# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 10-K

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

**For the fiscal year ended December 31, 2015**

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

**For the transition period from to**

**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**

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| Common Stock, $0.001 Par Value Per Share | The NASDAQ Stock Market, LLC |
| Preferred Stock Purchase Rights | The NASDAQ Stock Market, LLC |

**Securities registered pursuant to Section 12(g) of the Act:**

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock held by non-affiliates of the registrant computed by reference to the last reported sale price of the Common Stock as reported on The NASDAQ Global Market on June 30, 2015 was approximately $1.8 billion.

The number of shares outstanding of each of the registrant's classes of common stock as of February 25, 2016:

| Title of Class | Shares Outstanding |
|---|---|
| Common Stock, $0.001 Par Value Per Share | 57,015,489 |
| Preferred Stock Purchase Rights | — |

**DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2015. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

**INSULET CORPORATION**

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# PART I

## *Item 1. Business*

### Overview

We are primarily engaged in the development, manufacturing and sale of our proprietary OmniPod Insulin Management System (the “OmniPod System”), an innovative, discreet and easy-to-use continuous insulin delivery system for people with insulin-dependent diabetes. 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 Personal Diabetes Manager (“PDM”). Conventional insulin pumps require people with insulin-dependent diabetes to learn to use, manage and wear a number of cumbersome components, including up to 42 inches of tubing. In contrast, the OmniPod System features only two discreet, easy-to-use devices that eliminate the need for a bulky pump, tubing and separate blood glucose meter, provides for virtually pain-free automated cannula insertion, communicates wirelessly and integrates a blood glucose meter. We believe that the OmniPod System’s unique proprietary design 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 and other diabetes management supplies in the United States through direct sales to customers or through our distribution partners. The OmniPod System is currently available in multiple countries in Europe, Canada and Israel. In July 2015, we executed an asset purchase agreement with GlaxoSmithKline ("GSK") whereby we acquired assets associated with the Canadian distribution of our products and we assumed the distribution, sales, marketing, training and support activities for the OmniPod system in Canada. Additional information regarding this acquisition is provided in note 3 to the consolidated financial statements included under Item 8 of this Form 10-K.

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

In June 2011, we acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, “Neighborhood Diabetes”). Through Neighborhood Diabetes, we provided customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals, processing claims as either durable medical equipment or through pharmacy benefits. In February 2016, we sold Neighborhood Diabetes to Liberty Medical LLC ("Liberty Medical"). Additional information regarding the sale of Neighborhood Diabetes is provided in note 18 to the consolidated financial statements included under Item 8 of this Form 10-K.

Insulet Corporation is a Delaware corporation formed in 2000. Our principal offices are located at 600 Technology Park Drive, Suite 200, Billerica, Massachusetts 01821, and our telephone number is (978) 600-7000. Our website address is http://www.insulet.com. We make available, free of charge, on or through our website, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. The information on our website is not part of this Annual Report on Form 10-K for the year ended December 31, 2015.

### Our Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. Diabetes is caused by the body’s inability to produce or effectively utilize the hormone insulin. This inability prevents the body from adequately regulating blood glucose levels. Glucose, the primary source of energy for cells, must be maintained at certain concentrations in the blood in order to permit optimal cell function and health. In people with diabetes, blood glucose levels fluctuate between very high levels, a condition known as hyperglycemia, and very low levels, a condition called hypoglycemia. Hyperglycemia can lead to serious short-term complications, such as confusion, vomiting, dehydration and loss of consciousness and long-term complications, such as blindness, kidney disease, nervous system disease, occlusive vascular diseases, stroke and cardiovascular disease, or death. Hypoglycemia can lead to confusion, loss of consciousness or death.

Diabetes is typically classified as either Type 1 or Type 2:

- Type 1 diabetes is characterized by the body's nearly complete inability to produce insulin. It is frequently diagnosed during childhood or adolescence. Individuals with Type 1 diabetes require daily insulin therapy, typically administered via injections or continuous infusion through pump therapy, to survive.
- Type 2 diabetes, the more common form of diabetes, is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Historically, Type 2 diabetes has occurred in later adulthood, but its incidence is increasing among the younger population, due primarily to increasing childhood obesity. Initially, many people with Type 2 diabetes attempt to manage their diabetes with improvements in diet, exercise and/or oral medications. As their diabetes advances, some patients progress to multiple drug therapy, which often includes insulin therapy. Guidelines, including those published by the American Diabetes Association in 2014, suggest more aggressive treatment for people with Type 2 diabetes, including the early adoption of insulin therapy and more frequent testing. It is now becoming more accepted for insulin therapy to be started earlier in people with Type 2 diabetes, and, in some cases, as part of the initial treatment.

Throughout this Annual Report on Form 10-K, we refer to both Type 1 diabetes and insulin-requiring Type 2 diabetes as insulin-dependent diabetes.

The OmniPod Delivery System is an automated drug delivery platform. In addition to using the Pod for insulin delivery we have also partnered with multiple pharmaceutical and biotechnology companies that utilize a customized form of the OmniPod system to deliver a drug over a specified interval of time, at a certain administered volume.

## Managing Diabetes

### *Diabetes Management Challenges*

Diabetes is often frustrating and difficult for patients to manage. Blood glucose levels can be affected by the carbohydrate and fat content of meals, exercise, stress, illness or impending illness, hormonal releases, variability in insulin absorption and changes in the effects of insulin on the body. For people with insulin-dependent diabetes, many corrections, consisting of the administration of additional insulin or ingestion of additional carbohydrates, are needed throughout the day in order to maintain blood glucose levels within normal ranges. Achieving this result can be very difficult without multiple daily injections of insulin or the use of continuous subcutaneous insulin infusion ("CSII") therapy. Patients attempting to control their blood glucose levels tightly to prevent the long-term complications associated with fluctuations in blood glucose levels are at greater risk for overcorrection and the resultant hypoglycemia. As a result, many patients have difficulty managing their diabetes optimally. Additionally, the time spent in managing diabetes, the swings in blood glucose levels and the fear of hypoglycemia can all render diabetes management overwhelming to patients and their families.

### *Current Insulin Therapy*

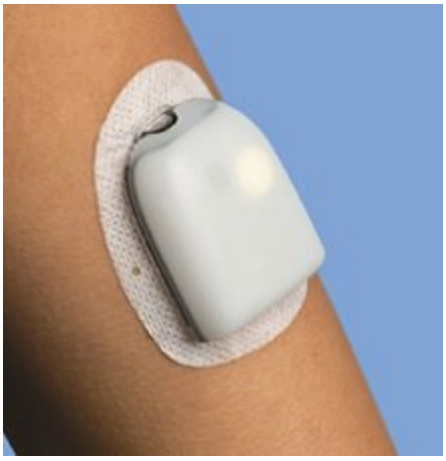
People with insulin-dependent diabetes need a continuous supply of insulin, known as basal insulin, to provide for background metabolic needs. In addition to basal insulin, people with insulin-dependent diabetes require supplemental insulin, known as bolus insulin, to compensate for carbohydrates ingested during meals or snacks or for a high blood glucose level.

There are three primary types of insulin therapy practiced today: conventional therapy; multiple daily injection ("MDI") therapy using syringes or insulin pens; and CSII therapy using insulin pumps. Both MDI and CSII therapies are considered intensive insulin management therapies.

Many healthcare professionals believe that intensive insulin management therapies are superior to conventional therapies in delaying the onset and reducing the severity of diabetes-related complications. As a result, we believe that the use of intensive insulin management therapies has significantly expanded over the past decade, and that many Type 1 patients manage their diabetes using an intensive insulin management therapy. A significantly smaller percentage of people with insulin-requiring Type 2 diabetes manage their diabetes using an intensive insulin management therapy.

## The OmniPod System

The OmniPod Insulin Management System is an innovative continuous insulin delivery system that provides all the proven benefits of CSII therapy in a way no conventional insulin pump can. The System's innovative design and features allows people with insulin-dependent diabetes to live their life, and manage their diabetes, with unprecedented freedom, comfort, convenience, and ease.



The long-term health benefits of better blood glucose control are well known. Maintaining near-normal blood glucose levels can help people with insulin-dependent diabetes live a longer, healthier life with fewer diabetes-related complications. The OmniPod System also has many practical, everyday benefits, including convenience, freedom, flexibility and ease of use.

Continuous insulin delivery at preset rates eliminates the need for injections and the interruptions that come with them. In addition, with the OmniPod System, insulin delivery can be changed with the press of a button to adapt to snacks or unexpected changes in daily routine.

The OmniPod System works much like the pancreas of a person without diabetes by delivering insulin in two ways:

- A small, constant background supply of insulin (called a basal rate) is delivered automatically at a programmed rate, all day and night.
- An extra dose of insulin (called a bolus) can be delivered when a patient needs it to match the carbohydrates in a meal or snacks or to correct high blood glucose.

The OmniPod System is a discreet two part design, the OmniPod (Pod) and the PDM, that eliminates the need for the external tubing required with conventional pumps.

- The Pod is a small, lightweight, self-adhesive device that the patient fills with insulin and wear directly on the body. The Pod delivers precise, personalized doses of insulin into the body through a small flexible tube (called a cannula), based on instructions that the patient programs into the Pod's wireless companion, the PDM.

- The PDM is a wireless, handheld device that programs the Pod with the patient's personalized insulin-delivery instructions, wirelessly monitors the Pod's operation and includes a FreeStyle® blood glucose meter.

We have designed the OmniPod System to fit within the normal daily routines of patients. The OmniPod System requires the fewest steps to start insulin delivery of all CSII therapies on the market by automating much of the process. In addition, the OmniPod System consists of just two devices, as opposed to up to seven for conventional insulin pumps. As a result, the OmniPod System is easy for patients to use, which reduces the training burden on healthcare professionals. We believe that the OmniPod System's overall ease of use makes it very attractive to people with insulin-dependent diabetes. We also believe that the OmniPod System's ease of use and substantially lower training burden helps to redefine which diabetes patients are appropriate for CSII therapy, enabling healthcare professionals to prescribe CSII therapy to a broader pool of patients.

The OmniPod System's unique patented design and proprietary manufacturing process have enabled us to provide CSII therapy at a relatively low up-front investment compared to conventional insulin pumps. We believe that our pricing model reduces the risk of investing in CSII therapy for third-party payors and makes CSII therapy much more accessible for people with insulin-dependent diabetes.

### Research and Development

Our current research and development efforts are primarily focused on the development of mobile applications for the OmniPod, including a Bluetooth-enabled PDM, integration with continuous glucose monitoring technology, an artificial pancreas platform, and development to support the use of concentrated insulin for Type I and Type II patients with higher insulin-requirements. In addition to insulin delivery, we continue to work with multiple pharmaceutical and biotechnology companies on alternative uses for our OmniPod System technology to use our technology as a delivery platform for a range of different pharmaceuticals.

### Manufacturing and Quality Assurance

We believe a key contributing factor to the overall attractiveness of the OmniPod System is the disposable OmniPod continuous insulin delivery device. In order to manufacture sufficient volumes and achieve a cost-effective per unit production price for the OmniPod, we have designed the OmniPod to be manufactured through a semi-automated process.

We are currently producing the OmniPod on varying degrees of semi-automated manufacturing lines at a facility in China, operated by a subsidiary of Flextronics International Ltd. ("Flextronics"). We purchase OmniPods pursuant to our agreement with Flextronics. Under the agreement, Flextronics agrees to supply us with OmniPods at a price reflective of the forecast that we provide pursuant to the agreement. The current term of the agreement expires in December 2017 and is subject to automatic renewal for one-year successive terms subsequently. It may be terminated by either party upon compliance with certain advance written notice provisions that are intended to provide the parties with sufficient time to make alternative arrangements.

We seek to increase manufacturing capacity and reduce the per-unit production cost for the OmniPod. We continue to invest in our manufacturing capacity in order to meet our expected 2016 demand and beyond for the OmniPod.

We rely on outside vendors for the supply of components, sub-assemblies, and various services used in the manufacture of the OmniPod System. Although a number of these suppliers are sole-source suppliers, we continue to focus on identifying alternate supply sources and duplicate custom tooling.

All outside vendors produce the components to our specifications and they are audited periodically by our Quality Assurance Department to ensure conformity with the specifications, policies and procedures for the OmniPods. Our Quality Assurance Department also inspects and tests the OmniPods at various steps in the manufacturing cycle to facilitate compliance with our stringent specifications. We have received approval of our Quality Management System from the BSI Group London, U.K., an accredited Notified Body for CE Marking and the International Standards Organization (“ISO”). Processes utilized in the manufacture, test and release of the OmniPod have been verified and validated as required by the U.S. Federal Food and Drug Administration ("FDA") and other regulatory bodies. As a medical device manufacturer and distributor, our manufacturing facilities and the facilities of our suppliers and sterilizer are subject to periodic inspection by the FDA, our notified body and certain corresponding state agencies.

## Intellectual Property

We believe that to maintain a competitive advantage, we must develop and preserve the proprietary aspect of our technologies. We rely on a combination of copyright, patent, trademark, trade secret and other intellectual property laws, non-disclosure agreements and other measures to protect our proprietary rights. Currently, we require our employees, consultants and advisors to execute non-disclosure agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants and advisors who we expect to work on our current or future products to agree to disclose and assign to us all inventions conceived during their work with us that are developed using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of the OmniPod System or to obtain and use information that we regard as proprietary.

*Patents.* As of December 31, 2015, we had obtained 15 issued United States patents, and had 10 additional pending United States patent applications. We believe it will take up to four years, and possibly longer, for the most recent of these U.S. patent applications to result in issued patents. We are also seeking patent protection for our proprietary technology in other countries and regions throughout the world. The issued patents and pending patent applications cover, among other things:

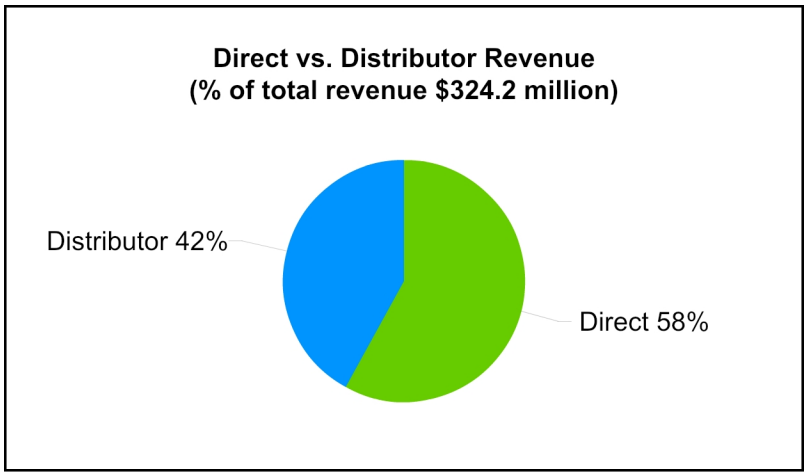
- the basic architecture of the OmniPod System, including the pump and the PDM;
- the OmniPod shape memory alloy drive system;
- the OmniPod System cannula insertion system;
- communication features between system components;
- software for controlling the OmniPod System; and
- various novel aspects of the OmniPod System and potential future generations of OmniPod Systems.

*Trademarks.* We have registered various trademarks associated with our business, including INSULET, OMNIPOD and the OMNIPOD design with the United States Patent and Trademark Office on the Principal Register and in other appropriate jurisdictions.

## Markets and Distribution Methods

We sell our OmniPod System through a combination of direct sales representatives and independent distributors in both the United States and outside of the United States. Independent distributors can represent as much as 40% of our total sales in the United States. We have been distributing the OmniPod System in certain countries in Europe, through Ypsomed Distribution AG ("Ypsomed"), since 2010. In Canada, we had historically sold our product through an independent distributor, however we acquired that business in July 2015.

For the year ending December 31, 2015 the percentage of our total consolidated revenue from direct sales and independent distributors was as follows:




*Comprehensive approach across three interrelated constituencies.* Our sales and marketing effort for the OmniPod System is focused on patient retention and growing patient, clinician and payor demand for the OmniPod System. We have a uniform sales and marketing approach, aligned across patients, physicians and providers, to capitalize on the unique benefits of our OmniPod technology. We have three areas of focus:

- First, build patient awareness about the features and benefits that the OmniPod System provides.
- Second, build physician support by increasing the clinical evidence that clearly demonstrates the benefits that the OmniPod System provides.
- Third, provide payors with the clinical and economic justification of why the OmniPod System is a greater benefit for the patients whom they insure.

*Training.* We believe that patient training is critical to ensure successful outcomes and retain patients on the OmniPod System. We have streamlined our new patient training by developing improved online resources, a standardized approach as well as increasing our field clinician team to directly train our new patients.

*Customer Support.* We seek to provide our customers with high quality customer support, from product ordering to insurance investigation, order fulfillment and ongoing support. We have integrated our customer support systems with our sales, reimbursement and billing processes and also offer support by telephone and through our website to provide customers with seamless and reliable customer support.

## Competition

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The majority of our patients have previously undertaken MDI therapy, which is substantially less expensive than CSII therapy. The OmniPod System competes with a number of existing insulin delivery devices as well as other methods for the treatment of diabetes. Medtronic MiniMed, a division of Medtronic has historically held the majority share of the conventional insulin pump market in the United States. Other significant competitors in the United States are Animas Corporation, a division of Johnson & Johnson, and Tandem Diabetes Care, Inc. We also compete with drug delivery device companies such as West Pharmaceuticals.

