INSULET CORP
Form 10-Q
November 02, 2018
Table of Contents

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

Form 10-Q

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

For the quarterly period ended September 30, 2018

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	04-3523891
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
600 Technology Park Drive, Suite 200 Billerica, Massachusetts	01821
(Address of Principal Executive Offices)	(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 x 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 x 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 x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

As of October 31, 2018, the registrant had 59,077,244 shares of common stock outstanding.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements	3
Consolidated Balance Sheets as of September 30, 2018 (Unaudited) and December 31, 2017	3
Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2018 and 2017	4
Consolidated Statements of Comprehensive Income (Loss) (Unaudited) for the three and nine months ended September 30, 2018 and 2017	5
Consolidated Statements of Cash Flows (Unaudited) for the nine months ended September 30, 2018 and 2017	6
Condensed Notes to Consolidated Financial Statements (Unaudited)	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3. Quantitative and Qualitative Disclosures About Market Risk	29
Item 4. Controls and Procedures	30

PART II. OTHER INFORMATION

Item 1. Legal Proceedings	30
Item 1A. Risk Factors	30
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	30
Item 3. Defaults Upon Senior Securities	30
Item 4. Mine Safety Disclosures	30
Item 5. Other Information	31
Item 6. Exhibits	32
Signatures	33

Table of Contents

PART I - FINANCIAL INFORMATION
Item 1. Consolidated Financial Statements (Unaudited)
INSULET CORPORATION
CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	September 30, 2018	December 31, 2017
ASSETS	(Unaudited)	
Current Assets		
Cash and cash equivalents	$ 126,563	$ 272,577
Short-term investments	163,281	167,479
Accounts receivable, net	69,950	53,373
Unbilled receivable (Note 3)	9,963	—
Inventories	58,050	33,793
Prepaid expenses and other current assets (Note 9)	17,905	9,949
Total current assets	445,712	537,171
Long-term investments	145,539	125,549
Property and equipment, net	229,433	107,864
Other intangible assets, net	7,791	4,351
Goodwill	39,774	39,840
Other assets (Note 9)	18,057	1,969
Total assets	$ 886,306	$ 816,744
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 26,845	$ 24,413
Accrued expenses and other current liabilities	68,169	59,256
Deferred revenue	2,210	2,356
Total current liabilities	97,224	86,025
Convertible debt, net (Note 5)	584,485	566,173
Other long-term liabilities	6,668	6,030
Total liabilities	688,377	658,228
Commitments and contingencies (Note 12)		
Stockholders' Equity		
Preferred stock, $.001 par value:		
Authorized: 5,000,000 shares at September 30, 2018 and December 31, 2017.		
Issued and outstanding: zero shares at September 30, 2018 and December 31, 2017.	—	—
Common stock, $.001 par value:		
Authorized: 100,000,000 at September 30, 2018 and December 31, 2017.		
Issued and outstanding: 59,068,586 and 58,319,348 at September 30, 2018 and December 31, 2017, respectively.	59	58
Additional paid-in capital	893,829	866,206
Accumulated other comprehensive loss	(2,452)	(493)
Accumulated deficit	(693,507)	(707,255)
Total stockholders' equity	197,929	158,516
Total liabilities and stockholders' equity	$ 886,306	$ 816,744

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

Table of Contents

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	2018	2017	2018	2017
Revenue	$151,076	$121,775	$398,916	$333,244
Cost of revenue	49,107	48,151	139,060	135,583
Gross profit	101,969	73,624	259,856	197,661
Operating expenses:				
Research and development	21,762	20,141	60,092	55,670
Sales and marketing	34,922	28,718	102,660	86,288
General and administrative	38,420	22,718	85,914	62,322
Total operating expenses	95,104	71,577	248,666	204,280
Operating income (loss)	6,865	2,047	11,190	(6,619)
Interest expense	6,846	4,709	22,054	14,512
Other income, net	1,834	556	5,202	1,478
Interest expense and other income, net	5,012	4,153	16,852	13,034
Income (loss) before income taxes	1,853	(2,106)	(5,662)	(19,653)
Income tax expense	194	121	939	318
Net income (loss)	$1,659	$(2,227)	$(6,601)	$(19,971)
Net income (loss) per share:				
Basic	$0.03	$(0.04)	$(0.11)	$(0.34)
Diluted	$0.03	$(0.04)	$(0.11)	$(0.34)
Weighted-average number of shares used in calculating net income (loss) per share:				
Basic	59,016,863	58,099,593	58,779,672	57,924,920
Diluted	61,146,466	58,099,593	58,779,672	57,924,920

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

Table of Contents

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Net income (loss)	$1,659	$(2,227)	$(6,601)	$(19,971)
Other comprehensive income (loss), net of tax				
Foreign currency translation adjustment, net of tax	4	329	(1,055)	594
Unrealized (loss) gain on available-for-sale debt securities, net of tax	(70)	76	(904)	9
Total other comprehensive (loss) income, net of tax	(66)	405	(1,959)	603
Total comprehensive income (loss)	$1,593	$(1,822)	$(8,560)	$(19,368)

The accompanying condensed notes are an integral part of these consolidated financial statements.
5

Table of Contents

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Months Ended September 30,	
(in thousands)	2018	2017
Cash flows from operating activities		
Net loss	$(6,601)	$(19,971)
Adjustments to reconcile net income (loss) to net cash used in operating activities		
Depreciation and amortization	11,254	10,533
Non-cash interest expense	21,790	12,185
Stock-based compensation expense	31,205	23,551
Provision for bad debts	2,588	1,502
Other	(235)	519
Changes in operating assets and liabilities:		
Accounts receivable and unbilled receivable	(24,581)	(19,757)
Inventories	(25,279)	428
Prepaid expenses and other assets	(5,258)	(1,290)
Accounts payable, accrued expenses and other current liabilities	2,938	10,502
Deferred revenue	(2,761)	537
Other long-term liabilities	400	668
Net cash provided by operating activities	5,460	19,407
Cash flows from investing activities		
Purchases of property, equipment and intangible assets [1]	(127,559)	(47,813)
Purchases of investments	(145,575)	(115,056)
Receipts from the maturity or sale of investments	129,415	101,384
Net cash used in investing activities	(143,719)	(61,485)
Cash flows from financing activities		
Principal payments of capital lease obligations	—	(269)
Repayment of convertible debt	(6,699)	—
Proceeds from exercise of stock options [2]	13,464	10,735
Payment of withholding taxes in connection with vesting of restricted stock units	(13,846)	(3,816)
Net cash (used in) provided by financing activities	(7,081)	6,650
Effect of exchange rate changes on cash	(674)	487
Net decrease in cash, cash equivalents and restricted cash	(146,014)	(34,941)
Cash, cash equivalents and restricted cash, beginning of period	272,577	137,174
Cash, cash equivalents and restricted cash, end of period	$126,563	$102,233

[1] Cash outflows from purchases of property, equipment and intangible assets for the nine months ended September 30, 2018 includes $4.0 million of purchases made in prior periods that were included in accounts payable and accrued expenses as of December 31, 2017 and excludes $12.7 million of purchases made during the nine months ended September 30, 2018 that were included in accounts payable and accrued expenses as of September 30, 2018.

[2] During the period, the Company acquired 9,733 shares of its common stock with a value of $0.8 million in return for the exercise of stock options. The acquired shares were subsequently retired.

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 continuous insulin delivery system for people with insulin-dependent diabetes. There are two primary types of insulin therapy practiced today: multiple daily injection (“MDI”) therapy using syringes or insulin pens; and pump therapy using insulin pumps. Insulin pumps are used to perform continuous subcutaneous insulin infusion, or insulin pump therapy, and typically use a programmable device and an infusion set to administer insulin into the person’s body. Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. The Company estimates that approximately one-third of the Type 1 diabetes population in the United States use insulin pump therapy, and that less than 10% of the Type 2 diabetes population in the United States who are insulin-dependent use insulin pump therapy. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod device, which is worn on the body for approximately three days at a time (the "Pod"), and its wireless companion, the handheld Personal Diabetes Manager ("PDM"). The Omnipod System, which features two discreet, easy-to-use devices, communicates wirelessly, provides for virtually pain-free automated cannula insertion and eliminates the need for traditional MDI therapy or the use of traditional pump and tubing. The Company believes that the Omnipod System’s unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience, and ease. Commercial sales of the Omnipod System began in the United States in 2005. The Company sells the Omnipod System through direct sales to customers or through intermediaries. The Omnipod System is currently available in multiple countries in Europe, as well as in Canada and Israel. On July 1, 2018, the Company commenced direct sales of the Omnipod System in Europe following the expiration of its distribution agreement on June 30, 2018 with Ypsomed Distribution AG ("Ypsomed" or the "European Distributor").

In addition to using the Omnipod System for insulin delivery, the Company also partners with global pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of subcutaneous drugs across other therapeutic areas. The majority of the Company's drug delivery revenue currently consists of sales of Amgen's Neulasta Onpro kit.

To lower manufacturing costs, increase supply redundancy, add capacity closer to its largest customer base and support growth, the Company is constructing a highly-automated manufacturing facility in Acton, Massachusetts, with planned production out of the facility beginning in early 2019. The facility will also serve as the Company's global headquarters.

