Form 10-Q.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014, which could materially affect our business, financial condition or future results. These risks are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. There have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Table of Contents

Item 6. Exhibits

Exhibit Number	Description of Document
31.1	Certification of Patrick J. Sullivan, 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 Michael L. Levitz, 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 Patrick J. Sullivan, President and Chief Executive Officer, and Michael L. Levitz, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	<p>The following materials from Insulet Corporation’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language), as follows:</p> <ul style="list-style-type: none"> <li>(i) Consolidated Balance Sheets as of September 30, 2015 (Unaudited) and December 31, 2014</li> <li>(ii) Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2015 and September 30, 2014 (Unaudited)</li> <li>(iii) Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2015 and September 30, 2014 (Unaudited)</li> <li>(iv) Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2015 and September 30, 2014 (Unaudited)</li> <li>(iv) Condensed Notes to Consolidated Financial Statements (Unaudited)</li> </ul>

Table of Contents

SIGNATURES

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

INSULET CORPORATION

(Registrant)

Date: November 6, 2015

/s/ Patrick J. Sullivan  
Patrick J. Sullivan  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 6, 2015

/s/ Michael L. Levitz  
Michael L. Levitz  
Chief Financial Officer  
(Principal Financial and Accounting Officer)