Several of our competitors are large, well-capitalized companies with significantly more market share and resources than we have. They are able to spend aggressively on product development, marketing, sales and other product initiatives. Some of these competitors have:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;

- larger and more established sales forces and distribution networks;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory approval for products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

In addition to the established insulin pump competitors, several companies are working to develop and market new insulin "patch" pumps and other methods for the treatment of diabetes, such as inhaled insulin. These companies are at various stages of development. The companies working in this area of which we are aware include Medtronic, Johnson & Johnson, Valeritas Inc., Cellnovo Limited, VinCentra, Debiotech S.A., Becton Dickinson and Co., Enable Injections, Sensile Medical and Unilife.

## Government Regulation

*Domestic Regulation.* The OmniPod System is a medical device subject to extensive and ongoing regulation by the FDA and other federal, state, and local regulatory bodies. FDA regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, labeling, post-market adverse event reporting, post-market surveillance, complaint handling, repair or recall of products, product storage, record keeping, pre-market clearance or approval, advertising and promotion, and sales and distribution.

*FDA's Pre-Market Notification (510(k)) and Pre-Market Approval Requirements.* Unless an exemption applies, each medical device we seek to commercially distribute in the United States will require either prior 510(k) clearance or pre-market approval ("PMA") from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose low to moderate risk are placed in either class I or II, which, absent an exemption, requires the manufacturer to submit to the FDA a premarket notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in class III, requiring approval of a PMA application. We have obtained 510(k) clearance for the OmniPod System. Both the 510(k) clearance and PMA processes can be expensive and lengthy and entail significant user fees, unless an exemption is available.

In order to obtain pre-market approval and, in some cases, a 510(k) clearance, a product sponsor must conduct well-controlled clinical trials designed to test the safety and effectiveness of the product. Conducting clinical trials generally entails a long, costly and uncertain process that is subject to delays and failure at any stage. The data obtained from clinical trials may be inadequate to support approval or clearance of a submission. In addition, the occurrence of unexpected findings in connection with clinical trials may prevent or delay obtaining approval or clearance. If we conduct clinical trials, they may be delayed or halted, or be inadequate to support approval or clearance.

- *510(k) Clearance*. To obtain 510(k) clearance for any of our potential future devices (or for certain modifications to devices that have previously received 510(k) clearance), we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway generally takes from three to twelve months from the date the application is completed, but can take significantly longer. After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. As further described below, as part of an inspection conducted by the FDA in December of 2015, we agreed to submit a 510 (k) for modifications previously made to the OmniPod System. In addition, we also agreed to submit a 510(k) associated with the field action described below that we initiated in October 2015.

  If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can, at its discretion, require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite PMA application(s).

- *PMA.* Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, devices deemed not substantially equivalent to a previously cleared 510(k) device or devices in commercial distribution before May 28, 1976 for which PMAs have not been required, generally require a PMA before they can be commercially distributed. A PMA application must be supported by extensive data, including technical information, pre-clinical and clinical trials, manufacturing and labeling to demonstrate the safety and effectiveness of the device to the FDA's satisfaction. After a PMA application is complete, the FDA begins an in-depth review of the submitted information, which generally takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulations, or QSRs, which impose elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. After any pre-market approval, a new pre-market approval application or application supplement may be required in the event of modifications to the device, its labeling, intended use or indication or its manufacturing process. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

*Ongoing Regulation by FDA.* Even after a device is placed on the market, regardless of its classification or premarket pathway, numerous regulatory requirements apply. These include, but are not limited to:

- establishment registration and device listing;
- quality system regulation, or QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses, and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug and Cosmetic Act that may present a risk to health. In addition, FDA may order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

With respect to corrections and removals, in July 2015 we implemented a field removal of certain lots due to the possibility that some OmniPod Systems had a higher rate of failure than its current manufacturing standards. In September 2015, as part of our product quality monitoring process, we identified that certain lots of the OmniPod® had a slight increase (1% - 2%) in the reported cases in which the Pod's cannula failed to deploy. On October 29, 2015, we implemented a field correction to advise patients of the possibility of a needle deployment failure and provided recommendations on how to manage such an event. Both field actions were initiated with the knowledge of the FDA and were reported to the agency in accordance with the requirements of 21 C.F.R. Part 806.

Failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies, which may include any of the following sanctions: untitled letters or warning letters, fines, injunctions, consent decrees, civil or criminal penalties, recall or seizure of our current or future products, operating restrictions, partial suspension or total shutdown of production, refusal of or delay in granting 510(k) clearance or PMA approval of new products or modified products, rescinding previously granted 510(k) clearances or withdrawing previously granted PMA approvals, or refusal to grant export approval of our products.

We are subject to announced and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our subcontractors. If, as a result of these inspections, the FDA determines that our equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations. Since approval of the OmniPod System, we have been subject to FDA inspections of our facility on multiple occasions. Our facility located at 600 Technology Park Drive, Suite 200, Billerica, MA 01821 was inspected by the FDA between March 11, 2015 and March 27, 2015, which resulted in four inspectional observations (FDA Form 483) and a subsequent Warning Letter dated June 5, 2015. We have completed all of the commitments from the Form 483 and Warning Letter responses, but have not yet received notification that the FDA has closed the Warning Letter. More recently, our facility located in Billerica, MA was re-inspected by the FDA between November 30, 2015 and December 11, 2015. This inspection also resulted in four inspectional observations (FDA Form 483). We responded to the most recent inspectional observations on December 31, 2015.

*International Regulation.* International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries. In April 2009, we received CE Mark approval for the original OmniPod System, and in August 2011, we received CE Mark approval for our OmniPod product. The CE Mark gives us authorization to distribute the OmniPod System throughout the European Union and in other countries that recognize the CE Mark. In September 2009, we received Health Canada approval to distribute the original OmniPod System throughout Canada, and in March 2013, we received Health Canada approval for our new OmniPod product. We have been distributing the OmniPod System in certain countries in Europe, through Ypsomed, since 2010. In Canada, we had historically sold our product through a distributor, however as a result of our acquisition in July 2015, we now sell the OmniPod System direct.

*Licensure.* Several states require that durable medical equipment ("DME") providers be licensed in order to sell products to patients in that state. Certain of these states require, among other things, that DME providers maintain an in-state location. Although we believe we are in compliance with all applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could lose our licensure in that state, which could prohibit us from selling our current or future products directly to patients in that state.

In addition, we are subject to certain state laws regarding professional licensure. We believe that our certified diabetes educators are in compliance with all such state laws. However, if our educators or we were to be found non-compliant in a given state, we may need to modify our approach to providing education, clinical support and customer service.

*Federal Anti-Kickback and Self-Referral Laws.* The Federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce the:

- referral of a person;
- furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs; or
- purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable under Medicare, Medicaid or other governmental programs.

We provide the initial training to patients necessary for appropriate use of the OmniPod System either through our own diabetes educators or by contracting with outside diabetes educators that have completed a Certified Pod Trainer training course. Outside diabetes educators are reimbursed for their services at contracted rates deemed to be consistent with the market. Although we believe that these arrangements do not violate the law, regulatory authorities may determine otherwise, especially as enforcement of this law historically has been a high priority for the federal government. In addition, because we may provide some coding and billing information to purchasers of the OmniPod System, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, the federal anti-kickback legislation may apply to us. Noncompliance with the federal anti-kickback legislation can result in exclusion from Medicare, Medicaid or other governmental programs, restrictions on operating in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on our business and results of operations.

Federal law also includes a provision commonly known as the "Stark Law," which prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exceptions from the law.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider and training arrangements may ultimately be found not to be in compliance with applicable federal law.

*Federal False Claims Act.* The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits against companies under the Federal False Claims Act. Penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. In any event, we believe that we are in compliance with the federal government's laws and regulations concerning the filing of reimbursement claims.

*Civil Monetary Penalties Law.* The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs. We believe that our arrangements comply with the requirements of the Federal Civil Monetary Penalties Law.

*State Fraud and Abuse Provisions.* Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act. We believe that we are in conformance with such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

*Administrative Simplification of the Health Insurance Portability and Accountability Act of 1996.* The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") mandated the adoption of standards for the exchange of electronic health information in an effort to encourage overall administrative simplification and enhance the effectiveness and efficiency of the healthcare industry. Ensuring privacy and security of patient information is one of the key factors driving the legislation. We believe we are in substantial compliance with the applicable HIPAA regulations.

*Patient Protection and Affordable Care Act*. The Patient Protection and Affordable Care Act ("ACA") enacted significant changes to the provision of and payment for healthcare in the United States. Under the ACA and related laws and regulations, federal and state government initiatives are focused on limiting the growth of healthcare costs and implementing changes to healthcare delivery structures. These reforms are intended in part to put increased emphasis on the delivery to patients of more cost-effective therapies. While uncertainty exists regarding some aspects of the ACA, we expect that the ACA will continue to have a significant impact on the delivery of healthcare in the United States and on our business.

*Physician Payments Sunshine Act*. The Physician Payments Sunshine Act ("Sunshine Act") seeks to increase the transparency of relationships between medical device, pharmaceutical and other companies and healthcare professionals ("HCPs"). Under the Sunshine Act, we are required to track and publicly report many types of payments made and items of value provided to HCPs. Moreover, several states have imposed similar or more restrictive requirements. In addition, we have adopted policies and codes of conduct regarding our interactions with HCPs. Our failure to adhere to these requirements could materially adversely impact our business and financial results.

### Third-Party Reimbursement

In the United States, our products are generally reimbursed by third-party payors, and we bill those payors for products provided to patients. Our fulfillment and reimbursement systems are fully integrated such that product is generally shipped only after confirmation of a physician's valid statement of medical necessity and current health insurance information. We maintain an insurance benefits investigation department that works to simplify and expedite claims processing and to assist patients in obtaining third-party reimbursement.

We continue to work with third-party payors in the United States to establish coverage and payment for the OmniPod System and other diabetes management supplies. Our coverage contracts with third-party payors typically have a term of between one and three years and set coverage amounts during that term. Typically, coverage contracts automatically renew for specified incremental periods upon expiration, unless one of the parties terminates the contract.

Third-party payors may decline to reimburse for procedures, supplies or services determined not to be "medically necessary" or "reasonable." In a limited number of cases, some third-party payors have declined to reimburse us for a particular patient because such patient failed to meet its criteria, most often because the patient already received reimbursement for an insulin pump from that payor within the warranty period, which is generally four years, or because the patient did not meet their medical criteria for an insulin infusion device. Common medical criteria for third-party payors approving reimbursement for CSII therapy include a patient having elevated A1c levels, a history of recurring hypoglycemia, fluctuations in blood glucose levels prior to meals or upon waking or, severe glycemic variability.

As part of our international distribution agreements, our distribution partners establish appropriate reimbursement contracts with third-party payors in countries and provinces in which they distribute the OmniPod System prior to distributing the OmniPod System in each territory.

Currently, there is not an established mechanism for Medicare coverage for the majority of the OmniPod System. However, we are continuing a dialogue with Centers for Medicare & Medicaid Services ("CMS") about Medicare coverage for the OmniPod System.

### Employees

As of December 31, 2015, we had 647 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe that our employee relations are good.

## *Item 1A. Risk Factors*

This Annual Report on Form 10-K 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," "estimates," "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 this Item 1A Risk Factors and elsewhere in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K 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.

## Risks Relating to Our Business

***We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.***

Since our inception in 2000, we have incurred significant operating losses. We began commercial sales of the OmniPod System in 2005. For the year ended December 31, 2015, our operating loss was $60.8 million. Our net losses for the years ended December 31, 2015, 2014 and 2013 were $73.5 million, $51.5 million and $45.0 million, respectively. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve or sustain profitability. As of December 31, 2015, we had an accumulated deficit of $651.5 million.

***We may experience significant fluctuations in our quarterly results of operations.***

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

- delays in shipping due to capacity constraints;
- practices of health insurance companies and other third-party payors with respect to reimbursement for our current or future products;
- market acceptance of the OmniPod System;
- our ability to manufacture the OmniPod efficiently;
- timing of regulatory approvals and clearances;
- new product introductions;
- competition; and
- timing of research and development expenditures.

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

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

Our main product is the OmniPod System, which we introduced to the market in 2005. We expect to continue to derive a significant portion of our revenue from the sale of this product. Accordingly, our ability to generate revenue is highly reliant on our ability to market and sell the devices that comprise the OmniPod System. Our sales of the OmniPod System may be negatively impacted by many factors, including:

- the failure of the OmniPod System to achieve and maintain wide acceptance among opinion leaders in the diabetes treatment community, insulin-prescribing physicians, third-party payors and people with insulin-dependent diabetes;
- manufacturing problems;
- actual or perceived quality problems;
- changes in reimbursement rates or policies relating to the OmniPod System by third-party payors;
- claims that any portion of the OmniPod System infringes on patent rights or other intellectual property rights owned by other parties;

- adverse regulatory or legal actions relating to the OmniPod System;
- damage, destruction or loss of any of the facilities where our products are manufactured or of the equipment therein;
- conversion rate of patient referrals to actual sales of the OmniPod System;
- write-offs of receivables from our customers;
- attrition rates of customers who cease using the OmniPod System;
- competitive pricing and related factors; and
- results of clinical studies relating to the OmniPod System or our competitors' products.

If any of these events occurs, our ability to generate revenue could be significantly reduced.

***Our ability to achieve profitability from a current net loss level will depend on our ability to sustain or reduce the per unit cost of producing the OmniPod by increasing customer orders, increasing manufacturing volume and productivity and reducing raw material and overhead costs per OmniPod.***

Currently, the gross profit from the sale of the OmniPod System is not sufficient to cover our operating expenses. To achieve profitability, we need to, among other things, sustain or reduce the per unit cost of the OmniPod. If we are unable to sustain or reduce raw material and manufacturing overhead costs through volume purchase discounts, negotiation of improved pricing and increased productivity and production capacity, our ability to achieve profitability will be severely constrained. Any increase in manufacturing volumes must be supported by an associated increase in customer orders. Each OmniPod contains limited amounts of precious metals, the costs of which have fluctuated over the recent past. The occurrence of one or more factors that negatively impact the manufacturing or sales of the OmniPod System or increase our raw material costs may prevent us from achieving our desired increase in manufacturing volume, which would prevent us from attaining profitability.

***Adverse changes in general economic conditions in the United States and globally could adversely affect us.***

We are subject to the risks arising from adverse changes in general economic market conditions. While the U.S. economy appears to be improving at a moderate pace, the worldwide economy remains sluggish. Further deterioration of economic conditions, such as a U.S. or global recession, could negatively impact our current and prospective customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures.

Healthcare spending in the United States could be negatively affected in the event of a downturn in the U.S. economic conditions. For example, patients who have lost their jobs or healthcare coverage may no longer be covered by an employer-sponsored health insurance plan and patients reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the OmniPod System to a new patient is generally dependent on the availability of third-party reimbursement and normally requires the patient to make a significant co-payment, an economic downturn on our potential customers could reduce the referrals generated by our sales force and thereby reduce our customer orders. Similarly, existing customers could cease purchasing the OmniPod System and return to MDI or other less-costly therapies, which would cause our attrition rate to increase. Any decline in new customer orders or increase in our customer attrition rate would reduce our revenue, which in turn would make it more difficult to achieve our per-unit cost-savings goals, which we are attempting to attain in part through increases in our manufacturing volume.

***Healthcare reform laws could adversely affect our revenue and financial condition.***

During the past several years, the U.S. healthcare industry has been subject to an increase in governmental regulation at both the federal and state levels. Efforts to control healthcare costs, including limiting access to care, alternative delivery models and changes in the methods used to determine reimbursement scenarios and rates, are on-going at the federal and state government levels. There are new provisions of law that provide for the creation of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities. For example, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute are publicly disseminated. It is difficult at this time to determine, whether a comparative effectiveness analysis impacting our business will be done, and assuming one is, what impact that analysis will have on the OmniPod System or our future financial results.

Beginning in 2013, sales of certain medical devices became subject to a 2.3% federal excise tax. We believe, based on advice from our tax advisor, that the sales of our products are exempt from this excise tax. However, if it is subsequently determined that sales of one or more of our products are subject to this excise tax, these tax obligations could materially adversely affect our financial results, although that would not occur until 2018 because of recent federal legislation that suspended the tax for two years.

In addition, the Affordable Care Act and related healthcare reform laws, regulations and initiatives have significantly increased regulation of managed care plans and decreased reimbursement to Medicare managed care. Some of these initiatives purport to, among other things, require that health plan members have greater access to drugs not included on a plan's formulary. Moreover, to alleviate budget shortfalls, states have reduced or frozen payments to Medicaid managed care plans. We cannot accurately predict the complete impact of these healthcare reform initiatives, but they could lead to a decreased demand for our products and other outcomes that could adversely impact our business and financial results.

There may in the future be additional changes in government policy, including additional modifications to the healthcare laws, which could increase our cost of doing business and negatively impact our ability to sell our products and achieve profitability.

***We may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.***

Our capital requirements will depend on many factors, including:

- revenue generated by sales of our current products and any other future products that we may develop;
- costs associated with adding further manufacturing capacity;
- costs associated with expanding our sales and marketing efforts in the United States and internationally;
- expenses we incur in manufacturing and selling the OmniPod System;
- costs of developing new products or technologies and enhancements to the OmniPod System;
- the cost of obtaining and maintaining FDA approval or clearance of our current or future products;
- costs associated with any expansion;
- the cost of complying with regulatory requirements;
- costs associated with capital expenditures;
- costs associated with litigation; and
- the number and timing of any acquisitions or other strategic transactions.

We believe that our current cash and cash equivalents, together with the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements through at least the end of 2016.

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. In June 2014 we issued $201.3 million of 2% Convertible Senior Notes which will mature in 2019 and we may need to raise additional debt or equity financing to repay these Notes. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

Our ability to raise additional capital may be adversely impacted by current economic conditions, including the effects of any disruptions to the credit and financial markets in the United States and worldwide. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on terms favorable to us or our stockholders.