Note 2. Basis of Presentation and 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 (“U.S. GAAP” or "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 months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2018, 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, 2017.

Use of Estimates in Preparation of Financial Statements

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions in the application of certain of its significant accounting policies that may materially affect the reported amounts of assets, liabilities, equity, revenue and expenses. Actual results may differ from those estimates. See Note 3 related to the Company's adoption of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, for a discussion of judgments associated with the recognition of revenue and deferral of cost to obtain a contract.

Table of Contents

Principles of Consolidation
The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Summary of Significant Accounting Policies
The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies", in the Company's Annual Report on Form 10-K for fiscal year 2017.

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 ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company has concluded its Chief Executive Officer ("CEO") is the CODM as the CEO is the ultimate decision maker for key operating decisions, determining the allocation of resources and assessing the financial performance of the Company. These decisions, allocations and assessments are performed by the CODM using consolidated financial information. The Company’s products are relatively consistent and manufacturing is centralized and consistent across product offerings. Based on these factors, key operating decisions and resource allocations are made by the CODM using consolidated financial data and as such the Company has concluded that it operates as one segment.
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 unless non-standard shipping and handling services are requested. These shipping and handling costs are included in general and administrative expenses and were $2.2 million and $1.3 million for the three months ended September 30, 2018 and 2017, respectively, and were $4.6 million and $3.5 million for the nine months ended September 30, 2018 and 2017, respectively.

Recently Adopted Accounting Standards
In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 and its related amendments (collectively referred to as ASC 606) requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Under this guidance, an entity makes additional estimates regarding performance conditions and the allocation of variable consideration and must evaluate whether revenue derived from a contract should be recognized at a point in time or over time. The Company adopted the standard as of the required effective date of January 1, 2018 using the modified retrospective method. Under this method, the new guidance was applied to contracts that were not yet completed as of January 1, 2018 with the cumulative effect of initially applying the guidance recognized through accumulated deficit as the date of initial application. See Note 3 "Revenue from Contracts with Customers".
Effective January 1, 2018, the Company adopted ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 changes the GAAP model for the accounting of equity investments, whereby equity investments with readily determinable fair value are carried at fair value with changes reported in net income (loss) as opposed to other comprehensive income (loss). The Company adopted ASU 2016-01 as of the required effective date of January 1, 2018. There was no impact on the consolidated financial statements upon the adoption of ASU 2016-01 as of the effective date or as of and for the period ended September 30, 2018.
Effective January 1, 2018, the Company retrospectively adopted ASU 2016-15, Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force) ("ASU 2016-15"). ASU 2016-15 clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows. The guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. There was no impact on the consolidated statements of cash flows upon the adoption of ASU 2016-15.

Effective January 1, 2018, the Company adopted ASU 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting. ("ASU 2017-09"). ASU 2017-09 specifies the types of changes to the terms or conditions of a share-based payment award that require an entity to apply modification accounting in accordance with Topic 718. The adoption of ASU 2017-09 did not have an impact on the Company's consolidated financial statements. Effective January 1, 2018, the Company adopted ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory ("ASU 2016-16"). ASU 2016-16 requires than an entity recognized the income tax effects of an intra-entity transfer of an asset, other than inventory, when the transfer occurs as opposed to when the asset is sold to a third party. The adoption of this guidance did not have an impact on the Company's consolidated financial statements.

Table of Contents

Accounting Standards Issued and Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 and its related amendments (collectively referred to as ASC 842) requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. ASC 842 will also require disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases. The guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years. While the Company continues to assess all potential impacts of the standard and its method of adoption, the Company expects to record right-of-use assets, with an associated amount recorded to lease obligations, on its balance sheet primarily related to its leased office and warehousing space. While the Company expects that the adoption of this standard will require updates to its processes and internal controls over financial reporting, the Company has concluded that it will not be required to implement new information systems to account for its lease portfolio.

In January 2017, the FASB issued ASU 2017-04, Simplifying the Test for Goodwill Impairment ("ASU 2017-04"). ASU 2017-04 simplifies the accounting for goodwill impairments by eliminating "Step 2" from the goodwill impairment test, which requires an entity to calculate the implied fair value of goodwill to measure a goodwill impairment charge, and alternatively, requires an entity to measure the impairment of goodwill assigned to a reporting unit as the amount by which the carrying value of the assets and liabilities of the reporting unit, including goodwill, exceeds the reporting unit's fair value. The guidance is effective for annual reporting periods beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted for all entities. The Company is currently evaluating the impact of ASU 2017-04 but does not expect it to be material to the consolidated financial statements.

In August 2017, the FASB issued ASU 2017-12, Targeted Improvements to Accounting for Hedging Activities ("ASU 2017-12"). ASU 2017-12 updates the current hedge accounting guidance with the objective of improving the financial reporting of hedging activities by better portraying the economic results of an entity's risk management activities in its financial statements. The new guidance is effective for the Company on January 1, 2019 and early adoption is permitted. As the Company currently does not use derivative financial instruments, this guidance is not expected to impact on Company's financial statements upon adoption.

In August 2018, the FASB issued ASU 2018-13, Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). ASU 2018-13 modifies certain disclosure requirements related to fair value measurements primarily associated with Level 3 investments. The guidance is effective no later than January 1, 2020 for the Company and can be early-adopted prospectively in any interim period for certain disclosure requirements or retrospectively for others. The Company does not expect the adoption of this guidance to have a material impact on its fair value disclosures.

In August 2018, the FASB issued ASU 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract ("ASU 2018-15"). ASU 2018-15 requires that entities capitalize certain costs to implement a cloud computing arrangement that is service contract consistent with the rules applicable to internal use software capitalization projects. The guidance is effective no later than January 1, 2020 for the Company and can be early-adopted prospectively in any interim period or retrospectively. The Company is evaluating when and how it will adopt this new guidance. Upon adoption, the Company would defer eligible costs related to the implementation of cloud computing arrangements within other current and non-current assets and amortize these costs to the same income statement line as the associated hosting fees.

Note 3. Revenue from Contracts with Customers

The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. Under this method, the new guidance was applied to contracts that were not yet completed as of January 1, 2018 with the cumulative effect of initially applying the guidance recognized through accumulated deficit as the date of initial application. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price, which did not have a material effect on the adjustment to accumulated deficit. The reported results

for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition (ASC 605), which is also referred to herein as the "previous guidance". The adoption of ASC 606 represents a change in accounting principle that primarily impacts how revenue is recognized for the Company's drug delivery product line and how the Company accounts for contract acquisition costs such as commissions. In accordance with ASC 606, revenue is recognized when a customer obtains control of the promised products. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products. To achieve this core principle, the Company applies the following five steps as outlined in ASC 606:

1) Identify the contract with a customer;

2) Identify the performance obligations in the contract;

3) Determine the transaction price;

Table of Contents

4) Allocate the transaction price to performance obligations in the contract;
5) Recognize revenue when or as the Company satisfies a performance obligation.

The following table summarizes revenue from contracts with customers for the three and nine months ended September 30, 2018 and 2017:

	Three months		Nine months	
(in thousands)	2018	2017	2018	2017
U.S. Omnipod	$81,970	$70,065	$230,289	$195,081
International Omnipod	50,214	32,481	117,127	84,200
Drug Delivery	18,892	19,229	51,500	53,963
Total	$151,076	$121,775	$398,916	$333,244

U.S. and International Omnipod

The Company generates the majority of its revenue from sales of its Omnipod, which is sold in the U.S., Europe, Canada and Israel. The Omnipod is sold either directly to end users or indirectly through intermediaries, such as independent distributors who resell the Omnipod to end users or wholesalers who sell the Company's product to end users through the pharmacy channel.

- Contracts with Customers. The Company's contracts with its direct customers generally consist of a physician order form, a patient information form and, if applicable, third-party insurance (payor) approval. Contracts with the Company's intermediaries are generally in the form of master service agreements against which firm purchase orders are issued. At the outset of the contract, the Company assesses the customer’s ability and intention to pay, which is based on a variety of factors including historical payment experience or, in the case of a new intermediary, published credit, credit references and other available financial information pertaining to the customer and in the case of a new direct customer, an investigation of insurance eligibility.
- Performance Obligations. The performance obligations in contracts for the delivery of the Omnipod to new end users, either directly to end users or through intermediaries, primarily consist of the PDM and the initial and subsequent quantity of Pods ordered. To the extent a contract includes multiple promised items, the Company must apply judgment to determine whether promised items are capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised services are accounted for as a combined performance obligation.
- Transaction Price. The price charged for the PDM and Pods is dependent on the Company's pricing as established with third party payors and intermediaries. The Company provides a right of return for sales of its Omnipod to new patients. The Company also provides for certain rebates and discounts for sales of its product through intermediaries. These rights of return, discounts and rebates represent variable consideration and reduce the transaction price at the outset of the contract based on the Company's estimates, which are primarily based on the expected value method using historical and other data related to actual product returns, discounts and rebates paid in each market in which the Omnipod is sold. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. There were no constraints recorded to variable consideration and none of the Company's contracts as of January 1, 2018 or September 30, 2018 contained a significant financing component.
- Allocation of Transaction Price. The Company allocates the transaction price to each performance obligation based on its relative stand-alone selling price, which is determined based on the price at which the Company typically sells the deliverable or, if the performance obligation is not typically sold separately, the stand-alone selling price is estimated based on cost plus a reasonable profit margin or the price that a third party would charge for a similar product or service.
- Recognition of Revenue. The Company transfers the Omnipod at a point in time, which is determined based on when the customer gains control of the product. Generally, intermediaries in the U.S. obtain control upon shipment based on the contractual terms including right to payment and transfer of title and risk of loss. For sales directly to end users and international intermediaries, control is generally transferred at the time of delivery based on customary business practices related to risk of ownership.