If we are unable to raise additional capital due to these or other factors, we may need to further manage our operational expenses to reflect these external factors, including potentially curtailing our planned development activities. If we cannot raise additional funds in the future on acceptable terms, we may not be able to develop new products, execute our business plan, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements. If any of these events occur, it could adversely affect our business, financial condition and results of operations.

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

We rely on a number of suppliers who manufacture the components of the OmniPods and PDMs. For example, we rely on Phillips Medisize Corporation to manufacture and supply several injection molded components of the OmniPod and Freescale Semiconductor, Inc. to manufacture and supply the application specific integrated circuit that is incorporated into the OmniPod. In addition, a subsidiary of Flextronics in China provides the supply of complete OmniPods. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we make our purchases on a purchase order basis. In some other cases, where we do have agreements in place, our agreements with suppliers can be terminated by either party upon short notice. Additionally, our suppliers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

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

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

***Establishment of a competitive bid program by CMS for conventional insulin pumps could negatively affect our operating results.***

CMS has established through 2016 a pilot competitive bidding program in limited areas that includes conventional insulin pumps. Since the OmniPod System is not currently covered or reimbursed by Medicare, we are not directly affected by this pilot program. However, in the event this pilot program is geographically expanded, is extended beyond 2016, and results in a reduction in the amount reimbursed by CMS for conventional insulin pumps, then this may negatively impact our ability to negotiate future pricing with private payors comparing the price of the OmniPod System to conventional insulin pumps.

***If we are required to pay sales tax on sales of certain products, our results of operations could be adversely affected.***

We believe that sales of most diabetes supplies are exempt from sales tax in most jurisdictions. However, if it is subsequently determined that sales of one or more of our products are subject to sales tax in such jurisdictions, our obligation to pay such sales taxes could materially adversely affect our financial results.

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

Ypsomed is our exclusive distributor of the OmniPod System through 2018 in multiple countries including Germany, the United Kingdom, the Netherlands, Switzerland, Austria, Italy, Norway, and Sweden. Our agreement with Ypsomed also covers France, China, and a number of other countries. Ypsomed's introduction of the OmniPod System in certain countries has been delayed due to a number of factors. Future delays would likely result in reduced purchases by Ypsomed, which could adversely affect our revenue. In addition to the OmniPod System, Ypsomed also markets and sells a suite of other products for the treatment of diabetes and has announced its intention to introduce and sell its own branded conventional insulin pump. Ypsomed could have a greater financial incentive to sell its proprietary products rather than the OmniPod System. We also sell the OmniPod System in Canada. As a result of our international sales, we are exposed to fluctuations in product demand and sales productivity outside the United States, which may be partially attributed to foreign exchange rate changes, and have to manage the risks associated with market acceptance of the OmniPod System in foreign countries. Our efforts to introduce our current or future products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion. We do not have control over Ypsomed's operational and financial condition, and we are subject to foreign regulatory and export requirements.

In addition, in order to reduce our cost of goods sold and increase our production capacity, we increasingly rely on third-party suppliers located outside the United States. For example, currently all of our OmniPods are manufactured at a facility in China operated by Flextronics. As a result, our business is subject to risks associated with doing business internationally, including:

- political instability and adverse economic conditions;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulty in staffing and managing widespread operations;
- difficulties associated with foreign legal systems including increased costs associated with enforcing contractual obligations in foreign jurisdictions;
- changes in foreign currency exchange rates;
- differing protection of intellectual property;
- unexpected changes in regulatory requirements;
- failure to fulfill foreign regulatory requirements on a timely basis or at all to market the OmniPod System or other future products;
- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- adapting to the differing laws and regulations, business and clinical practices, and patient preferences in foreign markets;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign partners, distributors or sales or marketing agents; and
- difficulty in collecting accounts receivable and longer collection periods.

In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments and general management resources. Our future success will depend in large part on our ability to anticipate and effectively manage these and other risks associated with doing business outside of the United States. Any of these factors may have a material adverse effect on our production capacity and, consequently, our business, financial condition and results of operations.

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

We expect that sales of the OmniPod System will be limited unless a substantial portion of the sales price of the OmniPod System is paid for by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, federal and state government healthcare agencies and other managed care providers. We currently have contracts establishing reimbursement for the OmniPod System with national and regional third-party payors that provide reimbursement for patients residing in all 50 states. While we anticipate entering into additional contracts with other third-party payors, we cannot assure that we will be successful in doing so. In addition, these contracts can generally be terminated by the third-party payor without cause. Also, healthcare market initiatives in the United States may lead third-party payors to decline or reduce reimbursement for the OmniPod System. Moreover, compliance with administrative procedures or requirements of third-party payors may result in delays in processing approvals by those payors for patients to obtain coverage for the use of the OmniPod System. We are an approved Medicare supplier and current Medicare coverage for continuous subcutaneous insulin infusion, or CSII therapy exists. However, existing Medicare coverage for CSII therapy is based on conventional insulin pumps. We have been in the process for several years of seeking appropriate Medicare coverage for the OmniPod System. No assurance can be provided that we will ever secure Medicare coverage of the OmniPod System. As a result, we have focused our efforts in establishing reimbursement for the OmniPod System by negotiating contracts with private insurers. In addition, coverage decisions and rates of reimbursement increasingly require clinical evidence showing an improvement in patient outcomes. Generating this clinical evidence requires substantial time and investment and there is no guarantee of a desired outcome. Finally, as we expand our sales and marketing efforts outside of the United States, we face additional risks associated with obtaining and maintaining reimbursement from foreign health care payment systems on a timely basis or at all. Failure to secure or retain adequate coverage or reimbursement for the OmniPod System by third-party payors, including Medicare, could have a material adverse effect on our business, financial condition and results of operations.

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

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The OmniPod System competes with several existing insulin delivery devices as well as other methods for the treatment of diabetes. Medtronic MiniMed, a division of Medtronic has been the market leader for many years and has the majority share of the conventional insulin pump market in the United States. Other significant suppliers in the United States include Animas Corporation, a division of Johnson & Johnson and Tandem Diabetes Care, Inc.

In addition to the OmniPod System, our principal international distributor, Ypsomed, markets and sells a suite of other products for the treatment of diabetes. Also, Ypsomed has announced its intention to introduce and sell its own branded conventional insulin pump. Ypsomed may have a greater financial incentive to sell its proprietary products rather than the OmniPod System.

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

- significantly greater name recognition;
- different and more complete reimbursement profiles;
- established relations with healthcare professionals, customers and third-party payors;
- larger and more established distribution networks;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory approval; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

We also compete with MDI therapy, which is substantially less expensive than CSII therapy. MDI therapy has been made more effective by the introduction of long-acting insulin analogs that can be used in combination with easy to use bolus devices such as pens or nasal inhalants. While we believe that CSII therapy, in general, and the OmniPod System, in particular, have significant competitive and clinical advantages over traditional MDI therapy, improvements in the effectiveness of MDI therapy may result in fewer people with insulin-dependent diabetes converting from MDI therapy to CSII therapy than we expect and may result in negative price pressure.

In addition to the established insulin pump competitors, several companies are working to develop and market new insulin "patch" pumps and other methods for the treatment of diabetes, such as inhaled insulin. These companies are at various stages of development. The companies working in this area of which we are aware include Medtronic, Johnson & Johnson, Valeritas Inc., Cellnovo Limited, VinCentra, Debiotech S.A., Becton Dickinson and Co., Enable Injections, Sensile Medical and Unilife.

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

***We rely on the proper function, availability and security of our information technology systems to operate our business and a cyber-attack or other breach or disruption of these systems could have a material adverse effect on our business and results of operations.***

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. Moreover, the nature of our business involves the receipt and storage of personal and financial information regarding our patients. We use our information technology systems to manage or support a variety of business processes and activities, including sales, shipping, billing, customer service, procurement and supply chain, manufacturing and accounts payable. In addition, we use enterprise information technology systems to record, process, and summarize transactions and other financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions, disruptions or shutdowns, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets or the loss of key data and information, or otherwise compromise our confidential or proprietary information and disrupt our operations. If our information technology systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may be materially and adversely affected.

***Technological breakthroughs in diabetes monitoring, treatment or prevention could render the OmniPod System obsolete. In addition, our own new product development initiatives may prove to be ineffective or not commercially successful.***

The diabetes treatment market is subject to rapid technological change and product innovation. The OmniPod System is based on our proprietary technology, but a number of companies, medical researchers and existing pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and/or prevention of insulin-dependent diabetes. For example, FDA approval of a commercially viable "closed-loop" system that combines continuous "real-time" glucose sensing or monitoring and automatic continuous subcutaneous insulin infusion in a manner that delivers appropriate amounts of insulin on a timely basis without patient direction could have a material adverse effect on our revenue and future profitability. Medtronic has developed such an FDA-approved product combining continuous glucose sensing and CSII therapy, which could negatively impact our business. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve the treatment of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention

could render the OmniPod System obsolete, which would have a material adverse effect on our business, financial condition and results of operations.

We also have on-going initiatives to develop products to improve the treatment of Type 1 diabetes and to treat patients with highly insulin resistant Type 2 diabetes. For example, we are working with DexCom, Inc. to integrate its continuous glucose monitoring technology with the OmniPod System and we continue to explore partnership opportunities with other companies that have blood glucose monitoring and continuous glucose monitoring technologies. We are also developing with Eli Lilly and Company a new version of the OmniPod System specifically designed to deliver Humulin® R U-500 and U-200 insulin, which are more concentrated forms of insulin than traditional U-100 insulin for patients with higher insulin-resistance. In each of these cases, these projects are at an early stage of development, will require substantial clinical support and are subject to regulatory approvals. No assurances can be given that these or other development initiatives by us will be successful. The failure to successfully bring any of these products to market could have an adverse effect on our business and results of operations.

***If our existing license agreement with Abbott is terminated or we fail to enter into new license agreements allowing us to incorporate a blood glucose meter into the OmniPod System, or if Abbott's FreeStyle meter is less desirable to our current and potential customers, our business may be materially adversely impacted.***

Our rights to incorporate the FreeStyle blood glucose meter into the OmniPod System are governed by a development and license agreement with Abbott. This agreement provides us with a non-exclusive, fully paid, non-transferable and non-sublicensable license in the United States under patents and other relevant technical information relating to the FreeStyle blood glucose meter during the term of the agreement. As amended, this agreement runs through January 2020. The agreement may be terminated or limited in geographical scope by Abbott under certain circumstances. Termination of this agreement could require us to either remove the blood glucose meter from PDMs to be sold in the future, which would impair the functionality of the OmniPod System, or attempt to incorporate an alternative blood glucose meter into the PDM, either of which would require significant development and regulatory activities that might not be completed in time to prevent an interruption in the availability of the OmniPod System to our customers, which could have a material adverse effect on our business, financial condition and results of operations.

The FreeStyle blood glucose meter in our PDM is only approved for use with FreeStyle test strips. Not all third party payors reimburse patients for the purchase and use of FreeStyle test strips to the same extent as they reimburse patients for other brands of test strips. The absence or reduction in such reimbursement may make the OmniPod System less desirable to our current and potential customers.

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

***Our growing non-insulin drug delivery business faces challenges which, if not met, may impair its future success and continued growth.***

Our non-insulin drug delivery business has grown substantially over the past years. This business typically involves the development, manufacturing and sale of a modified OmniPod for delivery of a specific drug other than insulin. The marketing and sales initiatives driving this business differ markedly from those on which we rely for our sales of OmniPod Systems to treat diabetes since the non-insulin drug delivery devices depend on marketing and sales to pharmaceutical companies, not to patients and clinicians. We expect that the continued growth of our non-insulin drug delivery business will face several challenges, including:

- our identification of drug delivery opportunities appropriate for a modified OmniPod;
- our achievement of satisfactory development and pricing terms with the pharmaceutical companies that sell such drugs;
- our development of appropriate modifications to our OmniPods to address the needs and parameters required for the respective drug-delivery opportunities;
- manufacturing issues relating to the modified OmniPod;
- long lead-times associated with the development, regulatory approvals and ramp up applicable to the use of modified OmniPods for the delivery of such drugs;

- relatively small number of modified OmniPods needed to address each drug-delivery opportunity;
- uncertainties regarding the market acceptance of such drugs and the modified OmniPods as appropriate delivery devices;
- uncertainties relating to the success of the pharmaceutical companies in marketing and selling such drugs as well as the modified OmniPods as the appropriate delivery devices;
- intense competition in the drug-delivery industry, including from competitors which have substantially greater resources than we do;
- maintaining appropriate gross margins for non-insulin drug delivery products; and
- regulatory requirements and reimbursement rates associated with such drugs.

If we are unsuccessful in overcoming one or more of these challenges, our ability to capitalize on these opportunities and to continue to grow our non-insulin drug delivery business could be significantly impaired, which in turn could materially and adversely impact our business and financial results.

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

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

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

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

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

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

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

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

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

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

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

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

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

Substantial litigation over intellectual property rights exists in the medical device industry, and we have settled infringement suits in the past. We expect that we could be increasingly subject to third-party infringement claims as our revenue increases, the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe. For example, we are aware of certain patents and patent applications owned by our competitors that cover different aspects of insulin infusion and the related devices. Any of these third parties might make a claim of infringement against us.

Such litigation, regardless of its outcome, could result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, such litigation could cause negative publicity, adversely affect prospective customers, cause product shipment delays, limit or prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue could decrease substantially and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities.

***We are subject to extensive government regulation, both in the United States and abroad, which could restrict the sales and marketing of the OmniPod System and could cause us to incur significant costs.***

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state, local and foreign government authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- regulatory clearances and approvals including premarket clearance and approval;
- conformity assessment procedures;
- product traceability and record keeping procedures;

- advertising and promotion;
- product complaints, complaint reporting, recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Before a new medical device, or a significant modification of a medical device, including a new use of or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-market approval from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. In December 2012 we received 501(k) clearance for our new OmniPod System. We may be required to obtain a new 510(k) clearance or pre-market approval for significant post-market modifications to the OmniPod System. Obtaining 510(k) clearance or pre-market approval for medical devices can be expensive and lengthy, and entail significant user fees, unless an exemption is available. The FDA's process for obtaining 510(k) clearance usually takes three to twelve months, but it can last longer. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The process for obtaining pre-market approval is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA. Modifications to products that are approved through a PMA application generally need FDA approval. The FDA may demand that we obtain a PMA prior to marketing certain of our future products. Further, we may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, the OmniPod System in a timely fashion or at all. Delays in obtaining future clearances could adversely affect our ability to introduce new or enhanced products in a timely manner which in turn could harm our revenue and future profitability.

We also are subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacturing of our devices, labeling regulations and medical device reporting regulations, which require us to report to the FDA if our devices cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions:

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in 2011, the FDA announced a plan of action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, Congress enacted several reforms that further affect medical device regulation both pre- and post-approval. In addition, these regulatory requirements may change in the future in a way that adversely affects us. For instance, the FDA is in the process of reviewing the 510(k) approval process and criteria and has announced initiatives to improve the current pre-market and post-market regulatory processes and requirements associated with infusion pumps and other home use medical devices. As part of this effort, the FDA is reviewing the adverse event reporting and recall processes for insulin pumps. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

The OmniPod System is also sold in a number of European countries and Canada. As a result, we are required to comply with additional foreign regulatory requirements. For example, in April 2009, we first received CE Mark approval for our OmniPod System. The CE Mark gives us authorization to distribute the OmniPod System throughout the European Union and in other countries that recognize the CE Mark. Additionally, in September 2009, we first received Health Canada approval to distribute the OmniPod System throughout Canada. As we expand our sales efforts internationally, we may need to obtain additional foreign approval certifications.

***There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.***

Some of our new or modified products will require FDA clearance of a 510(k) or FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products. Even early stage review may result in issues. For example, the FDA has issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) and PMA submissions meets a minimum threshold of acceptability and should be accepted for substantive review. Under the "Refuse to Accept" guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) and PMA submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information. If the information is not provided within a defined time, the submission will not be accepted for FDA review. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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

We, our contract manufacturer and our component suppliers are required to comply with the FDA's quality system regulations, which is a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic, sometimes unannounced, inspections by the FDA. We cannot assure you that our facilities or our contract manufacturer or component suppliers' facilities would pass any future quality system inspection. If our or any of our contract manufacturer or component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our devices could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our labeling operations or the manufacturing operations of our contract manufacturer, or a recall of our devices.

If we, or our manufacturers, fail to adhere to QSR requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

Our facility located at 600 Technology Park Drive, Suite 200, Billerica, MA 01821 was inspected by the FDA from March 11-27, 2015, which resulted in four inspectional observations (FDA Form 483) and a subsequent Warning Letter dated June 5, 2015. The Company has completed all of the commitments from the 483 and Warning Letter responses, but has not yet received notification that FDA has closed the Warning Letter. More recently, our facility located in Billerica, MA was re-inspected by the FDA from November 30-December 11, 2015. This inspection also resulted in four inspectional observations (FDA Form 483). We responded to the most recent inspectional observations on December 31, 2015.

***If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.***

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Any such adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events involving our products have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

***Our current or future products may be subject to product recalls even after receiving FDA clearance or approval. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.***

The FDA and similar governmental bodies in other countries have the authority to require the recall of our current or future products if we or our contract manufacturers fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of these products. A government-mandated recall could occur if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death. A voluntary recall by us could occur as a result of any material deficiency in a device, such as manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

With respect to corrections and removals, in July 2015, Insulet implemented a field removal of certain lots due to the possibility that some of the OmniPod Systems have a higher rate of failure than its current manufacturing standards. In September 2015, as part of Insulet's product quality monitoring process, the company identified that certain lots of the OmniPod had a slight increase (1% - 2%) in the reported cases in which the Pod's cannula failed to deploy. On October 29, 2015, Insulet implemented a field correction to advise patients of the possibility of a needle deployment failure and provided recommendations on how to manage such an event. Both field actions were initiated with the knowledge of FDA and were reported to the agency in accordance with the requirements of 21 C.F.R. Part 806.