10

Table of Contents

Drug Delivery

The Company's drug delivery product line includes sales of a modified version of the Omnipod to pharmaceutical and biotechnology companies who use the Company’s technology as a delivery method for their drugs. Under ASC 606, for the majority of this product line, revenue is recognized as the product is produced pursuant to the customer’s firm purchase commitments as the Company has an enforceable right to payment for performance completed to date and the inventory has no alternative use to the Company. Judgment is required in the assessment of progress toward completion of in-process inventory. The Company recognizes revenue over time using a blend of costs incurred to date relative to total estimated costs at completion and time incurred to date relative to total production time to measure progress toward the satisfaction of its performance obligations. The Company believes that both incurred cost and elapsed time reflect the value generated, which best depicts the transfer of control to the customer. Contract costs include third party costs as well as an allocation of manufacturing overhead. Changes from quarter to quarter in quantity and stage of production of in-process inventory could have a significant quarterly impact on revenue.

Financial Statement Impact of Adopting ASC 606

The cumulative effect of applying the new guidance to all contracts with customers that were not completed as of January 1, 2018 was recorded as an adjustment to accumulated deficit as of the adoption date. The following table shows the adjustments made to accounts on the consolidated balance sheet as of January 1, 2018 as a result of adopting the new guidance. The table also compares the reported consolidated balance sheet accounts as of September 30, 2018 that were impacted by the new guidance to pro forma balance sheet amounts had the previous guidance been in effect.

(in thousands)	As Reported 12/31/2017	Adjustments 1/1/2018	As Adjusted 1/1/2018	As Reported 9/30/2018	Adjustments 9/30/2018	Pro forma 9/30/2018
Unbilled receivable (a)	$ —	$ 5,119	$ 5,119	$ 9,963	$ (9,963)	$ —
Inventories	33,793	(753)	33,040	58,050	1,430	59,480
Prepaid expenses and other current assets (b)	9,949	5,568	15,517	17,905	(6,869)	11,036
Total current assets	537,171	9,934	547,105	445,712	(15,402)	430,310
Other assets (b)	1,969	13,326	15,295	18,057	(15,567)	2,490
Total assets	816,744	23,260	840,004	886,306	(30,969)	855,337
Deferred revenue (c)	2,356	2,625	4,981	2,210	(771)	1,439
Total current liabilities	86,025	2,625	88,650	97,224	(771)	96,453
Other long-term liabilities	6,030	271	6,301	6,668	(270)	6,398
Total liabilities	658,228	2,896	661,124	688,377	(1,041)	687,336
Accumulated deficit	(707,255)	20,349	(686,906)	(693,507)	(29,937)	(723,444)
Total stockholders' equity	158,516	20,364	178,880	197,929	(29,928)	168,001
Total liabilities and stockholders' equity	816,744	23,260	840,004	886,306	(30,969)	855,337

(a) Unbilled receivable that reflects revenue for a portion of the Company's drug delivery product line as the product is produced. The unbilled receivable is reclassified to accounts receivable as the product is completed and shipped to the customer.

(b) Other current and non-current assets include contract acquisition costs related to the sale of the Omnipod. These costs are amortized over the estimated period of benefit.

(c) The adoption of ASC 606 required the Company to record a contract liability, or deferred revenue, on January 1, 2018, primarily associated with a volume-based pricing discount granted to the Company's European Distributor at the outset of the distribution contract in 2010. The deferred revenue was recognized as revenue through the completion of the distributor contract during the first half of 2018.

The following summarizes the significant changes on the Company’s consolidated statement of operations for the three and nine months ended September 30, 2018 as a result of the adoption of ASC 606 on January 1, 2018 compared to if the Company had continued to recognize revenue under ASC 605:

11

Table of Contents

(in thousands, except per share amounts)	Three months ended September 30, 2018			Nine months ended September 30, 2018		
	As reported	Adjustments	Pro forma	As reported	Adjustments	Pro forma
U.S. Omnipod	$81,970	$ (135)	$81,835	$230,289	$ (9)	$230,280
International Omnipod (a)	50,214	53	50,267	117,127	(1,845)	115,282
Drug Delivery (b)	18,892	3,995	22,887	51,500	(4,844)	46,656
Revenue	151,076	3,913	154,989	398,916	(6,698)	392,218
Cost of revenue	49,107	674	49,781	139,060	(677)	138,383
Gross profit	101,969	3,239	105,208	259,856	(6,021)	253,835
Sales and marketing (c)	34,922	394	35,316	102,660	3,567	106,227
Total operating expenses	95,104	394	95,498	248,666	3,567	252,233
Operating income	6,865	2,845	9,710	11,190	(9,588)	1,602
Income (loss) before income taxes	1,853	2,845	4,698	(5,662)	(9,588)	(15,250)
Net income (loss)	$1,659	$ 2,845	$4,504	$(6,601)	$ (9,588)	$(16,189)
Net income (loss) per share: basic	$0.03	$ 0.05	$0.08	$(0.11)	$ (0.17)	$(0.28)
Net income (loss) per shares: diluted	$0.03	$ 0.04	$0.07	$(0.11)	$ (0.17)	$(0.28)

(a) International Omnipod revenue under ASC 606 includes the amortization of a material right associated with a volume-based pricing discount granted to the Company's European Distributor at the outset of the distribution contract in 2010. The deferred revenue was recognized as revenue through the completion of the distributor contract during the first half of 2018.

(b) ASC 606 accelerated the recognition of revenue and fulfillment costs related to certain drug delivery contracts for which recognition was previously recorded when the product was shipped to the customer and is recorded as the product is produced under ASC 606. During the three and nine months ended September 30, 2018, revenue was lower by $4.0 million and higher by $4.8 million, respectively, due to changes in quantity and stage of production of in-process inventory relative to the prior period.

(c) ASC 606 resulted in the amortization of capitalized commission costs that were recorded as part of the cumulative effect adjustment upon adoption and during the nine months ended September 30, 2018. Amortization of these capitalized costs to selling and marketing expenses, net of commission costs that were capitalized in the three and nine month periods, reduced sales and marketing expenses in each period.

Statement of Cash Flows (in thousands)	Nine Months Ended September 30, 2018		
	As Reported	Adjustments	Pro Forma
Net loss	$(6,601)	$ (9,588)	$(16,189)
Adjustments to reconcile net loss to net cash used in operating activities			
Non-cash items	66,602	—	66,602
Changes in operating assets and liabilities:			—
Accounts receivable and unbilled receivable	(24,581)	4,844	(19,737)
Inventories	(25,279)	(677)	(25,956)
Prepaid expenses and other assets	(5,258)	3,567	(1,691)
Accounts payable, accrued expenses and other current liabilities	2,938	—	2,938
Deferred revenue	(2,761)	1,854	(907)
Other long-term liabilities	400	—	400
Net cash provided by operating activities	$5,460	$ —	$5,460

The adoption of ASC 606 had no net impact on the Company’s cash used in operating, investing or financing activities. Revenue recognized during the three and nine months ended September 30, 2018 from amounts included in deferred revenue at the beginning of the period was approximately $0.6 million and $2.5 million, respectively. No revenue was recognized during the three and nine months ended September 30, 2018 from performance obligations satisfied or

partially satisfied in previous periods. As of September 30, 2018, unbilled receivable associated with the Company's drug delivery product line increased by $4.8 million relative to the beginning of the year due to an increase in the quantity and stage of production of in-process inventory during the year. There were no contract modifications entered into during the three and nine months ended September 30, 2018 impacting the Company’s unbilled receivable or deferred revenue.

Table of Contents

Revenue for customers comprising more than 10% of total revenue were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Amgen, Inc.	12%	16%	13%	16%
Ypsomed and affiliates	*	23%	11%	21%
Cardinal Health Inc. and affiliates	12%	11%	12%	10%

* Represents less than 10% of consolidated revenue.

Note 4. Investments and Fair Value

Cash and Cash Equivalents:
For the purpose of 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 mutual funds, corporate bonds, U.S. government and agency bonds, and certificates of deposit, and are carried at cost which approximates their fair value. Included in the Company's cash and cash equivalents are restricted cash amounts set aside for collateral on outstanding letters of credit totaling $2.7 million as of September 30, 2018 and $0.5 million as of December 31, 2017.

Marketable Securities:
The Company's short-term and long-term investments in debt securities have maturity dates that range from 11 days to 23.9 months as of September 30, 2018. The Company’s investment portfolio included approximately 75 available-for-sale debt securities that had insignificant unrealized loss positions as of September 30, 2018. The Company has the intent and ability to hold these investments until maturity whereby these unrealized losses are expected to be recovered. There were no charges recorded in the period for other-than-temporary declines in the fair value of available-for-sale debt securities. The Company's investments had insignificant realized gains or losses for the nine months ended September 30, 2018.