Further, under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a

risk to health and have not otherwise been reported under the MDR regulations. In addition, in October 2014, the FDA issued guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the Federal Food, Drug, and Cosmetic Act, that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

***If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval or commercialize our products.***

We rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our clinical trials and pre-clinical investigations. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

***We may be subject to enforcement action if we engage in improper marketing or promotion of our products.***

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Doctors may use our products off-label, as the FDA does not restrict or regulate a doctor's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

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

The federal anti-kickback statute and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services and impose civil and criminal penalties for noncompliance that can be substantial. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices.

We conduct various marketing and product training activities that involve making payments to healthcare providers and entities. While we believe that our activities are compliant with all applicable laws, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations.

We participate in federal and state programs such as Medicare and Medicaid, under which we are subject to numerous state and federal laws and regulations overseeing reimbursement and intended to prevent fraud and abuse. Medicare and Medicaid regulations are complex and may require management's interpretation. Our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the United States Department of Health and Human Services' Office of the Inspector General ("OIG"), CMS, and the Department of Justice. To ensure compliance with Medicare, Medicaid and other regulations, government agencies conduct periodic audits of us to ensure compliance with various supplier standards and billing requirements.

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

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

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

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

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

A key to driving our revenue growth is the retention of a high percentage of our customers. We have developed retention programs aimed at both healthcare professionals and patients, which include appeals assistance, ongoing patient communications, newsletters, support, training and an automatic re-order program for certain patients. We have had a satisfactory customer retention rate; however, we cannot assure you that we will maintain this retention rate in the future. Current uncertainty in global economic conditions, higher levels of unemployment, changes in insurance reimbursement levels and negative financial news may negatively affect product demand. If demand for our products fluctuates as a result of economic conditions or otherwise, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our revenue growth and may have a material adverse effect on our business, financial condition and results of operations.

We depend on a small number of customers for a large portion of our business, and changes in our customers' orders could have a significant impact on our operating results. If a major customer, either in our insulin or non-insulin drug delivery businesses significantly reduces the amount of business it does with us, there would be an adverse impact on our operating results. In the year ended December 31, 2015, two customers represented 11% and 10% of total revenue, respectively. In the year ended December 31, 2014, two customers represented 15% and 11% of total revenue, respectively. In the year ended December 31, 2013, one customer represented 13% of total revenue.

***We have sponsored, and expect to continue to sponsor market studies seeking to demonstrate certain aspects of the efficacy of the OmniPod System, which may fail to produce favorable results.***

To help improve, market and sell the OmniPod System, we have sponsored, and expect to continue to sponsor market studies to assess various aspects of the OmniPod System's functionality and its relative efficacy. The data obtained from the studies may be unfavorable to the OmniPod System or may be inadequate to support satisfactory conclusions. In addition, in the future we may sponsor clinical trials to assess certain aspects of the efficacy of the OmniPod System. If future clinical trials fail to support the efficacy of our current or future products, our sales may be adversely affected and we may lose an opportunity to secure clinical preference from prescribing clinicians, which may have a material adverse effect on our business, financial condition and results of operations.

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

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

***Substantially all of our operations related to the OmniPod System are conducted at a single location and substantially all of our OmniPod System inventory is held at a single location. Any disruption at either of these locations could increase our expenses.***

Substantially all of our manufacturing of complete OmniPods is currently conducted at a single location on manufacturing lines owned by us at a facility located in China, operated by a subsidiary of Flextronics. We take precautions to ensure that Flextronics safeguards our assets, including insurance and health and safety protocols. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our manufacturing equipment, and cause us to incur additional expenses. The insurance we maintain may not be adequate to cover our losses in any particular case. With or without insurance, damage to our manufacturing equipment, or to any of our suppliers, may have a material adverse effect on our business, financial condition and results of operations.

In addition, substantially all of our OmniPod System inventory is held at a single location in Billerica, Massachusetts. We take precautions to safeguard our facility, including insurance, health and safety protocols and off-site storage of computer data. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our inventory, and cause us to incur additional expenses. The insurance we maintain may not be adequate to cover our losses in any particular case. With or without insurance, damage to our facility or our other property may have a material adverse effect on our business, financial condition and results of operations.

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

We recently made significant changes to our senior management team. We believe we will benefit substantially from the leadership and performance of our new senior management. As such, our success will depend on our ability to retain our new management and to attract and retain additional qualified personnel in the future, including clinicians, engineers and other highly skilled personnel. In addition, it is important to the success of the Company that the transition of the new senior management be largely seamless. Our failure to effect this seamless transition may result in a disruption to our business. Competition for senior management personnel, as well as clinicians, engineers and other highly skilled personnel, is intense and there can be no assurances that we will be able to retain our personnel. The loss of the services of members of our senior management, clinicians, engineers and other highly skilled personnel could prevent or delay the implementation and completion of our objectives, or divert management's attention to seeking qualified replacements.

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

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

Since the commercial launch of the OmniPod System, we have progressively expanded our marketing efforts to cover the entire United States. In addition, the OmniPod System is sold in a number of European countries and Canada. As we continue to expand our sales internationally, we will need to obtain regulatory approvals and reimbursement agreements with government agencies or private third-party payors in those countries. Failure to obtain such agreements would limit our ability to successfully penetrate those foreign markets. In addition, the geographic expansion of our business will require additional manufacturing capacity to supply those markets as well as additional sales and marketing resources.

We expect to continue to increase our manufacturing capacity, our personnel and the scope of our U.S. and international sales and marketing efforts. This growth, as well as any other growth that we may experience in the future, will provide challenges to our organization and may strain our management and operations resources. In order to manage future growth, we will be required to improve existing, and implement new, management systems, sales and marketing efforts and distribution channels. We will need to manage our relationship with Flextronics and other suppliers going forward. We may also need to partner with additional third-party suppliers to manufacture certain components of the OmniPod System and complete additional manufacturing lines in the future. A transition to new suppliers may result in additional costs or delays. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to manufacture sufficient inventory or attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver the OmniPod System in a timely manner and our results of operations may be adversely affected.

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

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

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

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

- dilutive issuances of equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which in future periods may result in significant charges to earnings.

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

***We may not be able to generate sufficient cash to service our indebtedness represented by our 2% Convertible Senior Notes due June 15, 2019. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.***

In 2014, we sold $201.3 million in principal amount of 2% Convertible Senior Notes, due in 2019. Our ability to make scheduled payments or to refinance the 2% Convertible Senior Notes or other debt obligations depends on our financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness, including the 2% Convertible Senior Notes. We cannot assure you that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations when due.

***We need to expand our distribution network to maintain and grow our business and revenue. If we fail to expand and maintain an effective sales force or successfully develop our relationship with distributors, our business, prospects and brand may be materially and adversely affected.***

We currently promote, market and sell the majority of our OmniPod Systems through our own direct sales force. We currently utilize a limited number of domestic distributors to augment our sales efforts. In addition, in January 2010 we entered into an exclusive distribution agreement with Ypsomed to promote, advertise, distribute and sell the OmniPod System in certain countries. This agreement expires in mid-2018. We cannot assure you that we will be able to successfully develop our relationships with third-party distributors. If we fail to do so, our sales could fail to grow or could decline, and our ability to grow our business could be adversely affected. Distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our products and grow or maintain product sales. If our distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products.

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

As a public company, we are required to maintain internal control over financial reporting and our management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Additionally, we are required to disclose in our Annual Reports on Form 10-K our management's assessment of the effectiveness of our internal control over financial reporting along with a registered public accounting firm's attestation report on the effectiveness of our internal controls. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the Securities and Exchange Commission. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective. These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets or cause our stock to be delisted from The NASDAQ Global Market or any other securities exchange on which it is then listed.

***The price of our common stock may be volatile.***

The market price of our common stock is affected by a number of factors, including:

- failure to maintain and increase production capacity and reduce per unit production costs;
- changes in the availability of third-party reimbursement in the United States or other countries;
- volume and timing of orders for the OmniPod System;
- developments in administrative proceedings or litigation related to intellectual property rights;
- issuance of patents to us or our competitors;

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

At times, the fluctuations in the market price of our common stock have been unrelated or disproportionate to our operating performance. In particular, the U.S. equity markets have at times experienced significant price and volume fluctuations that have affected the market prices of equity securities of many technology companies. Broad market and industry factors such as these could materially and adversely affect the market price of our stock, regardless of our actual operating performance.

***Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price.***

We have been a public company since May 2007. Since becoming a public company, the average daily trading volume of our common stock on The NASDAQ Global Market has been approximately 400,000 shares.

In addition to our outstanding shares of common stock, we issued $201.3 million of 2% Convertible Senior Notes in June 2014. A substantial number of shares of our common stock could potentially be issued upon the conversion of these Convertible Senior Notes. The issuance of substantial amounts of common stock underlying the Convertible Senior Notes, or the perception that such issuance may occur, could adversely affect the market price of our common stock.

Furthermore, the price of our common stock also could be affected by possible sales of our common stock by investors who view the 2% Convertible Senior Notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect will develop involving our common stock. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

***Conversion of any of our 2% Convertible Senior Notes may dilute the ownership interest of existing stockholders.***

The conversion of some or all of the 2% Convertible Senior Notes may dilute the ownership interests of existing stockholders. Any sales in the public market of any of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the anticipated conversion of the Convertible Senior Notes into a combination of cash and shares of our common stock could depress the price of our common stock.

***We could be subject to indemnification obligations in connection with the disposition of our former Neighborhood Diabetes supplies business.***

In February 2016, we sold Neighborhood Diabetes to Liberty Medical for $5 million in cash. Under the terms of the sale, we agreed to indemnify Liberty Medical for certain customary matters primarily related to our pre-closing operation of the business. Although we currently do not expect any material indemnification obligations to arise, we could be required to reimburse Liberty Medical for such claims in the event that they were to arise.

***Our ability to use net operating loss carryforwards may be subject to limitation.***

Section 382 of the U.S. Internal Revenue Code of 1986, as amended, imposes an annual limit on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership or equity structure. Our ability to use net operating losses may be limited by prior changes in our ownership, and may be further limited by the issuance of common stock in connection with the conversion of our Convertible Senior Notes, or by the consummation of other transactions. As a result, if we earn net taxable income, our ability to use net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liabilities for us.

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

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

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

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

In addition, in November 2008, our board of directors adopted a shareholder rights plan, implementing what is commonly known as a “poison pill.” This poison pill significantly increases the costs that would be incurred by an unwanted third party acquirer if such party owns or announces its intent to commence a tender offer for more than 15% of our outstanding common stock or otherwise “triggers” the poison pill by exceeding the applicable stock ownership threshold. The existence of this poison pill could delay, deter or prevent a takeover of us.

## *Item 1B. Unresolved Staff Comments*

None.

## *Item 2. Properties*

We lease a total of approximately 120,000 square feet of office space, laboratory, warehousing and other related facilities. Approximately 90,000 of the total square footage consists of laboratory and office space for our corporate headquarters in Billerica, Massachusetts under leases expiring in 2022.

Additionally, we lease approximately 18,000 square feet of warehousing space in Billerica, Massachusetts under a lease expiring in 2019. We lease other facilities in Canada, Singapore, New York and Florida containing a total of approximately 12,000 square feet under leases expiring from July 2016 to July 2019.

## *Item 3. Legal Proceedings*

The information required by this Item is provided under "Legal Proceedings" in note 13 to the consolidated financial statements included under Item 8 of this Form 10-K, and is incorporated herein by reference.

## *Item 4. Mine Safety Disclosures*

Not applicable.

## PART II

### *Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

### MARKET FOR REGISTRANT'S COMMON EQUITY

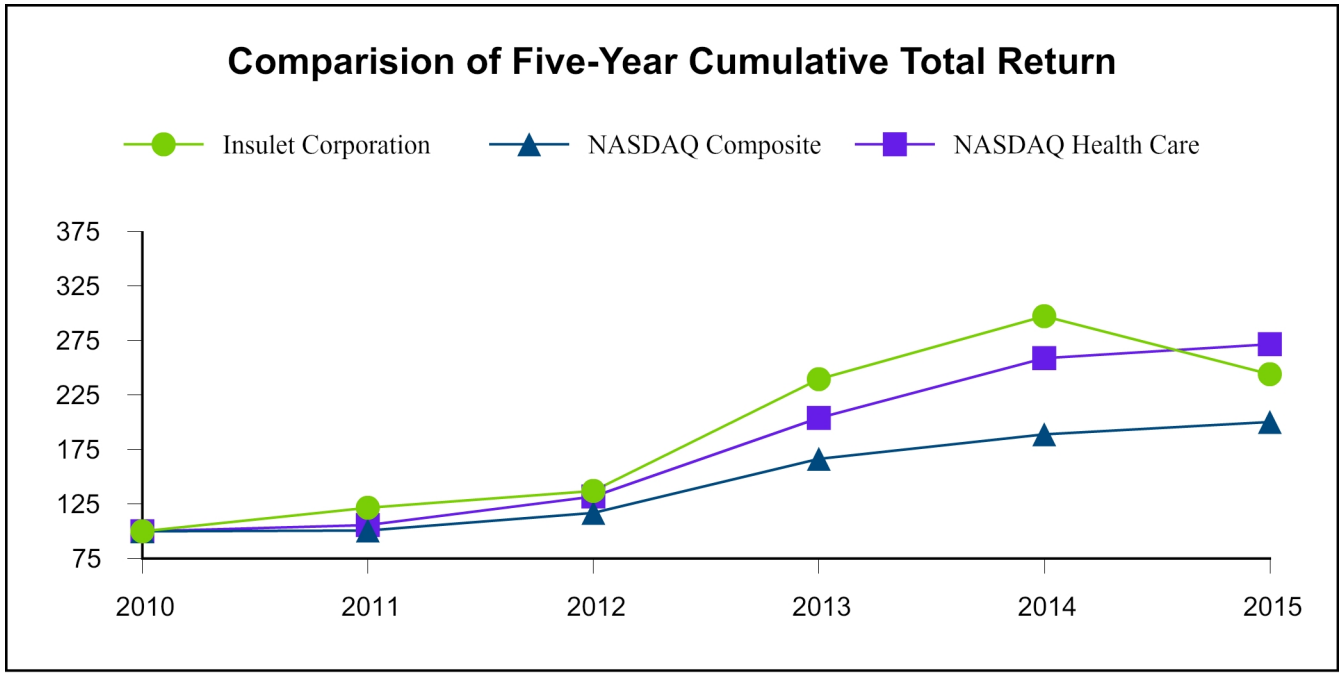
Our common stock has been listed on The NASDAQ Global Market under the trading symbol “PODD” since our initial public offering on May 15, 2007. The following table sets forth the high and low closing sales prices of our common stock, as reported by The NASDAQ Global Market, for each of the periods listed.

| | High | Low |
|---|---|---|
| **Fiscal Year 2014** | | |
| First Quarter | $ 50.18 | $ 35.83 |
| Second Quarter | $ 49.07 | $ 31.69 |
| Third Quarter | $ 41.11 | $ 32.94 |
| Fourth Quarter | $ 47.51 | $ 36.75 |
| **Fiscal Year 2015** | | |
| First Quarter | $ 45.18 | $ 29.39 |
| Second Quarter | $ 31.85 | $ 26.23 |
| Third Quarter | $ 34.39 | $ 25.64 |
| Fourth Quarter | $ 39.32 | $ 26.36 |

As of February 25, 2015, there were approximately 11 registered holders of record of our common stock. The number of beneficial stockholders of our shares is greater than the number of stockholders of record.

**Performance Graph**

The chart set forth below shows the value of an investment of $100 on December 31, 2010 in each of Insulet Corporation common stock, the NASDAQ Composite Index, and the NASDAQ Health Care Index. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices and are calculated as of December 31, 2015. The historical stock price performance of our common stock shown in the performance graph below is not necessarily indicative of future stock price performance.




| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|---|---|
| Insulet Corporation | $ 100 | $ 121 | $ 137 | $ 239 | $ 297 | $ 244 |
| NASDAQ Composite | 100 | 101 | 117 | 166 | 189 | 200 |
| NASDAQ Health Care | 100 | 106 | 132 | 204 | 259 | 271 |

The material in this performance graph is not soliciting material, is not deemed filed with the Securities and Exchange Commission ("SEC") and is not incorporated by reference in any filing of Insulet Corporation under the Securities Act of 1933, as amended (the "Securities Act") or the Exchange Act of 1934, as amended, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

**Dividend Policy**

We currently intend to retain future earnings for the development, operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

**Securities Authorized For Issuance Under Equity Compensation Plans**

The following table sets forth information regarding securities authorized for issuance under our equity compensation plans as of December 31, 2015.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders[1] | 2,929,887 | $ 23.43 | 6,152,904 |
| Equity compensation plans not approved by security holders[2] | 881,277 | $ 28.87 | — |
| Total[4] | 3,811,164 | $ 24.69 | 6,152,904 [3] |

[1] Includes our Amended and Restated 2007 Stock Option and Incentive Plan. Outstanding restricted stock units convert to common stock without the payment of consideration. As of December 31, 2015, 655,792 restricted stock units were outstanding. The weighted-average exercise price of outstanding options as of such date issued under these Plans (excluding restricted stock units) was $30.19

[2] Consists of the following inducement grants made to certain executive officers upon their initial hire by us: one inducement grant of 499,468 shares of non-qualified stock option awards made to Patrick J. Sullivan upon being hired by us in September 2014; one inducement grant of 26,756 non-qualified stock options and 18,182 restricted stock units (6,060 of which were exercised during the year ended December 31, 2015) made to Brad Thomas upon being hired by us in November 2014; one inducement grant of 79,936 non-qualified stock options and 56,965 restricted stock units made to Shacey Petrovic upon being hired by us in February 2015; one inducement grant of 58,852 non-qualified stock options and 43,028 restricted stock units made to Michael Levitz upon being hired by us in May 2015; one inducement grant of 29,581 non-qualified stock options and 21,627 restricted stock units made to David Colleran upon being hired by us in June 2015; and one inducement grant of 30,511 non-qualified stock options and 22,431 restricted stock units to Michael Spears upon being hired by us in July 2015. These non-qualified stock option awards and restricted stock units were granted outside of our Amended and Restated 2007 Stock Option and Incentive Plan in compliance with Nasdaq Listing Rule 5635.