To measure fair value of assets and liabilities required to be measured or disclosed at fair value, the Company uses the following fair value hierarchy based on three levels of inputs 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 Company had no Level 3 assets or liabilities as of September 30, 2018.

Table of Contents

The following table provides amortized cost, gross unrealized gains and loses, fair value and the level in the fair value hierarchy within which those measurements fall:

(in thousands)	Amortized cost	Gross Unrealized Gains (Losses)	Fair Value	Level 1	Level 2
September 30, 2018					
Money market mutual funds	$66,141	$ —	$66,141	$66,141	$—
Total cash equivalents	$66,141	$ —	$66,141	$66,141	$—
U.S. government and agency bonds	$120,832	$ (444)	$120,388	$77,128	$43,260
Corporate bonds	38,897	(108)	38,789	—	38,789
Certificates of deposit	4,104	—	4,104	—	4,104
Total short-term investments	$163,833	$ (552)	$163,281	$77,128	$86,153
U.S. government and agency bonds	$96,038	$ (646)	$95,392	$73,652	$21,740
Corporate bonds	44,808	(245)	44,563	—	44,563
Certificates of deposit	5,584	—	5,584	—	5,584
Total long-term investments	$146,430	$ (891)	$145,539	$73,652	$71,887
December 31, 2017					
Money market mutual funds	$236,936	$ —	$236,936	$236,936	$—
U.S government and agency bonds	$5,000	—	$5,000	$5,000	—
Total cash equivalents	$241,936	$ —	$241,936	$241,936	$—
U.S. government and agency bonds	$112,311	$ (235)	$112,076	$90,703	$21,373
Corporate bonds	47,713	(32)	47,681	—	47,681
Certificates of deposit	7,722	—	7,722	—	7,722
Total short-term investments	$167,746	$ (267)	$167,479	$90,703	$76,776
U.S. government and agency bonds	$92,677	$ (213)	$92,464	$49,651	$42,813
Corporate bonds	27,871	(59)	27,812	—	27,812
Certificates of deposit	5,273	—	5,273	—	5,273
Total long-term investments	$125,821	$ (272)	$125,549	$49,651	$75,898

Table of Contents

Note 5. Convertible Debt, Net

The Company had outstanding convertible debt and related debt issuance costs on its consolidated balance sheet as follows:

(in thousands)	As of September 30, 2018	December 31, 2017
Principal amount of 2.0% Convertible Senior Notes, due June 2019	$ —	$ 3,664
Principal amount of 1.25% Convertible Senior Notes, due September 2021	344,992	345,000
Principal amount of 1.375% Convertible Senior Notes, due November 2024	402,500	402,500
Unamortized debt discount	(150,439)	(170,448)
Debt issuance costs	(12,568)	(14,543)
Total convertible debt, net	$ 584,485	$ 566,173

Interest expense related to the convertible debt was as follows:

(in thousands)	Three Months Ended September 30, 2018	2017	Nine Months Ended September 30, 2018	2017
Contractual coupon interest	$2,440	$1,449	$7,382	$4,276
Accretion of debt discount	6,702	3,612	19,840	10,690
Amortization of debt issuance costs	661	505	1,950	1,495
Total interest expense related to convertible debt	$9,803	$5,566	$29,172	$16,461

Interest expense related to convertible debt for the three and nine months ended September 30, 2018 is as follows:

	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018			
(in thousands)	1.375%	1.25%	Total	1.375%	1.25%	2.0%	Total
Contractual coupon interest	$1,362	$1,078	$2,440	$4,129	$3,234	$ 19	$7,382
Amortization of debt discount and issuance costs	3,736	3,627	7,363	11,001	10,729	60	21,790
Total interest expense	$5,098	$4,705	$9,803	$15,130	$13,963	$ 79	$29,172

Interest expense related to convertible debt for the three and nine months ended September 30, 2017 is as follows:

	Three Months Ended September 30, 2017			Nine Months Ended September 30, 2017		
(in thousands)	1.25%	2.0%	Total	1.25%	2.0%	Total
Contractual coupon interest	$1,102	$347	$1,449	$3,259	$1,017	$4,276
Amortization of debt discount and issuance costs	3,403	714	4,117	10,073	2,112	12,185
Total interest expense	$4,505	$1,061	$5,566	$13,332	$3,129	$16,461

The carrying amount and the estimated fair value of the Company's convertible debt, which is based on the Level 2 quoted market prices as of September 30, 2018 and December 31, 2017 are as follows:

(in thousands)	As of September 30, 2018		December 31, 2017	
	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
2% Convertible Senior Notes, due June 2019	$—	$—	$3,421	$5,467
1.375% Convertible Senior Notes, due November 2024	287,183	515,627	276,172	407,652
1.25% Convertible Senior Notes, due September 2021	297,302	630,041	286,580	450,881
Total	$584,485	$1,145,668	$566,173	$864,000

1.375% Convertible Senior Notes

15

Table of Contents

In November 2017, the Company issued and sold $402.5 million in aggregate principal amount of 1.375% Convertible Senior Notes, due November 15, 2024 (the "1.375% Notes"). The interest rate on the notes is 1.375% per annum, payable semi-annually in arrears in cash on May 15 and November 15 of each year. Interest began accruing on November 10, 2017 and the first interest payment was made on May 15, 2018. The 1.375% Notes are convertible into the Company's common stock at an initial conversion rate of 10.7315 shares of common stock per $1,000 principal amount of the 1.375% Notes, which is equivalent to a conversion price of approximately $93.18 per share, subject to adjustment under certain circumstances. The 1.375% Notes will be convertible prior to the close of business on the business day immediately preceding August 15, 2024 only under certain circumstances and during certain periods, and will be convertible on or after August 15, 2024 until the close of business on the second scheduled trading day immediately preceding November 15, 2024, regardless of those circumstances.

The Company recorded a debt discount of $120.7 million related to the 1.375% Notes resulting from the allocation of a portion of the proceeds to the fair value of the conversion feature reflecting a nonconvertible debt borrowing rate of 6.8% per annum. The debt discount was recorded as additional paid-in capital and is being amortized as non-cash interest expense over the seven year term of the 1.375% Notes. The Company also incurred debt issuance costs and other expenses related to the 1.375% Notes of approximately $10.9 million, of which $3.3 million was reclassified as a reduction to the value of the conversion feature allocated to equity. The remaining $7.6 million of debt issuance costs is presented as a reduction of debt in the consolidated balance sheet and is being amortized using the effective interest method as non-cash interest expense over the seven year term of the 1.375% Notes. As of September 30, 2018, the Company included $287.2 million on its balance sheet in long-term debt related to the 1.375% Notes.

1.25% Convertible Senior Notes

In September 2016, the Company issued and sold $345.0 million in principal amount of 1.25% Convertible Senior Notes, due September 15, 2021 (the "1.25% Notes"). The interest rate on the notes is 1.25% per annum, payable semi-annually in arrears in cash on March 15 and September 15 of each year. The 1.25% Notes are convertible into the Company's common stock at an initial conversion rate of 17.1332 shares of common stock per $1,000 principal amount of the 1.25% Notes, which is equivalent to a conversion price of approximately $58.37 per share, subject to adjustment under certain circumstances. The 1.25% Notes will be convertible prior to the close of business on the business day immediately preceding June 15, 2021 only under certain circumstances and during certain periods, and will be convertible on or after June 15, 2021 until the close of business on the second scheduled trading day immediately preceding September 15, 2021, regardless of those circumstances.

The Company recorded a debt discount of $66.7 million related to the 1.25% Notes resulting from allocating a portion of the proceeds to the fair value of the conversion feature reflecting a nonconvertible debt borrowing rate of 5.8% per annum. The debt discount is being amortized as non-cash interest expense over the five year term of the 1.25% Notes. The Company incurred debt issuance costs and other expenses related to this offering of approximately $11.3 million, of which $2.2 million was reclassified as a reduction to the value of the amount allocated to equity. The remainder is presented as a reduction of debt in the consolidated balance sheet and is being amortized using the effective interest method as non-cash interest expense over the five year term of the 1.25% Notes. As of September 30, 2018, the Company has $297.3 million, net of discounts and issuance costs, on its balance sheet in long-term debt related to the 1.25% Notes.

2% Convertible Senior Notes

In June 2014, the Company issued and sold $201.3 million in principal amount of 2% Convertible Senior Notes due June 15, 2019 (the "2% Notes"). The 2% Notes were 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. In separately negotiated transactions, the Company repurchased $134.2 million in principal of the notes in September 2016 and $63.4 million in principal of the notes in November 2017. The Company elected to call the remaining notes in March 2018 and settled the outstanding principal and conversion feature of the notes for $6.7 million in cash in the second quarter of 2018. The Company allocated approximately $3.2 million of the settlement to the fair value of the equity component and $3.5 million to the debt component, which was consistent with the carrying value of the notes as of the settlement date, resulting in no gain or loss on extinguishment.

Note 6. Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. Diluted net income (loss) per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from outstanding stock options and restricted stock units (using the treasury-stock method), and potential common shares from the Company's convertible debt (using the if-converted method).