[3] The maximum number of shares of our common stock that remain available for future issuance under our 2007 Stock Option and Incentive Plan as of December 31, 2015 is 6,152,904 shares.

[4] As of December 31, 2015, 811,965 restricted stock units were outstanding. The weighted-average exercise price of outstanding options as of such date issued as inducement grants (excluding restricted stock units) was $35.08.

For more information relating to our equity compensation plans, see footnote 14 to our consolidated financial statements.

**Issuer Repurchases of Equity Securities**

We did not repurchase any of our equity securities during the quarter ended December 31, 2015, nor issue any securities that were not registered under Securities Act.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

## *Item 6. Selected Financial Data*

| | Years Ended December 31, | | | | |
|---|---|---|---|---|---|
| | **2015** | **2014** | **2013** | **2012** | **2011[3]** |
| | (In thousands, except share and per share data) | | | | |
| **Consolidated Statements of Operations Data:** | | | | | |
| Revenue | **$ 324,225** | $ 288,720 | $ 247,084 | $ 211,369 | $ 152,255 |
| Cost of revenue | **176,071** | 145,432 | 134,683 | 119,033 | 85,543 |
| Gross profit | **148,154** | 143,288 | 112,401 | 92,336 | 66,712 |
| Operating expenses: | | | | | |
| Research and development | **43,208** | 27,900 | 21,765 | 24,359 | 21,863 |
| Sales and marketing | **88,352** | 60,844 | 55,694 | 52,708 | 43,233 |
| General and administrative[4] | **77,359** | 66,841 | 64,077 | 51,240 | 44,083 |
| Total operating expenses | **208,919** | 155,585 | 141,536 | 128,307 | 109,179 |
| Operating loss | **(60,765)** | (12,297) | (29,135) | (35,971) | (42,467) |
| Interest and other expense, net | **(12,464)** | (39,061) | (15,739) | (15,684) | (14,576) |
| Income tax benefit (expense) | **(291)** | (142) | (100) | (212) | 11,212 |
| Net loss | **$ (73,520)** | $ (51,500) | $ (44,974) | $ (51,867) | $ (45,831) |
| Net loss per share basic and diluted | **$ (1.29)** | $ (0.93) | $ (0.83) | $ (1.08) | $ (0.98) |
| Weighted-average number of shares used in calculating net loss per share[1] | **56,785,646** | 55,628,542 | 54,010,887 | 47,924,324 | 46,689,880 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | **2015** | **2014** | **2013** | **2012** | **2011[3]** |
| | (In thousands) | | | | |
| **Consolidated Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | **$ 122,672** | $ 151,193 | $ 149,727 | $ 57,293 | $ 93,955 |
| Working capital | **$ 125,605** | $ 163,900 | $ 155,824 | $ 61,650 | $ 104,640 |
| Total assets | **$ 275,126** | $ 297,182 | $ 286,541 | $ 196,055 | $ 218,725 |
| Current portion of long-term debt and capital lease obligations | **$ 5,519** | $ 3,380 | $ 2,637 | $ 14,429 | $ — |
| Long-term debt and capital lease obligations[2] | **$ 171,967** | $ 166,283 | $ 117,627 | $ 101,726 | $ 105,943 |
| Other long-term liabilities | **$ 3,952** | $ 2,774 | $ 1,943 | $ 1,867 | $ 2,052 |
| Total stockholders' equity | **$ 34,051** | $ 83,829 | $ 124,597 | $ 44,176 | $ 82,735 |

(1) In June 2011, we issued 1.2 million shares in connection with the acquisition of Neighborhood Diabetes. In January 2013, we sold 4.7 million shares of common stock to the public. In July 2014, we issued 0.3 million shares of common stock in connection with the repurchase of the 3.75% Senior Convertible Notes. See Footnote 14 to our consolidated financial statements included in this Annual Report on Form 10-K.

(2) In June 2008, we sold $85.0 million principal amount of 5.375% Convertible Senior Notes due June 2013 in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. In June 2011, we issued $143.8 million of 3.75% Convertible Notes due June 2016 and repurchased $70 million in principal of the 5.375% Notes. In June 2014, we issued $201.3 million of 2% Convertible Notes due June 2019 and repurchased $114.9 million in 3.75% Notes. In July 2014, the remaining principal balance of the 3.75% Notes were converted and the principal was settled in cash. In 2013 and 2014 we acquired $9.0 million and $1.5 million, respectively, of manufacturing equipment under capital leases. See Footnotes 5 and 6 to our consolidated financial statements included in this Annual Report on Form 10-K.

(3) On June 1, 2011, we completed the acquisition of Neighborhood Diabetes, a durable medical equipment distributor, specializing in direct to consumer sales of diabetes supplies for an aggregate purchase price of approximately $37.9 million in cash and $24.4 million in common stock. Neighborhood Diabetes supplied its customers with blood glucose testing supplies, insulin pumps, pump supplies, pharmaceuticals, and other products for the management and treatment of diabetes.

(4) Included an impairment charge of $9.1 million related to the impairment of the Neighborhood Diabetes asset group. See Footnote 11 to our consolidated financial statements included in this Annual Report on Form 10-K.

## *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*

### 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. 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. Conventional insulin pumps require people with insulin-dependent diabetes to learn to use, manage and wear a number of cumbersome components, including up to 42 inches of tubing. In contrast, the OmniPod System features only two discreet, easy-to-use devices that eliminate the need for a bulky pump, tubing and separate blood glucose meter, provides for virtually pain-free automated cannula insertion, communicates wirelessly and integrates a blood glucose meter. We believe that the OmniPod System's unique proprietary design 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 and other diabetes management supplies in the United States through direct sales to customers or through our distribution partners. The OmniPod System is currently available in multiple countries in Europe, Canada and Israel. In July 2015, we executed an asset purchase agreement with GSK whereby we acquired assets associated with the Canadian distribution of our products and we assumed the distribution, sales, marketing, training and support activities for the OmniPod system in Canada. Additional information regarding this acquisition is provided in note 3 to the consolidated financial statements included under Item 8 of this Form 10-K.

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

In June 2011, we acquired Neighborhood Diabetes. Through Neighborhood Diabetes, we provided customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and had the ability to process claims as either durable medical equipment or through pharmacy benefits. In February 2016, we sold Neighborhood Diabetes to Liberty Medical. Additional information regarding the sale of our Neighborhood Diabetes business is provided in note 18 to the consolidated financial statements included under Item 8 of this Form 10-K.

*Highlights and Recent Developments:*

- Exceeded expectation within our Drug Delivery business with initial launch of the OmniPod technology for use with Amgen's Neulasta product and expanded the pipeline to six development agreements.
- Sold our Neighborhood Diabetes business in February 2016 to focus on faster growing innovative products.
- Signed development agreement with Eli Lilly and Company for OmniPod delivery of U200 concentrated insulin, significantly expanding OmniPod's addressable market for Type 1 and Type 2 diabetes.
- Signed development agreement with algorithm partner for OmniPod Artificial Pancreas.

*2015 Revenue Results:*

- Total revenue of $324.2 million
    - U.S. OmniPod revenue of $186.8 million
    - International OmniPod revenue of $40.3 million
    - Drug Delivery revenue of $34.0 million
    - Neighborhood Diabetes revenue of $63.1 million.

Our long-term financial objective is to achieve and sustain profitable growth. Our efforts in 2016 will be focused primarily on the expansion of our customer base in the United States and internationally and increasing our profitability. Achieving these objectives is expected to require additional investments in certain personnel and initiatives, as well as enhancements to our manufacturing efficiency and effectiveness. We believe that we will continue to incur net losses in the near term in order to achieve these objectives. However, we believe that the accomplishment of our near term objectives will have a positive impact on our financial condition in the future.

## Components of Financial Operations

*Revenue.* We derive most of our revenue from global sales of the OmniPod System. Our revenue also includes (i) sales through Neighborhood Diabetes of other diabetes related products including blood glucose testing supplies, traditional insulin pumps, pump supplies and other pharmaceuticals to customers and third-party distributors who resell the product to customers and (ii) sales of devices based on the OmniPod technology platform to global pharmaceutical and biotechnology companies for the delivery of subcutaneous drugs across multiple therapeutic areas.

In June 2011, we entered into a development agreement with a U.S. based pharmaceutical company (the "Development Agreement"). Under the Development Agreement, we were required to perform design, development, regulatory, and other services to support the pharmaceutical company as it worked to obtain regulatory approval to use our drug delivery technology as a delivery method for its pharmaceutical. The pharmaceutical company received regulatory approval in December 2014 and now purchases product from us for use with its pharmaceutical under a supply agreement.

*Cost of revenue.* Cost of revenue consists primarily of raw material, labor, warranty, inventory reserve 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, customer care and training functions, sales commissions paid to our sales representatives and costs associated with participation in medical conferences, physician symposia and promotional activities.

*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.

## Results of Operations

This section discusses our consolidated results of operations for 2015 compared to 2014, as well as 2014 compared to 2013, and should be read in conjunction with the consolidated financial statements and accompanying notes included under Item 8 of this Form 10-K.

**TABLE 1: RESULTS OF OPERATIONS**

| | Years Ended December 31, | | | | Years Ended December 31, | | | |
|---|---|---|---|---|---|---|---|---|
| **(In Thousands)** | **2015** | **2014** | **$ Change** | **% Change** | **2014** | **2013** | **$ Change** | **% Change** |
| Revenue | **$324,225** | $288,720 | $ 35,505 | 12 % | $288,720 | $247,084 | $ 41,636 | 17 % |
| Cost of revenue | **176,071** | 145,432 | 30,639 | 21 % | 145,432 | 134,683 | 10,749 | 8 % |
| Gross profit | **148,154** | 143,288 | 4,866 | 3 % | 143,288 | 112,401 | 30,887 | 27 % |
| Gross margin | **45.7%** | 49.6% | | | 49.6% | 45.5% | | |
| Operating expenses: | | | | | | | | |
| Research and development | **43,208** | 27,900 | 15,308 | 55 % | 27,900 | 21,765 | 6,135 | 28 % |
| Sales and marketing | **88,352** | 60,844 | 27,508 | 45 % | 60,844 | 55,694 | 5,150 | 9 % |
| General and administrative | **77,359** | 66,841 | 10,518 | 16 % | 66,841 | 64,077 | 2,764 | 4 % |
| Total operating expenses | **208,919** | 155,585 | 53,334 | 34 % | 155,585 | 141,536 | 14,049 | 10 % |
| Operating loss | **(60,765)** | (12,297) | 48,468 | 394 % | (12,297) | (29,135) | (16,838) | (58)% |
| Interest and other expense, net | **(12,464)** | (39,061) | (26,597) | (68)% | (39,061) | (15,739) | 23,322 | 148 % |
| Income tax expense | **(291)** | (142) | 149 | 105 % | (142) | (100) | 42 | 42 % |
| Net loss | **$ (73,520)** | $ (51,500) | $ 22,020 | 43 % | $ (51,500) | $ (44,974) | $ 6,526 | 15 % |

### *Comparison of the Years Ended December 31, 2015 and December 31, 2014*

*Revenue*

Our total revenue increased to $324.2 million, up $35.5 million, or 12%, in the year ended 2015 compared to the year ended 2014, primarily led by growth in U.S. OmniPod revenue and our on-body injection device for drug delivery, offset by lower international OmniPod revenue. Our U.S. OmniPod revenue increased to $186.8 million, up $13.2 million, or 8%, reflecting growth in our installed base of OmniPod users, offset in part by unfavorable distributor ordering patterns and a reduction in royalty revenues of $3.2 million. Our drug delivery revenue increased to $34.0 million, up $28.6 million, due to strong growth in demand for our on-body injection device following regulatory approval in December 2014. Our Neighborhood Diabetes revenue increased to $63.1 million, up $3.4 million, or 6%, reflecting growth in patient demand. Our international OmniPod revenue decreased to $40.3 million, down $9.7 million, or 19%, primarily reflecting lower distributor sales due to changes in distributor ordering patterns despite continued growth in our installed base of OmniPod users. This decrease internationally was partially offset by growth in Canada (we acquired our Canadian distributor in July 2015).

For the year ending December 31, 2016 we expect strong revenue growth in our continuing operations from all of our product lines as we continue our expansion in the United States and internationally. As we increase commercial sales with our drug delivery partners, we expect that the revenue from our on-body injection devices will be a higher relative percentage of our overall growth. In the fourth quarter of 2015, we continued to see strong growth of approximately 20% in U.S. OmniPod new patient starts and expect this pattern to continue. New patient starts is an early indicator of future growth in our recurring revenue model rather than an explanation of growth for a given quarterly period. Increased revenue is dependent upon the success of our sales efforts, our customer retention and our ability to produce our products in sufficient volumes as our patient base grows and is subject to other risks and uncertainties. Beginning in the first quarter of 2016, Neighborhood Diabetes will be reported as discontinued operations, and not included in revenue, as a result of the sale in February 2016.

*Cost of Revenue*

Cost of revenue increased $30.6 million in the year ended 2015 compared to the same period in 2014 primarily due to an increase in sales volumes, as well as $11.5 million of costs directly and indirectly attributable to a voluntary Field Safety Notification that we initiated in November 2015 after identifying certain lots of OmniPod product which had a slight increase in the reported cases in which the needle mechanism failed to deploy or there was a delay in the deployment of the needle mechanism. The product manufactured in this condition was contained prior to distribution and will ultimately be scrapped.

*Gross Margin*

Gross margin in the year ended 2015 decreased by approximately 4 points compared to the same period in 2014. The decrease primarily resulted from approximately $11.5 million of costs directly and indirectly attributable to the voluntary field safety notification. The decrease in gross margin also reflects an increased investment in product quality and related policies and procedures to stand behind our products, which contributed to a $3.3 million increase in warranty expense year over year, of which $0.4 million related to the voluntary field safety notification.

For the year ending December 31, 2016, we expect gross margin to increase primarily from enhancements to our manufacturing efficiency and effectiveness, a favorable product mix primarily driven by the sale of our Neighborhood Diabetes business.

*Research and Development*

Research and development expenses increased $15.3 million to $43.2 million for the year ended December 31, 2015, compared to $27.9 million for the same period in 2014. The increase was the result of expenses related to our development projects, including a new PDM, the use of concentrated insulin for patients with higher insulin-resistance and investment in our artificial pancreas program, as well as expenses related to software development costs of $10.5 million.

For the year ending December 31, 2016, we expect overall research and development spending to increase due to the development efforts on our on-going projects including mobile application development, integration with continuous glucose monitoring technology, development efforts with Eli Lilly and Company for the use of concentrated insulin, our artificial pancreas program, and the continued investment to support the use our technology as a delivery platform for other pharmaceuticals.

*Sales and Marketing*

Sales and marketing expenses increased $27.5 million to $88.4 million for the year ended December 31, 2015, compared to $60.8 million for the same period in 2014. The increase was mainly the result of a $19.9 million increase in employee related expenses associated with the expansion of our sales force and customer support personnel. Additionally, there was a $7.3 million increase in costs associated with marketing campaigns, new market opportunities and other strategic initiatives as we continue to expand awareness of the OmniPod System and our on-body injection devices for drug delivery.

We expect sales and marketing expenses in the year ending December 31, 2016 to increase as we see the full-year impact of the 2015 commercial team expansion and invest in initiatives that will enhance awareness, customer satisfaction and drive increased adoption of the OmniPod System as well as increased adoption of our technology as a delivery platform for other pharmaceuticals.

*General and Administrative*

General and administrative expenses increased $10.5 million to $77.4 million for the year ended December 31, 2015, compared to $66.8 million for the same period in 2014, mainly the result of the $9.1 million impairment charge associated with our Neighborhood Diabetes business, a $2.0 million increase in expenses associated with claims and settlements, and an increase of $1.8 million in technology and license fees and technology consulting services. Additionally, there was an increase in shipping costs of $1.0 million, an increase of $0.8 million in audit, professional services and consulting fees and an increase in employee related expenses of $0.8 million. This increase was offset by a decrease in legal fees of approximately $7.4 million related to the Becton, Dickinson and Company litigation settlement in 2014.

For the year ending December 31, 2016, we expect overall general and administrative expenses to increase as compared to 2015 as we continue to grow the business and make investments in our operating structure to support this continued growth.

*Interest and Other Expense, Net*

Interest and other expense, net was $12.5 million for the year ended December 31, 2015, compared to $39.1 million for the year ended December 31, 2014. The significant changes in interest and other expense, net was primarily related to the loss from extinguishment of long-term debt of $23.2 million in 2014 as well as the change in interest rate on our long-term debt to 2% in mid 2014 from 3.75%.

*Income Tax Expense*

In the years ended December 31, 2015 and 2014 Income tax expense was $0.3 million and $0.1 million, respectively. Income tax expense is comprised of a current and deferred portion. The current portion primarily related to state and foreign taxes and the deferred portion primarily related to federal and state tax amounts.

Additional information regarding income tax expenses is provided in note 16 to the consolidated financial statements included under Item 8 of this Form 10-K.

### *Comparison of the Years Ended December 31, 2014 and December 31, 2013*

*Revenue*

Total revenue increased $41.6 million in the year ended 2014 compared to the same period in 2013, primarily the result of an increase in U.S. and international OmniPod revenue, partially offset by lower revenue from Neighborhood Diabetes. Our U.S. OmniPod revenue increased to $173.6 million, up $22.2 million, or 15%, reflecting growth in our installed base of OmniPod users. Our international OmniPod revenue increased to $50.0 million, up $25.5 million, reflecting increased installed base as well as increased stock of on hand inventory from our international distributor during 2014. Our Neighborhood Diabetes revenue decreased to $59.7 million, down $4.1 million, or 6%, reflecting a reduction in revenue related to certain mail-order diabetic testing supplies such as blood glucose testing strips and lancets to Medicare beneficiaries that we were no longer eligible to service under the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program, which took effect on July 1, 2013.

*Cost of Revenue*

In the year ended December 31, 2014, cost of revenue increased $10.7 million compared to the same period in 2013 primarily due to higher sales volumes in the United States and internationally. These increases were partially offset by lower per-unit costs of the OmniPod System resulting from cost savings on raw materials, volume discounts from our suppliers and increased absorption of manufacturing overhead driven by increased production volumes.

*Gross Margin*

Gross margin in the year ended 2014 increased by approximately 4 points compared to the same period in 2013 due to efficiencies in the manufacturing process.

*Research and Development*

Research and development expenses increased $6.1 million to $27.9 million for the year ended December 31, 2014, compared to $21.8 million for the same period in 2013. The increase was primarily the result of expenses related to our development projects and included a $3.3 million increase in employee related expenses. Additionally, we incurred a $2.0 million increase in consulting and temporary labor related to our development projects and a $0.5 million increase in supplies and consumables.

*Sales and Marketing*

Sales and marketing expenses increased $5.1 million to $60.8 million for the year ended December 31, 2014, compared to $55.7 million for the same period in 2013. The increase was primarily the result of a $3.5 million increase in employee related expenses including management transition costs and stock-based compensation and costs related to the addition of employees as we continue to expand our sales force. Additionally, we incurred a $1.2 million increase in costs associated with marketing campaigns and other advertising costs.

*General and Administrative*

General and administrative expenses increased $2.7 million to $66.8 million for the year ended December 31, 2014, compared to $64.1 million for the same period in 2013 The increase included approximately $9.1 million related to management retirement and transition costs, an increase of $1.2 million in employee related expenses including stock compensation and $0.5 million in infrastructure costs. The increase was partially offset by a year over year decrease of $4.0 million in legal expenses, $2.5 million of nonrecurring impairment charges for equipment no longer being used which was recorded in 2013, a decrease of $0.9 million in amortization expense related to the customer relationship asset acquired in the June 2011 acquisition of Neighborhood Diabetes, and a decrease of $0.7 million in shipping expenses.

*Interest and Other Expense, Net*

Interest and other expense, net was $39.1 million and $15.7 million for the years ended December 31, 2014 and 2013, respectively. The significant change in interest and other expense, net was primarily related to the loss from extinguishment of long-term debt of $23.2 million in 2014, as well as the change in interest rate on our long-term debt to 2% in mid 2014 from 3.75% in the prior periods.

*Income Tax Expense*

Income tax expense was $0.1 million for both the years ended December 31, 2014 and 2013. Income tax expense is comprised of a current and deferred portion. The current portion primarily related to state and foreign taxes and the deferred portion primarily related to federal and state tax amounts.

## Liquidity and Capital Resources

As of December 31, 2015, we had $122.7 million in cash and cash equivalents. We believe that our current cash and cash equivalents, together with the cash expected to be generated from sales, will be sufficient to meet our projected operating and debt service requirements for at least the next twelve months.

### *Equity*

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

Additional information about our common stock issuances is provided in note 14 to the consolidated financial statements included under Item 8 of this Form 10-K.

### *Debt*

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

Cash interest expense related to the 2% Notes was $4.0 million and $2.3 million in the years ended December 31, 2015 and 2014, respectively. Non-cash interest expense related to the 2% Notes was $7.7 million and $4.0 million in the years ended December 31, 2015 and 2014, respectively.

As of December 31, 2015, we included $171.7 million on the balance sheet in long-term debt related to the 2% Notes, which represents the principal amount of the notes, less unamortized debt discount and deferred financing costs.

Additional information regarding our debt issuances is provided in note 5 to the consolidated financial statements included under Item 8 of this Form 10-K.

### *Capital Leases*

As of December 31, 2015 and December 31, 2014, we have approximately $13.7 million and $8.0 million of manufacturing equipment acquired under capital leases, respectively. The obligations under the capital leases are being repaid in equal monthly installments over 24 to 36 month terms and include principal and interest payments with an effective interest rate of 13% to 17%. At December 31, 2015, $5.5 million was included in current liabilities and $0.3 million was included in long-term liabilities on our balance sheet related to these capital leases.

Additional information regarding our capital leases is provided in note 6 to the consolidated financial statements included under Item 8 of this Form 10-K.

*Summary of Cash Flows*

| (In thousands) | Years Ended December 31, 2015 | 2014 | 2013 |
|---|---|---|---|
| Cash (used in) provided by: | | | |
| Operating activities | **$ (12,552)** | $ 8,920 | $ 3,348 |
| Investing activities | **(15,323)** | (11,486) | (7,307) |
| Financing activities | **(371)** | 4,032 | 96,393 |
| Effect of exchange rate changes on cash | **(275)** | — | — |
| Net (decrease) increase in cash and cash equivalents | **$ (28,521)** | $ 1,466 | $ 92,434 |

*Operating Activities*

Our net cash used in operating activities for the year ended December 31, 2015 was $12.6 million compared to net cash provided by operating activities of $8.9 million in the year ended December 31, 2014. The decrease was primarily due to the increased investment in business operations in 2015 to support the growth of the business.

Our net cash provided by operating activities was $8.9 million for the year ended December 31, 2014 compared to $3.3 million in 2013. The $5.6 million increase in net cash provided by operating activities was primarily attributable to a lower net loss after non-cash adjustments including debt extinguishment costs and stock based compensation expense. This is partially offset by changes in working capital requirements, including an increase in accounts receivable and inventory.

*Investing Activities*

Our net cash used in investing activities in the year ended December 31, 2015 was $15.3 million compared to $11.5 million in 2014. The $3.8 million increase primarily related to the acquisition of our Canadian distributor in July 2015 of $4.7 million, partially offset by lower capital purchases.

Net cash used in investing activities in the year ended December 31, 2014 was $11.5 million compared to $7.3 million in 2013. The $4.2 million increase primarily related to the purchases of property and equipment, of which the majority related to the purchase of manufacturing equipment for use in the production of the OmniPod System.

*Financing Activities*

We had net cash used in financing activities for the year ended December 31, 2015 of $0.4 million compared to $4.0 million in net cash provided by financing activities in 2014. The $4.4 million decrease was primarily attributable to the increase in payments due to our purchase of additional capital lease property and equipment in 2015 as well as a $5.0 million net decrease in proceeds related to the 2014 issuance of long term debt.

Net cash provided by financing activities in the year ended December 31, 2014 was $4.0 million compared to $96.4 million in 2013. The decrease mainly related to the net proceeds from the 2013 issuance of common stock in connection with the public offering and the exercise of employee stock options.

*Commitments and Contingencies*

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

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

The following table summarizes our principal obligations as of December 31, 2015 (in thousands):

| Contractual Obligations | Total | 2016 | 2017 | 2018 | 2019 | 2020 | Later |
|---|---|---|---|---|---|---|---|
| Operating lease obligations | $ 15,174 | $ 2,285 | $ 2,322 | $ 2,306 | $ 2,181 | $ 2,146 | $ 3,934 |
| Debt obligations[1] | 215,170 | 4,025 | 4,025 | 4,025 | 203,095 | — | — |
| Capital lease obligations[2] | 6,143 | 5,874 | 269 | — | — | — | — |
| Purchase obligations | 2,000 | 2,000 | — | — | — | — | — |
| Total contractual obligations | $238,487 | $ 14,184 | $ 6,616 | $ 6,331 | $205,276 | $ 2,146 | $ 3,934 |

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

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

*Legal Proceedings*

The significant estimates and judgments related with establishing litigation reserves are discussed under "Legal Proceedings" in note 13 of the consolidated financial statements included under Item 8 of this Form 10-K.

## Off-Balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet financing arrangements.

## Critical Accounting Policies and Estimates

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying 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.

Based on the sensitivity of reported financial statement amounts to the underlying estimates and assumptions, the relatively more significant accounting policies applied by us have been identified by management as those associated with the following:

- Revenue recognition
- Stock-based compensation and equity investments
- Business Combinations
- Goodwill
- Intangibles and other long-lived assets
- Accounts receivable and allowance for doubtful accounts
- Warranty

Additional information on our critical accounting estimates and significant accounting policies, including references to applicable footnotes, is provided in note 2 to the consolidated financial statements included under Item 8 of this Form 10-K.

## Recent Accounting Pronouncements

Information with respect to recent accounting developments is provided in note 2 to the consolidated financial statements included under Item 8 of this Form 10-K.

### *Item 7A. Quantitative and Qualitative Disclosures about Market Risk*

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

As of December 31, 2015, we had outstanding debt recorded on our consolidated balance sheet of $201.3 million related to our 2% Notes and $5.8 million related to capital lease obligations. As the interest rates are fixed, changes in interest rates do not affect the value of our debt or capital lease obligations.

*Foreign Currency Exchange Risk.* Our business is subject to risks, including, but not limited to: unique economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. We are exposed to currency exchange rate fluctuations related to our subsidiary operations in Canada and Singapore.

Fluctuations in foreign currency rates could affect our sales, cost of goods and operating margins and could result in exchange losses. In addition, currency devaluations can result in a loss if we hold deposits of that currency. A hypothetical 10% increase or decrease in foreign currencies that we transact in would not have a material adverse impact on our business, financial condition or results of operations.

### *Item 8. Financial Statements and Supplementary Data*

Our financial statements as of December 31, 2015 and 2014 and for each of the three years in the period ended December 31, 2015, and the Report of the Registered Independent Public Accounting Firm are included in this report as listed in the index.

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## Report of Independent Registered Public Accounting Firm

**The Board of Directors and Stockholders of**

**Insulet Corporation**

We have audited the accompanying consolidated balance sheets of Insulet Corporation as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. Our audits also include the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Insulet Corporation at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method for presenting debt issuance costs as a result of the adoption of the amendments to the FASB Accounting Standards Codification resulting from Accounting Standards Update No. 2015-03, ‘‘Simplifying the Presentation of Debt Issuance Costs,’’ effective December 31, 2015.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Insulet Corporation's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework and our report dated February 29, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 29, 2016

## INSULET CORPORATION

## CONSOLIDATED BALANCE SHEETS

| (In thousands, except share and per share data) | December 31, 2015 | December 31, 2014 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets** | | |
| Cash and cash equivalents | **$ 122,672** | $ 151,193 |
| Accounts receivable, net | **48,387** | 39,882 |
| Inventories, net | **14,043** | 13,099 |
| Prepaid expenses and other current assets | **5,659** | 4,022 |
| Total current assets | **190,761** | 208,196 |
| Property and equipment, net | **41,793** | 37,069 |
| Intangible assets, net | **2,721** | 14,064 |
| Goodwill | **39,747** | 37,536 |
| Other assets | **104** | 317 |
| Total assets | **$ 275,126** | $ 297,182 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current Liabilities** | | |
| Accounts payable | **$ 18,649** | $ 14,659 |
| Accrued expenses and other current liabilities | **38,627** | 24,703 |
| Deferred revenue | **2,361** | 1,554 |
| Current portion of capital lease obligations | **5,519** | 3,380 |
| Total current liabilities | **65,156** | 44,296 |
| Capital lease obligations | **269** | 2,263 |
| Long-term debt, net of discount | **171,698** | 164,020 |
| Other long-term liabilities | **3,952** | 2,774 |
| Total liabilities | **241,075** | 213,353 |
| Commitments and contingencies (Note 13) | | |
| **Stockholders' Equity** | | |
| Preferred stock, $.001 par value: | | |
| Authorized: 5,000,000 shares at December 31, 2015 and 2014. Issued and outstanding: zero shares at December 31, 2015 and 2014. | **—** | — |
| Common stock, $.001 par value: | | |
| Authorized: 100,000,000 shares at December 31, 2015 and 2014. Issued and outstanding: 56,954,830 and 56,299,022 shares at December 31, 2015 and 2014, respectively. | **57** | 56 |
| Additional paid-in capital | **686,193** | 661,811 |
| Accumulated other comprehensive loss | **(654)** | (13) |
| Accumulated deficit | **(651,545)** | (578,025) |
| Total stockholders' equity | **34,051** | 83,829 |
| Total liabilities and stockholders' equity | **$ 275,126** | $ 297,182 |

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

## INSULET CORPORATION

## CONSOLIDATED STATEMENTS OF OPERATIONS

| (In thousands, except share and per share data) | Years Ended December 31, 2015 | 2014 | 2013 |
|---|---|---|---|
| Revenue | **$ 324,225** | $ 288,720 | $ 247,084 |
| Cost of revenue | **176,071** | 145,432 | 134,683 |
| Gross profit | **148,154** | 143,288 | 112,401 |
| Operating expenses: | | | |
| Research and development | **43,208** | 27,900 | 21,765 |
| Sales and marketing | **88,352** | 60,844 | 55,694 |
| General and administrative | **77,359** | 66,841 | 64,077 |
| Total operating expenses | **208,919** | 155,585 | 141,536 |
| Operating loss | **(60,765)** | (12,297) | (29,135) |
| Interest expense | **(12,580)** | (14,687) | (16,889) |
| Other income (expense), net | **116** | (1,171) | 1,475 |
| Loss on extinguishment of long-term debt | **—** | (23,203) | (325) |
| Interest and other expense, net | **(12,464)** | (39,061) | (15,739) |
| Loss before income taxes | **(73,229)** | (51,358) | (44,874) |
| Income tax expense | **(291)** | (142) | (100) |
| Net loss | **$ (73,520)** | $ (51,500) | $ (44,974) |
| Net loss per share basic and diluted | **$ (1.29)** | $ (0.93) | $ (0.83) |
| Weighted-average number of shares used in calculating net loss per share | **56,785,646** | 55,628,542 | 54,010,887 |

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

## INSULET CORPORATION

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| | Years Ended December 31, | | |
|---|---|---|---|
| **(In thousands)** | **2015** | **2014** | **2013** |
| Net loss | **$ (73,520)** | $ (51,500) | $ (44,974) |
| Other comprehensive loss, net of tax | | | |
| Foreign currency translation adjustment, net of tax | **(641)** | 6 | (19) |
| Total other comprehensive (loss) income, net of tax | **(641)** | 6 | (19) |
| Total comprehensive loss | **$ (74,161)** | $ (51,494) | $ (44,993) |

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

## INSULET CORPORATION

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

## (In thousands, except share data)

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| Balance at December 31, 2012 | 48,359,063 | $ 48 | $ 525,679 | $ (481,551) | | $ 44,176 |
| Exercise of options to purchase common stock | 872,073 | 1 | 9,479 | — | | 9,480 |
| Issuance for employee stock purchase plan | 12,970 | — | 445 | — | | 445 |
| Stock-based compensation expense | — | — | 12,616 | — | | 12,616 |
| Restricted stock units vested, net of shares withheld for taxes | 217,281 | — | (3,265) | — | | (3,265) |
| Issuance of common stock, net of offering costs of $5.0 million | 4,715,000 | 5 | 92,807 | — | | 92,812 |
| Exercise of warrants to purchase common stock | 47,392 | — | — | — | | — |
| Issuance of common stock pursuant to conversion of debt | 646,645 | 1 | 13,325 | — | | 13,326 |
| Foreign currency translation adjustment, net of tax | | | | | (19) | (19) |
| Net loss | — | — | — | (44,974) | | (44,974) |
| Balance at December 31, 2013 | 54,870,424 | $ 55 | $ 651,086 | $ (526,525) | $ (19) | $ 124,597 |
| Exercise of options to purchase common stock | 754,522 | 1 | 11,084 | — | | 11,085 |
| Issuance for employee stock purchase plan | 13,620 | — | 583 | — | | 583 |
| Stock-based compensation expense | — | — | 22,432 | — | | 22,432 |
| Restricted stock units vested, net of shares withheld for taxes | 311,921 | — | (8,665) | — | | (8,665) |
| Net impact of conversion of 3.75% Notes | — | — | (61,728) | — | | (61,728) |
| Allocation to equity for conversion feature on 2% Notes, net of issuance costs | — | — | 34,455 | — | | 34,455 |
| Issuance of common stock pursuant to conversion of debt | 348,535 | | 12,564 | — | | 12,564 |
| Foreign currency translation adjustment, net of tax | | | | | 6 | 6 |
| Net loss | — | — | — | (51,500) | | $ (51,500) |
| Balance at December 31, 2014 | 56,299,022 | $ 56 | $ 661,811 | $ (578,025) | $ (13) | $ 83,829 |
| Exercise of options to purchase common stock | **449,149** | **1** | **7,198** | | | **7,199** |
| Issuance for employee stock purchase plan | **22,039** | **—** | **652** | | | **652** |
| Stock-based compensation expense | **—** | **—** | **19,178** | | | **19,178** |
| Restricted stock units vested, net of shares withheld for taxes | **184,620** | **—** | **(2,646)** | | | **(2,646)** |
| Foreign currency translation adjustment, net of tax | | | | | **(641)** | **(641)** |
| Net loss | **—** | **—** | **—** | **(73,520)** | **—** | **(73,520)** |
| Balance at December 31, 2015 | **56,954,830** | **$ 57** | **$ 686,193** | **$ (651,545)** | **$ (654)** | **$ 34,051** |