Table of Contents

The following table sets forth the components used in the computation of basic and diluted net income (loss) per share for the three and nine months ended September 30, 2018. Because the Company reported a net loss for the three and nine months ended September 30, 2017, all potential dilutive common shares have been excluded from the computation of the diluted net loss per share for the three and nine months ended September 30, 2017, as the effect would have been anti-dilutive.

(in thousands, except share and per share data)	September 30, 2018 Three months ended	Nine months ended
Numerator:		
Net income (loss)	$1,659	$ (6,601)
Denominator:		
Weighted average common shares outstanding	59,016,856	58,779,672
Effective of dilutive potential common share equivalents		
Stock options	1,719,796	—
Restricted stock units	409,807	—
Convertible debt	—	—
Shares used for diluted net income (loss) per share	61,146,459	58,779,672
Net income (loss) per share:		
Basic	$0.03	$ (0.11)
Diluted	$0.03	$ (0.11)

For the three months ended September 30, 2018, certain potential outstanding shares from stock options, restricted stock units and convertible debt were excluded from the computation of diluted net income per share because the effect of including these items was anti-dilutive. Additionally, certain performance-based restricted stock units were excluded from the computation of diluted net income per share because the underlying performance conditions for such restricted stock units had not been met as of these dates.

The number of potential common share equivalents excluded from the computation of diluted net income (loss) per share for the three and nine months ended September 30, 2018 and 2017 are as follows:

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018	Three and Nine Months Ended September 30, 2017
1.375% Convertible Senior Notes	4,319,429	4,319,429	—
2.00% Convertible Senior Notes	—	—	1,442,433
1.25% Convertible Senior Notes	5,910,954	5,910,954	5,910,954
Unvested restricted stock units	300,438	865,206	1,007,729
Outstanding stock options	223,183	3,117,326	3,489,393
Total potential common share equivalents excluded from computation of diluted net income (loss) per share	10,754,004	14,212,915	11,850,509

Note 7. Accounts Receivable, Net

Accounts receivable consist of amounts due from third-party payors, patients and third-party intermediaries. 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, and discussions with individual

customers. The Company believes the reserve is adequate to mitigate current collection risk. There were no customers that represented greater than 10% of gross accounts receivable as of September 30, 2018.

The components of accounts receivable are as follows:

(in thousands)	As of September 30, 2018	December 31, 2017
Trade receivables	$73,428	$55,914
Allowance for doubtful accounts	(3,478)	(2,541)
Total accounts receivable, net	$69,950	$53,373

Table of Contents

Note 8. Inventories

Inventories are carried at the lower of cost or market, determined under the first-in, first-out method, and include the costs of material, labor and overhead. Inventory has been recorded at cost, or net realizable value as appropriate, as of September 30, 2018 and December 31, 2017. The Company reviews inventories for net realizable value based on quantities on hand and expectations of future use. Work in process is calculated based upon a buildup in the stage of completion using estimated labor inputs for each stage in production.

The components of inventories are as follows:

(in thousands)	As of September 30, 2018	December 31, 2017
Raw materials	$5,390	$ 2,146
Work-in-process	17,187	23,918
Finished goods, net	35,473	7,729
Total inventories	$58,050	$ 33,793

Note 9. Prepaid Expenses and Other Assets

The components of prepaid expenses and other current assets are as follows:

(in thousands)	As of September 30, 2018	December 31, 2017
Prepaid expenses and other current assets	$11,036	$ 9,949
Capitalized contract acquisition costs, current portion	6,869	—
Total prepaid expenses and other current assets	$17,905	$ 9,949

The components of other assets are as follows:

(in thousands)	As of September 30, 2018	December 31, 2017
Other assets	$2,487	$ 1,969
Capitalized contract acquisition costs, net of current portion	15,570	—
Total other assets	$18,057	$ 1,969

The Company capitalizes commission costs that are related to new patient starts. These costs are deferred in other assets, net of the short term portion included in prepaid and other current assets. Costs to obtain a contract are amortized as sales and marketing expense on a straight line basis over the expected period of benefit, which considers future product upgrades for which a commission would be paid. These capitalized costs are periodically reviewed for impairment. As of September 30, 2018, capitalized contract acquisition costs were $22.4 million, including a current balance of $6.9 million and a non-current balance of $15.6 million. The Company recognized $5.0 million of amortization of capitalized commission costs during the nine months ended September 30, 2018. There were no impairments to capitalized costs to obtain a contract recorded during the period.

Table of Contents

Note 10. Goodwill and Other Intangible Assets, Net

Goodwill

The Company has $39.8 million of goodwill on its balance sheet from prior business acquisitions. 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 an impairment. The Company's annual impairment test date is October 1st. There was no impairment of goodwill during the three and nine months ended September 30, 2018.

Intangible Assets, Net

The Company’s finite-lived intangible assets are stated at cost less accumulated amortization and include customer relationships acquired in prior business acquisitions and from the Company's former European Distributor. See Note 12 for a discussion of the Company's accounting for estimated fees owed to its former European Distributor following the expiration of its distribution agreement on June 30, 2018.

The components of other intangible assets are as follows:

	As of September 30, 2018			December 31, 2017		
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Customer and contractual relationships	$4,078	$ (1,859)	$2,219	$2,135	$ (1,764)	$371
Internal-use software	10,271	(4,699)	5,572	7,545	(3,565)	3,980
Total intangible assets	$14,349	$ (6,558)	$7,791	$9,680	$ (5,329)	$4,351

Amortization expense for intangible assets was approximately $0.5 million and $0.3 million for the three months ended September 30, 2018 and 2017, respectively. Amortization expense for intangible assets was approximately $1.3 million and $0.8 million for the nine months ended September 30, 2018 and 2017, respectively. Amortization expense is recorded in general and administrative expenses in the consolidated statements of operations.

Amortization expense expected for the next five years and thereafter is as follows:

(in thousands)

Years Ending December 31,	Customer and Contractual Relationships	Internal-Use Software	Total
2018 (remaining)	$ 90	$ 465	$555
2019	334	1,767	2,101
2020	266	1,505	1,771
2021	200	1,080	1,280
2022	200	571	771
Thereafter	1,129	184	1,313
Total	$ 2,219	$ 5,572	$7,791

As of September 30, 2018, the weighted average amortization period of the Company’s customer and contractual relationships intangible assets and internal-use software intangible assets are approximately 9.1 years and 3.5 years , respectively.

Table of Contents

Note 11. Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities are as follows:

(in thousands)	As of September 30, 2018	December 31, 2017
Employee compensation and related costs	$32,265	$ 34,942
Professional and consulting services	10,190	9,273
Supplier charges	3,863	3,542
Warranty	2,303	1,653
Other	19,548	9,846
Total accrued expenses and other current liabilities	$68,169	$ 59,256

Product Warranty Costs

The Company generally provides a four-year warranty on its PDMs sold in the United States and Europe and a five-year warranty on its PDMs sold in Canada and may replace any Omnipod that does 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. Warranty expense is recorded in cost of goods sold on the statement of operations. Cost to service the claims reflects the current product cost. 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2018	2017	2018	2017
Product warranty liability at the beginning of the period	$5,503	$4,817	$5,337	$4,388
Warranty expense	1,763	1,483	5,264	3,123
Warranty claims settled	(1,548)	(1,303)	(4,883)	(2,514)
Product warranty liability at the end of the period	$5,718	$4,997	$5,718	$4,997

Composition of balance:

(in thousands)	As of September 30, 2018	December 31, 2017
Short-term	$2,303	$ 1,653
Long-term	3,415	3,684
Total warranty liability:	$5,718	$ 5,337

Note 12. Commitments and Contingencies

Legal Proceedings

Between May 5, 2015 and June 16, 2015, three class action lawsuits were filed by shareholders in the U.S. District Court, for the District of 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, (“ATRS”) alleged that the Company (and certain executives) committed 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. On February 8, 2018, the parties executed a binding stipulation of settlement, under which all claims were released and a payment was made to the plaintiffs and the class they purport to represent. On August 6, 2018, the Court issued an order finally approving the settlement. The Company had previously accrued fees and expenses in connection with this matter for the amount of the final settlement liability that was not covered by insurance, which amount was not material to the Company's consolidated

financial statements.

In addition, on April 26, 2017, a derivative action (Walker v. DeSisto, et al., 1:17-cv-10738) ("Walker") was filed, and on October 13, 2017, a second derivative action (Carnazza v. DeSisto, et al., 1:17-cv-11977) ("Carnazza") was filed, both on behalf of the Company, each by a shareholder in the U.S. District Court for the District of Massachusetts against the Company (as a nominal defendant) and certain individual current and former officers and directors of the Company. The allegations in the actions are substantially similar to those alleged in the securities class action. The actions seek, among other things, damages, disgorgement of certain types of compensation or profits, and attorneys' fees and costs. On July 11, 2018, the parties executed a binding stipulation of settlement, under

Table of Contents

which all claims were released and a payment of attorneys' fees and reimbursement of expenses will be paid to plaintiffs' counsel, subject to the Court's approval. On July 13, 2018, the plaintiffs filed a motion for preliminary approval of the settlement, which is pending. The Company expects that such fees and expenses payable to plaintiff's counsel will be covered by the Company's insurance.

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.

Fees To Former European Distributor

Following the expiration of its distribution agreement on June 30, 2018, the Company is required to pay to its former European Distributor a quarterly per unit fee for sales of its Omnipod device to identified customers (as that term is defined in the distribution agreement) of the former European Distributor over the twelve months following the expiration of the distribution agreement. The Company is recognizing a liability and an associated intangible asset for this fee as qualifying sales of the Omnipod device are made to these identified customers during the twelve-month period between July 1, 2018 and June 30, 2019. The actual total fee could vary significantly depending on the number of customers who qualify as eligible to be considered for purposes of calculating the fee under the terms of the distribution agreement, which is under dispute between the parties, and the number of Omnipod devices sold to those customers over the twelve month period. The Company estimates that the total fee could be in the range of approximately $10 million to $55 million over the twelve month period. The Company has accrued approximately $2 million for fees related to Omnipod devices sold to qualifying customers for the three months ended September 30, 2018.

Operating Leases

The Company leases approximately 100,000 square feet of laboratory and office space for its corporate headquarters in Billerica, Massachusetts. The lease expires in November 2022 and contains escalating payments over the its life. Additionally, the Company leases approximately 29,000 square feet of warehousing space in Billerica, Massachusetts under a lease expiring in September 2019. The Company also leases international and U.S. facilities under leases expiring from October 2018 to June 2021. Rental expense under operating leases was $0.9 million and $2.6 million for the three and nine months ended September 30, 2018, respectively. There have been no material changes to the Company's lease obligation in the nine months ended September 30, 2018.

Note 13. Stock-Based Compensation and Stockholder' Equity

The Company grants stock options, and both time-based and performance-based restricted stock units under its 2017 Stock Option and Incentive Plan and offers employees the opportunity to purchase its common stock through an Employee Stock Purchase Plan. The following table reflects the Company's stock-based compensation expense related to share-based awards recognized in the three and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,		Unamortized Expense	Weighted Average Remaining Expense Period (Years)
($ in thousands)	2018	2017	2018	2017	At September 30, 2018	
Stock options	$3,957	$3,127	$8,587	$8,815	$13,632	2.5
Restricted stock units	11,835	5,621	21,734	14,358	25,054	1.9
Employee stock purchase plan	296	149	884	379	197	0.2
Total	$16,088	$8,897	$31,205	$23,552	$38,883	

Table of Contents

The following summarizes stock option activity during the nine months ended September 30, 2018:

	Number of Options (#)	Weighted Average Exercise Price ($)	Aggregate Intrinsic Value ($ in thousands)	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2017	3,377,220	$ 35.10		
Granted	287,199	77.05		
Exercised	(384,887)	33.11	$ 21,419	
Cancelled	(162,206)	40.45		
Outstanding at September 30, 2018	3,117,326	$ 38.94	$ 208,898	7.1
Vested, September 30, 2018	2,077,854	$ 34.40	$ 148,671	6.6
Vested or expected to vest, September 30, 2018 [1]	3,019,139		$ 203,882	

[1] Represents total outstanding stock options as of September 30, 2018, adjusted for estimated forfeitures.

The following table summarizes the status of the Company’s restricted stock units during the nine months ended September 30, 2018:

	Number of Shares (#)	Weighted Average Fair Value ($)
Outstanding at December 31, 2017	994,364	$ 38.08
Granted	328,342	75.51
Adjustment [1]	147,301	29.54
Vested	(526,638)	33.59
Forfeited	(78,163)	44.58
Outstanding at September 30, 2018	865,206	$ 52.98

[1] Certain performance-based restricted stock units are subject to a three-year vesting period subject to meeting performance targets and continued employment. During the three months ended March 31, 2018, the Compensation Committee of the Board of Directors determined that the performance was achieved at 200% of target for certain performance-based awards issued in 2016, resulting in an adjustment to the shares that will ultimately vest for these awards.

Note 14. Income Taxes

The Company accounts for income taxes in accordance with ASC 740-10, Income Taxes (“ASC 740-10”). The Tax Cuts and Jobs Act ("Tax Reform Act"), which was enacted in December 2017, significantly changed U.S. tax law by, among other things, lowering corporate income tax rates to a flat 21% rate effective January 1, 2018 and imposing a tax on deemed repatriated earnings of foreign subsidiaries. The Company recognized the impact of the Tax Reform Act in the consolidated financial statements as of December 31, 2017. In accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), the Company recorded provisional amounts reflecting the impact of certain requirements of the Tax Reform Act in its consolidated financial statements and related disclosures as of December 31, 2017, including a reduction in net operating losses in 2017 of $0.8 million offset by an associated reduction in the valuation allowance of the $0.8 million related to the deemed repatriation. The deemed repatriation tax computation will be finalized in conjunction with the filing of the Company's federal and state tax returns in the fourth quarter and are not expected to vary significantly from the original estimate. The Tax Reform Act also subjects the Company to current tax on global intangible low-taxed income, or ("GILTI") earned by certain of its foreign subsidiaries. The Company has elected to recognize the income tax related to GILTI as a period expense in the period the tax is incurred or expected to occur for the year ended December 31, 2018. The inclusion of GILTI had no impact on the Company's income tax expense or effective tax rate in the period due to the full valuation allowance applied to the U.S. entity.

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 2015 through 2016 and 2014 through 2016, 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.

Table of Contents

As of September 30, 2018 and December 31, 2017, the Company has provided a full valuation allowance against its domestic net deferred tax asset because it is not more likely than not that the future tax benefit will be realized. In addition, the Company has a net deferred tax asset in foreign jurisdictions where no valuation allowance is recorded as it is more likely than not that the future tax benefit will be realized. As of September 30, 2018, the Company had no uncertain tax positions.

Income tax expense was $0.2 million and $0.1 million for the three months ended September 30, 2018 and 2017. Income tax expense was $0.9 million and $0.3 million for the nine months ended September 30, 2018 and 2017, respectively. Income tax expense for both periods in the current year was primarily driven by taxable income generated in foreign jurisdictions, mainly the United Kingdom and Canada.

Table of Contents

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

FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "predicts," "potential" or "continue" or the negative of these terms or other similar words. These statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, results of operations and financial condition.

The outcomes of the events described in these forward-looking statements are subject to risks, uncertainties and other factors described in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on February 22, 2018 in the section entitled "Risk Factors" as updated by Item 1A "Risk Factors" herein, and in our other filings from time to time with the Securities and Exchange Commission. Accordingly, you should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements made in this quarterly report on Form 10-Q relate only to events as of the date of this report. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

Executive Level Overview

We are primarily engaged in the development, manufacturing and sale of our proprietary Omnipod System, an innovative, discreet and easy-to-use continuous insulin delivery system for people with insulin-dependent diabetes. There are two primary types of insulin therapy practiced today: MDI therapy using syringes or insulin pens; and pump therapy using insulin pumps. Insulin pumps are used to perform continuous subcutaneous insulin infusion, or insulin pump therapy, and typically use a programmable device and an infusion set to administer insulin into the person's body. Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. We estimate that approximately one-third of the Type 1 diabetes population in the United States use insulin pump therapy, and that less than 10% of the Type 2 diabetes population in the United States who are insulin-dependent use insulin pump therapy. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod device which is worn on the body for approximately three days at a time and its wireless companion, the handheld PDM. The Omnipod System, which features two discreet, easy-to-use devices, communicates wirelessly, provides for virtually pain-free automated cannula insertion and eliminates the need for traditional MDI therapy or the use of traditional pump and tubing. We believe that the Omnipod System's unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience, and ease.

We began commercial sale of the Omnipod System in the United States in 2005. We sell the Omnipod System through direct sales to customers or through our distribution partners. The Omnipod System is currently available in multiple countries in Europe, as well as Canada and Israel. On July 1, 2018 we assumed all commercial activities (including, among other things, distribution, sales, marketing, training and support) for our Omnipod System across Europe following the expiration of our prior distribution agreement with our former European Distributor on June 30, 2018.

In addition to using the Omnipod System for insulin delivery, we also partner with global pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of subcutaneous drugs across other therapeutic areas.

We are constructing a highly-automated manufacturing facility in Acton, Massachusetts, with planned production out of the facility beginning in early 2019. The facility will also serve as our global headquarters. We expect that, following start up related activities, the new facility will allow us to lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base and support growth. We expect capital expenditures for

the construction of the Acton facility and related equipment purchases will be approximately $200 million when production begins in 2019 and will be funded by our cash flows from operations and proceeds from our senior convertible debt offerings.

In January 2018, we announced that the Centers for Medicare & Medicaid Services ("CMS") has issued guidance clarifying that Medicare Part D Plan Sponsors are permitted to provide coverage for products such as the Omnipod System under the Medicare Part D (prescription drug) program. We have been securing coverage with Medicare Part D carriers to ensure beneficiaries living with diabetes have access to the Omnipod System. Securing Medicare Part D coverage also provides us with a direct pathway to increased Medicaid coverage at the state level, as many state-run Medicaid programs follow CMS prescription drug guidance to determine coverage. This allows access for lower-income individuals and families on Medicaid for whom Omnipod currently is not a covered option. We estimate that obtaining Medicare and Medicaid coverage extends Omnipod System coverage access to approximately 450,000 additional individuals with Type 1 diabetes in the United States.