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

## INSULET CORPORATION

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| (In thousands) | Years Ended December 31, 2015 | 2014 | 2013 |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| Net loss | **$ (73,520)** | $ (51,500) | $ (44,974) |
| Adjustments to reconcile net loss to net cash used in operating activities | | | |
| Depreciation and amortization | **15,838** | 12,223 | 11,806 |
| Non-cash interest and other expense | **7,678** | 10,253 | 9,731 |
| Stock-based compensation expense | **19,178** | 22,519 | 12,683 |
| Loss on extinguishment of debt | **—** | 23,203 | 325 |
| Provision for bad debts | **1,184** | 3,254 | 4,741 |
| Impairment and other charges | **9,086** | — | 2,511 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | **(9,793)** | (10,069) | (4,514) |
| Inventories | **(722)** | (3,635) | 5,403 |
| Deferred revenue | **809** | 654 | (4,545) |
| Prepaid expenses and other assets | **(1,460)** | 662 | (320) |
| Accounts payable, accrued expenses and other current liabilities | **17,986** | 525 | 10,425 |
| Other long-term liabilities | **1,184** | 831 | 76 |
| Net cash (used in) provided by operating activities | **(12,552)** | 8,920 | 3,348 |
| **Cash flows from investing activities** | | | |
| Purchases of property and equipment | **(10,608)** | (11,486) | (7,307) |
| Acquisition of Canadian distribution business | **(4,715)** | — | — |
| Net cash used in investing activities | **(15,323)** | (11,486) | (7,307) |
| **Cash flows from financing activities** | | | |
| Principal payments of capital lease obligations | **(5,576)** | (3,858) | (994) |
| Proceeds from issuance of long-term debt, net of issuance costs | **—** | 194,490 | — |
| Repayment of long-term debt | **—** | (189,521) | (2,000) |
| Proceeds from issuance of common stock, net of offering costs | **7,851** | 11,586 | 102,652 |
| Payment of withholding taxes in connection with vesting of restricted stock units | **(2,646)** | (8,665) | (3,265) |
| Net cash (used in) provided by financing activities | **(371)** | 4,032 | 96,393 |
| Effect of exchange rate changes on cash | **(275)** | — | — |
| Net (decrease) increase in cash and cash equivalents | **(28,521)** | 1,466 | 92,434 |
| Cash and cash equivalents, beginning of period | **151,193** | 149,727 | 57,293 |
| Cash and cash equivalents, end of period | **$ 122,672** | $ 151,193 | $ 149,727 |
| **Supplemental disclosure of cash flow information** | | | |
| Cash paid for interest | **$ 4,025** | $ 4,657 | $ 5,704 |
| Cash paid for taxes | **$ 109** | $ 124 | $ 321 |
| **Non-cash investing and financing activities** | | | |
| Allocation to equity for conversion feature for the 2% Notes | **$ —** | $ 35,638 | $ — |
| Common stock issued in exchange for 3.75% Convertible Senior Notes | **$ —** | $ 12,564 | $ 13,000 |
| Purchases of property and equipment under capital lease | **$ 5,721** | $ 1,474 | $ 9,021 |

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

## Note 1. Nature of the Business

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

The Company acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, “Neighborhood Diabetes”) in June 2011. Through Neighborhood Diabetes, the Company provided customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and had the ability to process claims as either durable medical equipment or through pharmacy benefits. In February 2016, the Company sold Neighborhood Diabetes to Liberty Medical LLC ("Liberty Medical"). Additional information regarding the sale of Neighborhood Diabetes is provided in note 18 to the consolidated financial statements included under Item 8 of this Form 10-K.

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

On July 7, 2015, the Company executed an asset purchase agreement whereby it acquired the Canadian OmniPod distribution operations from GlaxoSmithKline ("GSK"). With the acquisition, the Company assumed all distribution, sales, marketing, training and support activities for the OmniPod system in Canada. Additional information regarding this acquisition is provided in note 3 to the consolidated financial statements included under Item 8 of this Form 10-K.

## Note 2. Summary of Significant Accounting Policies

### *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. The most significant estimates used in these financial statements include the valuation of; stock-based compensation expense, acquired businesses, accounts receivable, inventories, goodwill, deferred revenue, equity instruments, the lives of property and equipment and intangible assets, as well as warranty and doubtful accounts allowance reserve calculations. Actual results may differ from those estimates.

### *Foreign Currency Translation*

For foreign operations, asset and liability accounts are translated at exchange rates as of the balance sheet date; income and expenses are translated using weighted average exchange rates for the reporting period. Resulting translation adjustments are reported in accumulated other comprehensive loss, a separate component of stockholders' equity. Gains and losses arising from transactions and translation of period-end balances denominated in currencies other than the functional currency are included in other expense, net, and were not material for fiscal years 2015, 2014 and 2013.

### *Principles of Consolidation*

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

### *Cash and Cash Equivalents*

For the purpose of the financial statement classification, the Company considers all highly liquid investment instruments with original maturities of 90 days or less, when purchased, to be cash equivalents. Cash equivalents include money market accounts, which are carried at cost which approximates their fair value. Outstanding letters

of credit, related to security deposits for lease obligations, totaled $1.2 million as of December 31, 2015 and December 31, 2014.

### *Property and Equipment*

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

### *Business Combinations*

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

### *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 that their Chief Executive Officer is the CODM as he 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. Consolidated financial information is utilized by the CODM as the Company's current product offering primarily consists of drug delivery and diabetes supplies, including the OmniPod System as well as other diabetes related products and supplies such as blood glucose testing supplies, traditional insulin pumps, pump supplies, and pharmaceuticals. The Company's 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 they operate as one segment.

### *Goodwill*

Goodwill represents the excess of the cost of acquired businesses over the fair value of identifiable net assets acquired. The Company follows the provisions of Financial Accounting Standards Board ("FASB") ASC 350-20, *Intangibles - Goodwill and Other* ("ASC 350-20"). The Company performs an assessment of its goodwill for impairment on at least an annual basis or whenever events or changes in circumstances indicate there might be impairment. The Company's annual impairment test date is October 1st.

The majority of the Company's goodwill resulted from the acquisition of Neighborhood Diabetes in June 2011. This goodwill largely reflects operational synergies and expansion of product offerings across markets complementary to the existing core OmniPod offerings.

As the Company operates in one segment, the Company has considered whether that segment contains multiple reporting units. The Company has concluded that there is a single reporting unit as the Company does not have segment managers and discrete financial information below consolidated results is not reviewed on a regular basis. Based on this conclusion, goodwill was tested for impairment at the enterprise level. The Company performs an annual goodwill impairment test unless interim indicators of impairment exist. The Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of its sole reporting unit is less than its carrying amount. This qualitative analysis is used as a basis for determining whether it is necessary to perform the two-step goodwill impairment analysis. If the Company determines that it is more likely than not that its fair value is less than its carrying amount, then the two-step goodwill impairment test will be performed. The first step compares the carrying value of the reporting unit to its fair value using a discounted cash flow analysis. If the reporting unit's carrying value exceeds its fair value, the Company would record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. There was no impairment of goodwill during the years ended December 31, 2015, 2014 or 2013.

The following table presents the change in carrying amount of goodwill during the period indicated:

| | Years Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| **(In thousands)** | | |
| **Goodwill:** | | |
| Beginning balance | **$ 37,536** | $ 37,536 |
| Goodwill as a result of acquisition | **2,403** | — |
| Foreign currency adjustment | **(192)** | — |
| Ending balance | **$ 39,747** | $ 37,536 |

### *Revenue Recognition*

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

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

- The evidence of an arrangement generally consists of a physician order form, a patient information form and, if applicable, third-party insurance approval for sales directly to patients or a purchase order for sales to a third-party distributor.
- Transfer of title and risk and rewards of ownership are passed to the patient or third-party distributor upon shipment of the products.
- The selling prices for all sales are fixed and agreed with the patient or third-party distributor and, if applicable, the patient's third-party insurance provider(s) prior to shipment and are based on established list prices or, in the case of certain third-party insurers, contractually agreed upon prices. Provisions for discounts, rebates and other adjustments to customers are established as a reduction to revenue in the same period the related sales are recorded.

The Company offers a 45-day right of return for sales of its OmniPod System in the United States, and a 90-day right of return for sales of its OmniPod System in Canada to new patients and defers revenue to reflect estimated sales returns in the same period that the related product sales are recorded. Returns are estimated through a comparison of the Company's historical return data to its related sales. Historical rates of return are adjusted for known or expected changes in the marketplace when appropriate. When doubt exists about reasonable assuredness of collectability from specific customers, the Company defers revenue from sales of products to those customers until payment is received.

In June 2011, the Company entered into a development agreement with a U.S. based pharmaceutical company (the "Development Agreement"). Under the Development Agreement, the Company was required to perform design, development, regulatory, and other services to support the pharmaceutical company as it worked to obtain regulatory approval to use the Company's drug delivery technology as a delivery method for its pharmaceutical. Over the term of the Development Agreement, the Company has invoiced amounts based upon meeting certain deliverable milestones. Revenue on the Development Agreement was recognized using a proportional performance methodology based on efforts incurred and total payments under the agreement. The impact of changes in the expected total effort or contract payments was recognized as a change in estimate using the cumulative catch-up method. The pharmaceutical company received regulatory approval and now purchases product from the Company for use with its pharmaceutical under a supply agreement. Product revenue under this arrangement is recognized at the time that all of the revenue recognition criteria are met, typically upon shipment.

The Company deferred revenue of $2.5 million and $1.6 million as of December 31, 2015 and December 31, 2014, respectively. Deferred revenue as of December 31, 2015 included $0.2 million classified in other long-term liabilities. Deferred revenue primarily relates to undelivered elements on certain arrangements within our developmental arrangements and other instances where we have not yet met the revenue recognition criteria.

International OmniPod revenue accounted for approximately 12%, 17% and 10% in the years ended December 31, 2015, 2014 and 2013, respectively.

### *Shipping and Handling Costs*

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

### *Concentration of Credit Risk*

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

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

In the year ended December 31, 2015, two customers represented 11% and 10% of total revenue, respectively. In the year ended December 31, 2014, two customers represented 15% and 11% of total revenue, respectively. In the year ended December 31, 2013, one customer represented 13% of total revenue.

### *Reclassification of Prior Period Balance*

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

### *Recent Accounting Pronouncements*

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

In June 2014, the FASB issued ASU No. 2014-12, *Compensation - Stock Compensation (Topic 718), Accounting for Share-Based Payments when the terms of an award provide that a performance target could be achieved after the requisite service period* ("ASU 2014-12"). ASU 2014-12 clarifies the period over which compensation cost would be recognized in awards with a performance target that affects vesting and that could be achieved after the requisite service period. Compensation cost would be recognized over the required service period, if it is probable that the performance condition will be achieved. The guidance is effective in fiscal years beginning after January 1, 2016, with early adoption permitted. Based on the Company's current equity practices, the Company does not anticipate that the adoption will have a material impact.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements- Going Concern ("ASU 2014-15").* ASU No. 2014-15 requires management to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The new standard is effective for fiscal years ending after December 15, 2016. Early adoption is permitted. The Company has concluded, that if this standard had been adopted as of December 31, 2015, substantial doubt about the Company's ability to continue as a going concern would not exist.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). ASU 2015-03 amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. The guidance is effective for annual reporting periods beginning after December 15, 2015, and must be applied retrospectively. Early adoption is permitted. The Company has adopted ASU 2015-03, as of December 31, 2015. The Company historically presented deferred debt issuance costs, or fees related to directly issuing debt, as assets on the consolidated balance sheets. As of December 31, 2014, the adoption of this standard resulted in the reclassification of $5.0 million from other assets to long-term debt. These costs will continue to be amortized as interest expense over the term of the corresponding debt issuance.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory* ("ASU 2015-11"). ASU 2015-11 amends existing guidance and requires entities to measure most inventory at the lower of cost and

net realizable value. The guidance is effective prospectively for annual reporting periods beginning after December 15, 2016. Early adoption is permitted. Upon adoption, entities must disclose the nature of and reason for the accounting change. The Company is currently evaluating the impact of ASU 2015-11.

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

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes.* ASU 2015-17 requires companies to classify all deferred tax assets and liabilities, along with any valuation allowance, as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The guidance does not change the existing requirement that only permits offsetting within a jurisdiction. The ASU is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. During the fourth quarter of 2015, the Company elected early adoption of this standard as it improved the efficiency of the year end financial reporting process for income taxes and applied the changes retrospectively to all prior periods presented in its consolidated financial statements. Adoption did not have a material impact to the financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 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. It 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. Early adoption is permitted for all entities. The Company is currently evaluating the impact of ASU 2016-02.

### *Other Significant Policies:*

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


| | | | | |
|---|---|---|---|---|
| Fair Value Measurements | Note | 4 | Page | 57 |
| Accounts Receivable and Allowance for Doubtful Accounts | Note | 8 | Page | 62 |
| Inventories | Note | 9 | Page | 62 |
| Intangibles and Other Long-Lived Assets | Note | 11 | Page | 64 |
| Warranty | Note | 12 | Page | 65 |
| Stock-Based Compensation | Note | 14 | Page | 67 |
| Income Taxes | Note | 16 | Page | 71 |

## Note 3. Business Combinations

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

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

The Company has accounted for the acquisition as a business combination. Under business combination accounting, the assets and liabilities were recorded as of the acquisition date, at their respective fair values, and consolidated with the Company. The excess of the purchase price over the fair value of net assets acquired was recorded as goodwill and largely reflects operational synergies complimentary to the existing business. The operating results of GSK Canada have been included in the consolidated financial statements since July 7, 2015, the date the acquisition was completed. These results are not material to our revenues or operating results.

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

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

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

The assets acquired and liabilities assumed were recorded at fair value at date of acquisition as follows:

| | | |
|---|---|---|
| Goodwill | $ | 2,403 |
| Contractual relationships | | 2,100 |
| Inventory step up | | 230 |
| Assumed liabilities | | (18) |
| | $ | 4,715 |

During the year ended December 31, 2015, the Company incurred transaction costs of $0.1 million, consisting primarily of legal fees, which have been recorded as general and administrative expenses. The Company determined that there was no value to the reacquisition of the Canada exclusivity contract due to the contribution charges of the contractual relationships.

## Note 4. Fair Value Measurements

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

- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.
- Cost approach, which is based on the cost to acquire or construct comparable assets less an allowance for functional and/or economic obsolescence.
- Income approach, which is based on the present value of the future stream of net cash flows.

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

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

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

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

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

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

| | Fair Value Measurements | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| **December 31, 2015** | | | | |
| Recurring Fair Value Measurements: | | | | |
| Cash Equivalents - Money Market Funds | **$ 98,223** | **$ 98,223** | **$ —** | **$ —** |
| Non-Recurring Fair Value Measurements: | | | | |
| Long-lived assets held and used[(1)] | **$ 1,800** | **$ —** | **$ —** | **$ 1,800** |
| **December 31, 2014** | | | | |
| Recurring Fair Value Measurements: | | | | |
| Cash Equivalents - Money Market Funds | $123,141 | $123,141 | $ — | $ — |

(1) Long-lived assets held and used relate to the asset group of the Neighborhood Diabetes business which consists of definite lived intangible assets and property and equipment. During the fourth quarter, the Company recognized an impairment charge on this asset group totaling $9.1 million, which represented the difference between the fair value of the asset group and the carrying value. As a result of the impairment the asset group has been recorded at fair value as of December 31, 2015. The fair value for the asset group was determined using the direct cash flows expected to be received from the disposition of the asset group, which was completed in February 2016 (level 3 input).

### *Debt*

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

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

| | December 31, 2015 | | December 31, 2014 | |
|---|---|---|---|---|
| | Carrying Value | Estimated Fair Value | Carrying Value | Estimated Fair Value |
| 2% Convertible Senior Notes | **$ 171,698** | **$ 207,882** | $ 164,020 | $ 237,475 |

The Company issued $201.3 million in principal amount of 2% Notes (as defined below) in June 2014. The carrying value of the 2% Notes at December 31, 2015 includes a debt discount of $25.7 million which is being amortized as non-cash interest expense over the term of the 2% Notes. The decrease in the estimated fair values of these liabilities from December 31, 2014 to 2015 represents the impact of the quoted bond prices at those dates.

## Note 5. Debt

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

| | As of | |
|---|---|---|
| | **December 31, 2015** | **December 31, 2014** |
| Principal amount of the 2% Convertible Senior Notes | **$ 201,250** | $ 201,250 |
| Unamortized debt discount | **(25,704)** | (32,256) |
| Deferred financing costs | **$ (3,848)** | $ (4,974) |
| Long-term debt, net of discount | **$ 171,698** | $ 164,020 |

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2015** | **2014** | **2013** |
| Contractual coupon interest | **$ 4,025** | $ 4,657 | $ 5,704 |
| Accretion of debt discount | **6,552** | 8,007 | 10,492 |
| Amortization of debt issuance costs | **1,126** | 895 | 590 |
| Loss on extinguishment of long-term debt | **—** | 23,203 | 325 |
| Total interest and other expense | **$ 11,703** | $ 36,762 | $ 17,111 |

### *3.75% Convertible Senior Notes*

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

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

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

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

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

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

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

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

The Company recorded a loss on extinguishment of debt of $23.2 million in connection with the repurchase and redemption of the 3.75% Notes during the year ended December 31, 2014, representing the excess of the $140.3 million allocated to the debt over its carrying value, net of deferred financing costs.