Table of Contents

In June 2018, the U.S. Food and Drug Administration ("FDA") provided clearance for the commercial distribution of our DASH ™ System, which is our next-generation digital mobile Omnipod platform, featuring a secured Bluetooth enabled Pod and PDM with a touch screen color user interface supported by smartphone connectivity. We commenced a U.S. limited commercial release of Omnipod DASH ™ in Q3 2018 prior to a full market launch in early 2019.
On September 10, 2018, we announced that Shacey Petrovic, President and Chief Operating Officer, will succeed Patrick Sullivan as our Chief Executive Officer effective January 1, 2019. Timothy J. Scannell, who has served as a member of Insulet's Board for the last four years, will become Chairman, effective January 1, 2019. Ms. Petrovic joined Insulet's Board effective with the announcement. In accordance with the terms of his employment agreement and the Company's Amended and Restated Executive Severance Plan, Mr. Sullivan is entitled to severance payments, equity acceleration rights and other benefits.

Third Quarter 2018 Revenue Results:
Total revenue of $151.1 million
- U.S. Omnipod revenue of $82.0 million
- International Omnipod revenue of $50.2 million
- Drug Delivery revenue of $18.9 million

Our long-term financial objective is to sustain profitable growth. We expect our efforts in 2018 and 2019 to focus primarily on constructing and commissioning our U.S. manufacturing facility, continuing to establish our European operations, launching new products, such as the DASH ™ Omnipod System, continuing our product development efforts, and working with Medicare, Medicaid and commercial payors and intermediaries to expand access. Achieving these objectives is expected to require additional investments in certain personnel and initiatives, as well as enhancements to our supply chain operation capacity, efficiency and effectiveness. We believe that we may 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.

Components of Financial Operations
Revenue. We derive the majority of our revenue from global sales of the Omnipod System. Our revenue also includes sales of devices based on the Omnipod System technology platform to global pharmaceutical and biotechnology companies for the subcutaneous delivery of drugs across therapeutic areas.
Cost of revenue. Cost of revenue consists primarily of raw material, labor, warranty, inventory scrap and excess and obsolescence adjustments, and overhead costs such as freight-in and depreciation and the cost of products we acquire from third party suppliers.
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 generally expense research and development costs as incurred.
Sales and marketing. Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support and customer care functions, as well as sales commissions paid to our sales representatives, costs associated with promotional activities and participation in industry trade shows. Commission costs that are direct and incremental to obtaining a new customer are capitalized and amortized to sales and marketing expense over the expected period of benefit.
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 including depreciation of office facility-related property and equipment.

Table of Contents

Results of Operations

This section discusses our consolidated results of operations for the third quarter and the nine months ended September 30, 2018 compared to the same periods of 2017, 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

(Unaudited)	Three Months Ended September 30,				Nine Months Ended September 30,			
(in thousands)	2018	2017	Change $	Change %	2018	2017	Change $	Change %
Revenue:								
U.S. Omnipod	$81,970	$70,065	$11,905	17 %	$230,289	$195,081	$35,208	18 %
International Omnipod	50,214	32,481	17,733	55 %	117,127	84,200	32,927	39 %
Drug Delivery	18,892	19,229	(337)	(2)%	51,500	53,963	(2,463)	(5)%
Total revenue	151,076	121,775	29,301	24 %	398,916	333,244	65,672	20 %
Cost of revenue	49,107	48,151	956	2 %	139,060	135,583	3,477	3 %
Gross profit	101,969	73,624	28,345	38 %	259,856	197,661	62,195	31 %
Gross margin	67.5 %	60.5 %			65.1 %	59.3 %		
Operating expenses:								
Research and development	21,762	20,141	1,621	8 %	60,092	55,670	4,422	8 %
Sales and marketing	34,922	28,718	6,204	22 %	102,660	86,288	16,372	19 %
General and administrative	38,420	22,718	15,702	69 %	85,914	62,322	23,592	38 %
Total operating expenses	95,104	71,577	23,527	33 %	248,666	204,280	44,386	22 %
Operating income (loss)	6,865	2,047	4,818	(235)%	11,190	(6,619)	17,809	269 %
Interest expense and other, net	5,012	4,153	859	21 %	16,852	13,034	3,818	29 %
Income (loss) before income taxes	1,853	(2,106)	3,959	188 %	(5,662)	(19,653)	13,991	71 %
Income tax expense	194	121	73	60 %	939	318	621	195 %
Net income (loss)	$1,659	$(2,227)	$3,886	174 %	$(6,601)	$(19,971)	$13,370	67 %

Revenue

Our total revenue increased to $151.1 million, up $29.3 million, or 24%, in the third quarter of 2018 compared to the third quarter of 2017, primarily due to continued growth in our international and U.S. Omnipod revenue. Our U.S. Omnipod revenue increased to $82.0 million, up $11.9 million, or 17%, primarily due to growth in our Omnipod customer base as we continue to expand awareness of and access to the Omnipod System. Our International Omnipod revenue increased to $50.2 million, up $17.7 million, or 55%, over the prior period. The growth in our international revenue was driven by both higher volumes and more favorable pricing as a result of our commencement of direct sales of our Omnipod System across Europe following the expiration of our distribution agreement with our former European Distributor on June 30, 2018. Our drug delivery revenue was essentially flat year over year.

Our total revenue increased to $398.9 million, up $65.7 million, or 20%, in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, due to strong growth in our U.S. Omnipod revenue and international Omnipod revenue. Our U.S. Omnipod revenue increased to $230.3 million, up $35.2 million, or 18%, primarily due to growth in our Omnipod customer base as we continue to expand awareness of and access to the Omnipod System. Our international Omnipod revenue increased to $117.1 million, up $32.9 million, or 39%, due to the continued adoption of our product in existing international markets and by both higher volumes and more favorable pricing as a result of our commencement of direct sales of our Omnipod System across Europe following the expiration of our distribution agreement with our former European Distributor on June 30, 2018. Our drug delivery revenue was down 5% year over year primarily reflecting a lower number of shipments in the period.

For the year ending December 31, 2018, we expect strong revenue growth driven by our international growth, driven by the transition to direct distribution of our Omnipod System across Europe, and our continued expansion of patient access in the U.S. market, partially offset by lower drug delivery revenue.

Cost of Revenue

Cost of revenue increased to $49.1 million, up $1.0 million, or 2%, in the third quarter of 2018 compared to the same period in 2017 due to increased sales volumes, partially offset by improvements in supply-chain operations. Cost of revenue increased to $139.1 million, up $3.5 million, or 3%, in the nine months ended September 30, 2018 compared to the same period in 2017, reflecting an increase in sales volumes partially offset by improvements in gross margins.

Table of Contents

Gross Margin

Gross margin increased to 67.5%, up 700 basis points in the third quarter of 2018 compared to the same period in 2017. Gross margin for the nine months ended September 30, 2018 was 65.1% compared with 59.3% for the nine months ended September 30, 2017. The margin increase in each period was primarily due to our assumption of commercial activities in Europe in mid-2018, which allowed us to contract directly with our customers. Gross margins in each period also increased due to improvements in supply chain operations. We expect gross margin to increase for the year ending December 31, 2018 as compared to 2017 primarily due to improvements in supply chain operations and our assumption of commercial activities associated with of our Omnipod System in Europe.

Research and Development

Research and development expenses increased to $21.8 million, up $1.6 million, or 8%, for the three month period ended September 30, 2018 compared to the same period in 2017 and increased to $60.1 million, up $4.4 million, or 8%, for the nine months ended September 30, 2018 compared to the same period in 2017. The increase in both periods was primarily due to an increase in expenses related to our development projects, including our DASH ™ System. For the year ending December 31, 2018, we expect overall research and development spending to increase as compared to 2017 due to development efforts on our on-going projects.

Sales and Marketing

Sales and marketing expenses increased to $34.9 million, up $6.2 million, or 22%, for the three month period ended September 30, 2018 compared to the same period in 2017 and increased to $102.7 million, up $16.4 million, or 19%, for the nine months ended September 30, 2018 compared to the same period in 2017. These increases were primarily attributable to investments to support our assumption in mid-2018 of direct commercial support for Omnipod in Europe. For the year ending December 31, 2018, we expect sales and marketing expense to increase as compared to 2017 due to the sales and marketing effort as described above, partially offset by the capitalization of commission costs under ASC 606.

General and Administrative

General and administrative expenses increased to $38.4 million, up $15.7 million, or 69%, for the three month period ended September 30, 2018 compared to the same period in 2017 and increased to $85.9 million, up $23.6 million, or 38%, for the nine month period ended September 30, 2018 compared to the same period in 2017. This increase was primarily attributable to severance-related charges related to the retirement of our CEO, including $8.2 million of stock-based compensation for the acceleration of share-based award vesting and $4.4 million for the accrual of cash severance benefits. In addition, general and administrative expenses increased due to increased personnel-related costs and fees related to our assumption in mid-2018 of direct support for Omnipod in Europe. For the year ending December 31, 2018, we expect overall general and administrative expenses to increase as compared to 2017 due to investments in our operating structure to support continued growth and the aforementioned expenses related to our CEO's retirement.

Interest Expense and Other, Net

Interest expense and other, net, increased to $5.0 million, up $0.9 million, or 21%, for the three month period ended September 30, 2018 compared to the same period in 2017 and increased to $16.9 million, up $3.8 million, or 29%, for the nine month period ended September 30, 2018. The increase in both periods is primarily due to the effect of interest expense, including cash interest expense of $1.4 million and non-cash interest of $3.7 million, related to our 1.375% Notes, which were issued in November 2017, partially offset by a reduction in interest expense related to our 2% Notes, which were retired in 2018, and an increase in interest income on our investments in marketable securities.

Liquidity and Capital Resources

As of September 30, 2018, we had $126.6 million in cash and cash equivalents and $308.8 million of investments in marketable securities. We believe that our current liquidity will be sufficient to meet our projected operating, investing and debt service requirements for at least the next twelve months.

To lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base and support growth, we are constructing a highly-automated manufacturing facility in Acton, Massachusetts, with planned

production out of the facility beginning in 2019. This facility will also serve as our global headquarters. As a result, capital expenditures have increased above historic levels to fund the construction of the Acton facility and related equipment purchases. As of September 30, 2018, investments in the Acton facility were approximately $168.3 million. We expect that capital expenditures for this facility will approach $200 million when production begins in 2019.

Table of Contents

In connection with our assumption on July 1, 2018, of all commercial activities of our Omnipod System across Europe following the expiration of our distribution agreement with our European Distributor on June 30, 2018, we are required to pay to the European Distributor a per unit fee for sales of our Omnipod device over the subsequent twelve months following the expiration of the global distribution agreement. The fee will be based on our sales of the Omnipod device to identified customers (as that term is defined in the distribution agreement) of the European Distributor who had previously entered into an agreement with the distributor for the purchase of Omnipod devices. The actual total fee could vary significantly depending on the number of customers who qualify as eligible to be considered for purposes of calculating the fee under the terms of the distribution agreement and the number of Omnipod devices sold to those customers over the twelve month period. While the actual total fee could vary significantly, we estimate that the total fee could be in the range of approximately $10 million to $55 million over the twelve month period. The fee will be determined and paid on a quarterly basis following the expiration of the distribution agreement and the actual amount of the fee will depend on a number of factors and will not be known until the number of qualifying sales of Omnipod devices is determined following each quarter beginning with the quarter ending September 30, 2018. We have accrued approximately $2 million for fees related to Omnipod devices sold to qualifying customers for the three months ended September 30, 2018.

Convertible Debt

To finance our operations and global expansion, we have periodically issued and sold Convertible Senior Notes, which are convertible into our common stock. As of September 30, 2018, the following notes were outstanding:

Issuance Date	Coupon	Principal Outstanding (in thousands)	Due Date	Initial Conversion Rate per Share of Common Stock	Conversion Price per Share of Common Stock
September 2016	1.250%	$ 344,992	September 15, 2021	17.1332	$58.37
November 2017	1.375%	402,500	November 15, 2024	10.7315	$93.18
Total		$ 747,492			

We called our 2% Notes in March 2018 and settled the outstanding notes in May 2018. Additional information regarding our debt issuances is provided in Note 5 to the consolidated financial statements included in this Form 10-Q.

Summary of Cash Flows

	Nine Months Ended Sept 30,	
(In thousands)	2018	2017
Cash provided by (used in):		
Operating activities	$5,460	$19,407
Investing activities	(143,719)	(61,485)
Financing activities	(7,081)	6,650
Effect of exchange rate changes on cash	(674)	487
Net decrease in cash and cash equivalents	$(146,014)	$(34,941)

Operating Activities

Our net cash provided by operating activities for the nine months ended September 30, 2018 was $5.5 million, compared to net cash provided by operating activities of $19.4 million in the same period of 2017. The decrease in cash provided by operating activities in the current period is primarily due to investments in working capital, including inventory, accounts receivable and prepaid and other assets, in part associated with our assumption of direct operations in Europe in mid-2018, and a reduction in accounts payable, partially offset by improvements in operating results.

Investing Activities

Our net cash used in investing activities for the nine months ended September 30, 2018 was $143.7 million compared to $61.5 million in the same period of 2017. The increase in cash used in investing activities in the current period is primarily due to $127.6 million increase in capital expenditures, primarily associated with investments in our supply chain operations, which include approximately $105.3 million for facility and equipment in process of construction to support our U.S. manufacturing initiatives.

Financing Activities

Our net cash used in financing activities for the nine months ended September 30, 2018 was $7.1 million as compared to net cash provided by financing activities of $6.7 million in the same period of 2017. The increase in cash used in financing activities was

Table of Contents

primarily due to a $10.0 million increase in payments for amounts withheld for taxes related to the vesting of restricted stock units and $6.7 million in payments for the settlement of our 2% Notes, partially offset by an increase in proceeds from the exercise of stock options.

Commitments and Contingencies

We primarily lease our facilities in Massachusetts, California, and the United Kingdom. These leases are accounted for as operating leases and generally provide for a base rent plus real estate taxes and certain operating expenses related to the leases. 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 consolidated balance sheets.

Legal Proceedings

The significant estimates and judgments related with establishing litigation reserves are discussed under "Legal Proceedings" in Note 12 to the consolidated financial statements included in this Form 10-Q.

Off-Balance Sheet Arrangements

As of September 30, 2018, 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, 2018. 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, 2017 other than our accounting policies related to revenue recognition and our policies related to the accounting for commissions expense as a result of the adoption of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, which was adopted on January 1, 2018 as further described in Notes 3 and 9 to the consolidated financial statements included in this Form 10-Q.

Recent Accounting Pronouncements

Information with respect to recent accounting pronouncements is provided in Note 2 to the consolidated financial statements included in this Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We currently do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash, cash equivalents, short-term and long-term investments, accounts receivable, accounts payable, accrued expenses, debt and long-term obligations. 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 short-term investments and 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, 2018, we had outstanding debt related to our Convertible Senior Notes recorded on our consolidated balance sheet of $584.5 million, net of unamortized discount and issuance costs totaling $163.0 million. Changes in the fair value of our outstanding debt, which could be impacted by changes in interest rates, are not recorded in these consolidated financial statements as the debt is accounted for at cost less unamortized discount and issuance costs. The fair value of the debt, which is disclosed in Note 5 to the consolidated financial statements, is also impacted by changes on our stock price.

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. A substantial portion of our operations are located in the United States, and the majority of our sales since inception have been

made in United States dollars. Accordingly, we have assessed that we do not have any material net exposure to foreign currency exchange rate fluctuations at this time. However, as our business in markets outside of the United States continues to increase, we will be exposed to foreign currency exchange risk related to our foreign operations. Fluctuations in the rate of exchange between the United States dollar and foreign currencies, primarily the Euro, Canadian Dollar, and the British Pound, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities.

Table of Contents

We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the nine months ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Information regarding our material pending legal proceedings, which is incorporated herein by reference, 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, 2017, which could materially affect our business, financial condition or future results. These risks are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Other than the risks listed below, there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Our assumption on July 1, 2018 of the distribution, sales, marketing, training and support activities of our Omnipod System in Europe creates risk associated with Brexit.

On June 23, 2016, the United Kingdom ("U.K.") held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit.” As a result of the referendum, the U.K. government is attempting to negotiate the terms of the its future relationship with the European Union. Although it is unknown what those terms will be, it is possible that there will be greater restrictions on imports and exports and on the movement of people between the U.K. and European Union countries, and increased regulatory complexities associated with operating our business in the U.K. and Europe.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
None.

Item 3. Defaults Upon Senior Securities
None.

Item 4. Mine Safety Disclosures

Table of Contents

Not applicable.

Item 5. Other Information
None.

Table of Contents

Item 6. Exhibits

Number	Description
10.1+	Amendment No. 16, entered into effective as of August 15, 2018, to Supply Agreement, dated November 21, 2013, between Amgen Inc. and Insulet Corporation.
10.2	Offer Letter between Shacey Petrovic and Insulet Corporation, dated September 10, 2018 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 14, 2018).
10.3	Retirement Agreement between Patrick J. Sullivan and Insulet Corporation, dated September 10, 2018 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed September 14, 2018).
10.4	Amended and Restated Executive Severance Plan, effective as of January 1, 2019 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 22, 2018).
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer.
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Chief Executive Officer and Chief Financial Officer.
101	The following materials from Insulet Corporation's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 formatted in XBRL (eXtensible Business Reporting Language), as follows: (i) Consolidated Balance Sheets as of September 30, 2018 (Unaudited) and December 31, 2017 (ii) Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017 (Unaudited) (iii) Consolidated Statements of Comprehensive Income (Loss) for the Three and Nine Months Ended September 30, 2018 and 2017 (Unaudited) (iv) Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017 (Unaudited) (iv) Condensed Notes to Consolidated Financial Statements (Unaudited)
*	This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.
+	Confidential treatment requested as to certain portions of this exhibit.

32

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 1, 2018 /s/ Patrick J. Sullivan
Patrick J. Sullivan
Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2018 /s/ Michael L. Levitz
Michael L. Levitz
Chief Financial Officer
(Principal Financial and Accounting Officer)