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

No cash interest expense was recorded related to the 3.75% Notes in the year ended December 31, 2015. Cash interest expense related to the 3.75% Notes outstanding was $2.4 million and $5.4 million in the years ended December 31, 2014 and 2013, respectively. There was no non-cash interest expense recorded in the year ended December 31, 2015 related to the 3.75% Notes, compared to $4.9 million and $10.8 million in years ended December 31, 2014 and 2013, respectively.

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

### *2% Convertible Senior Notes*

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

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

The 2% Notes contain provisions that allow for additional interest to the holders of the Notes upon the failure to timely file documents or reports that the Company is required to file with the SEC. The additional interest is at a rate of 0.25% per annum of the principal amount of the notes outstanding for the first 180 days and 0.50% per annum of the principal amount of the notes outstanding for a period up to 360 days.

If the Company is purchased by a company outside of the US, then additional taxes may be required to be paid by the Company under the terms of the 2% Notes.

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

Cash interest expense related to the 2% Notes was $4.0 million and $2.3 million in the years ended December 31, 2015 and 2014, respectively. Non-cash interest expense related to the 2% Notes was $7.7 million and $4.0 million in the years ended December 31, 2015 and 2014, respectively.

As of December 31, 2015, the Company included $171.7 million on its balance sheet in long-term debt related to the 2% Notes.

## Note 6. Capital Lease Obligations

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

The assets acquired under capital leases are being amortized on a straight-line basis over 5 years in accordance with the Company's policy for depreciation of manufacturing equipment. Amortization expense on assets acquired under capital leases is included with depreciation expense. Amortization expense related to these capital leased assets was $2.5 million, $1.3 million and $0.6 million in the years ended December 31, 2015, 2014 and 2013, respectively.

Assets held under capital leases consist of the following (in thousands):

| | As of | |
|---|---|---|
| | **December 31, 2015** | **December 31, 2014** |
| Manufacturing equipment | **$ 13,705** | $ 7,984 |
| Less: Accumulated amortization | **(4,346)** | (1,885) |
| Total | **$ 9,359** | $ 6,099 |

The aggregate future minimum lease payments related to these capital leases as of December 31, 2015, are as follows (in thousands):

| **Years Ending December 31,** | **Minimum Lease Payments** |
|---|---|
| 2016 | $ 5,874 |
| 2017 | 269 |
| Total future minimum lease payments | $ 6,143 |
| Interest expense | (355) |
| Total capital lease obligations | $ 5,788 |

The Company recorded $1.2 million of interest expense on capital leases in the years ended December 31, 2015 and 2014, and $0.4 million of interest expense on capital leases in 2013.

## Note 7. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options, restricted stock units and warrants (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method). Because the Company reported a net loss for the years ended December 31, 2015, 2014 and 2013, all potential dilutive common shares have been excluded from the computation of the diluted net loss per share for all periods presented, as the effect would have been anti-dilutive.

Potential dilutive common share equivalents consist of the following:

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2015** | **2014** | **2013** |
| 3.75% Convertible Senior Notes | **—** | — | 5,487,642 |
| 2.00% Convertible Senior Notes | **4,327,257** | 4,327,257 | — |
| Unvested restricted stock units | **811,965** | 746,612 | 1,011,893 |
| Outstanding options | **2,999,199** | 1,847,669 | 1,828,613 |
| Total dilutive common shares | **8,138,421** | 6,921,538 | 8,328,148 |

## Note 8. Accounts Receivable

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

Accounts receivable from two customers represented approximately 18% and 16% of gross accounts receivable as of December 31, 2015, respectively. As of December 31, 2014 accounts receivable from two customers represented approximately 19% and 10% of gross accounts receivable, respectively.

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

| | As of | |
|---|---|---|
| | **December 31, 2015** | **December 31, 2014** |
| Trade receivables | **$ 52,841** | $ 45,719 |
| Allowance for doubtful accounts | **(4,454)** | (5,837) |
| Total accounts receivable | **$ 48,387** | $ 39,882 |

## Note 9. Inventories

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

Inventories consist of the following (in thousands):

| | As of | |
|---|---|---|
| | **December 31, 2015** | **December 31, 2014** |
| Raw materials | **$ 632** | $ 853 |
| Work-in-process | **1,960** | 254 |
| Finished goods, net | **11,451** | 11,992 |
| Total inventories | **$ 14,043** | $ 13,099 |

## Note 10. Property and Equipment

Property and equipment consist of the following (in thousands):

| | Estimated Useful Life (Years) | As of December 31, 2015 | As of December 31, 2014 |
|---|---|---|---|
| Machinery and equipment | 2-5 | **$ 49,059** | $ 35,690 |
| Lab equipment | 2-3 | **1,615** | 1,585 |
| Computers | 3 | **2,067** | 4,511 |
| Software | 3 | **2,566** | 5,618 |
| Office furniture and fixtures | 3-5 | **1,468** | 1,253 |
| Leasehold improvement | * | **927** | 826 |
| Construction in process | — | **12,275** | 10,502 |
| Total property and equipment | | **$ 69,977** | $ 59,985 |
| Less: accumulated depreciation | | **(28,184)** | (22,916) |
| Total property and equipment | | **$ 41,793** | $ 37,069 |

* Lesser of lease term or useful life of asset

Property and equipment by geographic location consist of the following (in thousands):

| | As of December 31, 2015 | As of December 31, 2014 |
|---|---|---|
| **Property and equipment:** | | |
| U.S. property and equipment | **$ 19,267** | $ 22,814 |
| Non-U.S. property and equipment | **50,710** | 37,171 |
| Less: accumulated depreciation | **(28,184)** | (22,916) |
| Total property and equipment | **$ 41,793** | $ 37,069 |

Depreciation expense related to property and equipment was $11.5 million, $8.2 million, and $6.9 million for the years ended December 31, 2015, 2014 and 2013, respectively. The Company recorded $0.2 million of capitalized interest in the years ended December 31, 2015 and 2014 and $0.3 million of capitalized interest in 2013.

Construction in process mainly consists of infrastructure improvements and internal use software. Depreciation on software does not begin until the assets are integrated into the current systems.

During the years ended December 31, 2015 and 2014, the Company wrote-off $5.4 million and $19.8 million, respectively, of fully depreciated assets, as the assets were no longer in use. No gain or loss was recognized in the year ended December 31, 2014 related to the write-off of these assets.

## Note 11. Other Intangible Assets

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

The Company recorded $32.9 million of other intangible assets as a result of the acquisition of Neighborhood Diabetes in 2011. In December 2015, the Company completed a long-lived asset impairment test for Neighborhood Diabetes and determined that the carrying value of the long-lived asset group, which included intangible assets, exceeded the undiscounted cash flows expected to be generated from the asset group. The Company compared the fair value of the intangible assets and the related asset group, which was estimated based on the subsequent sales price of the asset group as of February 2016. As a result, an impairment charge of $9.0 million was recorded within general and administrative expenses for the year ended December 31, 2015. The impairment charge was allocated on pro-rata basis based on the carrying value of the assets within the asset group. As a result, impairment charges of approximately $7.4 million and $1.6 million, respectively, were recorded on the customer relationship and trade name intangible assets.

The Company recorded $2.1 million of other intangible assets in the year ended December 31, 2015 as a result of the July 2015 acquisition of its Canadian distribution business (see Footnote 3 for further description). The Company determined that the estimated useful life of the contractual relationship asset is 5 years and is amortizing the asset over the estimated lives, based on the expected cash flows of the assets, accordingly. The amortization expense of other intangible assets was approximately $1.0 million for the year ended December 31, 2015, which was recorded in general and administration expenses on the statement of operations.

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

| | As of | | | | | |
|---|---|---|---|---|---|---|
| | December 31, 2015 | | | December 31, 2014 | | |
| | Gross Carrying Amount | Accumulated Amortization | Net Book Value | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
| Customer and contractual relationships, net[1] | **$ 3,399** | **$ (1,000)** | **$ 2,399** | $ 30,100 | $ (18,167) | $ 11,933 |
| Tradename | **322** | **—** | **322** | 2,800 | (669) | 2,131 |
| Total intangible assets [2] | **$ 3,721** | **$ (1,000)** | **$ 2,721** | $ 32,900 | $ (18,836) | $ 14,064 |

(1) Includes foreign currency translation loss of approximately $0.2 million.

(2) As a result of the impairment recorded on the Neighborhood Diabetes asset group, the Company recorded an impairment charge of approximately $9.0 million on the related Neighborhood Diabetes intangible assets. This resulted in the gross carrying value and accumulated amortization of the Neighborhood Diabetes intangibles being reduced by $31,112 and $22,087 respectively at December 31, 2015.

Amortization expense was approximately $4.3 million, $4.0 million and $4.9 million for the years ended December 31, 2015, 2014 and 2013, respectively.

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

| | Amortization Expense | | |
|---|---|---|---|
| Years Ending December 31, | Customer and Contractual Relationships | Tradename | Total |
| 2016 | $ 831 | $ 31 | $ 862 |
| 2017 | 507 | 31 | 538 |
| 2018 | 417 | 31 | 448 |
| 2019 | 341 | 31 | 372 |
| 2020 | 237 | 31 | 268 |
| Thereafter | 66 | 167 | 233 |
| Total | $ 2,399 | $ 322 | $ 2,721 |

As of December 31, 2015, the weighted average amortization period of the Company's intangible assets is approximately 5.8 years.

## Note 12. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

| | Years Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Employee compensation and related items | **$ 17,487** | $ 10,243 |
| Professional and consulting services | **5,661** | 4,373 |
| Sales and use tax | **1,484** | 3,843 |
| Supplier charges | **5,712** | 1,852 |
| Warranty | **1,592** | 981 |
| Other | **6,691** | 3,411 |
| Total accrued expenses and other current liabilities | **$ 38,627** | $ 24,703 |

### *Product Warranty Costs*

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

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

| | Years Ended December 31, | |
|---|---|---|
| | 2015 | 2014 |
| Balance at the beginning of the period | **$ 2,614** | $ 3,090 |
| Warranty expense | **4,964** | 1,665 |
| Warranty claims settled | **(3,426)** | (2,141) |
| Balance at the end of the period | **$ 4,152** | $ 2,614 |

| | As of | |
|---|---|---|
| | December 31, 2015 | December 31, 2014 |
| Composition of balance: | | |
| Short-term | **$ 1,592** | $ 981 |
| Long-term | **2,560** | 1,633 |
| | **$ 4,152** | $ 2,614 |

## Note 13. Commitments and Contingencies

### *Operating Leases*

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

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

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

The aggregate future minimum lease payments related to these leases as of December 31, 2015, are as follows (in thousands):

| Years Ending December 31, | Minimum Lease Payments |
|---|---|
| 2016 | 2,285 |
| 2017 | 2,322 |
| 2018 | 2,306 |
| 2019 | 2,181 |
| 2020 | 2,146 |
| Thereafter | 3,934 |
| Total | $ 15,174 |

### *Legal Proceedings*

The Company is in the process of responding to a revised audit report received in December 2015 on behalf of the Centers for Medicare and Medicaid Services and the State of New York alleging overpayment of certain Medicaid claims to Neighborhood Diabetes.

The Company is in the process of responding to a draft audit report received in June 2015 from the Connecticut Department of Social Services Office of Quality Assurance alleging overpayment of certain Medicaid claims to Neighborhood Diabetes.

The Company is in the process of responding to a revised audit report received in February 2016 from the Massachusetts Department of Revenue for sales and use tax audits related to Insulet Corporation.

The Company is in the process of responding to a revised audit report received in February 2016 from the Massachusetts Department of Revenue for sales and use tax audits related to Neighborhood Diabetes.

The Company has determined that it is probable that a loss has been incurred for the four audits discussed above and has recorded an aggregate liability of $1.7 million through general and administrative expense as of December 31, 2015 based on the Company's current estimate of potential loss.

In October 2013, the Company received a letter from the Office of the Massachusetts Attorney General contending that prior to September 2012 Neighborhood Diabetes engaged in improper sales practices by automatically refilling certain prescriptions for MassHealth patients. The Company responded to this letter, stating that Neighborhood Diabetes' refill practices during the period in question were appropriate and consistent with applicable laws. The Company entered into a Settlement and Release Agreement and paid approximately $1.5 million in connection with the settlement of this matter in the first quarter of 2015. This amount was previously accrued as of December 31, 2014.

In July 2015, the Company reached a settlement agreement for $0.8 million with the Massachusetts Department of Revenue for sales and use tax audits related to Neighborhood Diabetes, which included a $2.9 million reduction of the previously recorded liability and a credit to general and administrative expenses in the second quarter.

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

In November 2015, the Company initiated a voluntary Field Safety Notification after identifying 18 lots of OmniPod product which been distributed and had a slight increase in the reported cases in which the needle mechanism failed to deploy or there was a delay in the deployment of the needle mechanism. There were an additional 41 lots of product manufactured in this condition which were contained prior to distribution and will ultimately be scrapped. The Company incurred $0.4 million as warranty expense due to this Field Safety Notification.

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

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

## Note 14. Equity

The Company accounts for stock-based compensation under the provisions of FASB ASC 718-10, *Compensation — Stock Compensation* ("ASC 718-10"), which requires all share-based payments to employees, including grants of employee stock options and restricted stock units, to be recognized in the income statement based on their fair values. Share-based payments that contain performance conditions are recognized when such conditions are probable of being achieved.

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

Stock-based compensation expense related to share-based awards recognized in the years ended December 31, 2015, 2014 and 2013 was $19.2 million, $22.5 million and $12.7 million, respectively, and was calculated on awards ultimately expected to vest. At December 31, 2015, the Company had $37.6 million of total unrecognized compensation expense related to unvested stock options and restricted stock units.

### *Stock Options*

In May 2007, in conjunction with the Company's initial public offering, the Company adopted its 2007 Stock Option and Incentive Plan (the "2007 Plan"). The 2007 Plan was amended and restated in November 2008, May 2012 and May 2015 to provide for the issuance of additional shares and to amend certain other provisions. Under the 2007 Plan, awards may be granted to persons who are, at the time of grant, employees, officers, non-employee directors or key persons (including consultants and prospective employees) of the Company. The 2007 Plan provides for the granting of stock options, restricted stock units, stock appreciation rights, deferred stock awards, restricted stock, unrestricted stock, cash-based awards, performance share awards or dividend equivalent rights. Options granted under the 2007 Plan generally vest over a period of four years and expire ten years from the date of grant. As of December 31, 2015, 6,152,904 shares remain available for future issuance under the 2007 Plan.

In the year ended December 31, 2015, the Company awarded 194,500 shares of performance-based incentive stock options. The stock options were granted under the 2007 Plan and vest over a four year period from the grant date with the potential of an accelerated vesting period pursuant to the achievement of certain performance conditions.

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

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and the following assumptions, including expected volatility, expected life of the awards, the risk-free interest rate, and the dividend yield.

- Expected volatility measures the amount that a stock price has fluctuated or is expected to fluctuate during a period and is computed over expected terms based upon the historical volatility of the Company's stock.
- The expected life of the awards is estimated based on the midpoint scenario, which combines historical exercise data with hypothetical exercise data for outstanding options, as the Company believes this data currently represents the best estimate of the expected life of a new employee option. The Company stratifies its employee population into two groups based upon organizational hierarchy.
- The risk-free interest rate assumption is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.
- The dividend yield assumption is based on Company history and expectation of paying no dividends. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest. If the Company’s actual forfeiture rate is materially different from its estimate, the stock-based compensation expense could be significantly different from what the Company has recorded in the current period.

The Company evaluates the assumptions used to value the awards on a quarterly basis and if factors change and different assumptions are utilized, stock-based compensation expense may differ significantly from what has been recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense.

The estimated grant date fair values of the employee stock options were calculated using the Black-Scholes option pricing model, based on the following assumptions:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Risk-free interest rate | 1.16% - 1.75% | 0.12% - 1.98% | 0.93% - 1.91% |
| Expected term (in years) | 4.86 - 5.25 | 1.0 - 6.25 | 6.25 |
| Dividend yield | — | — | — |
| Expected volatility | 37% - 38% | 37% - 63% | 63% - 66% |

The Company grants share-based awards to employees in the form of options to purchase the Company's common stock, the ability to purchase stock at a discounted price under the employee stock purchase plan and restricted stock units. The weighted average grant date fair value of options granted for the years ended December 31, 2015, 2014 and 2013 was $11.09, $15.88 and $15.42, respectively.

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

| | Number of Options (#) | Weighted Average Exercise Price ($) | Aggregate Intrinsic Value ($) |
|---|---|---|---|
| | | | (In thousands) |
| Balance, December 31, 2014 | 1,847,669 | $ 26.99 | |
| Granted | 2,002,141 | 32.48 | |
| Exercised[1] | (449,149) | 16.03 | $ 8,582 |
| Canceled | (401,462) | 33.20 | |
| Balance, December 31, 2015 | 2,999,199 | $ 31.37 | $ 20,743 |
| Vested, December 31, 2015[2] | 947,909 | $ 27.91 | $ 9,613 |
| Vested and expected to vest, December 31, 2015[2][3] | 2,685,514 | | $ 18,899 |

(1) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of the date of exercise and the exercise price of the underlying options. The aggregate intrinsic value of options exercised in the years ended December 31, 2015, 2014 and 2013 was $8.6 million, $20.4 million and $17.8 million, respectively,

(2) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of December 31, 2015, and the exercise price of the underlying options.

(3) Represents the number of vested options as of December 31, 2015, plus the number of unvested options expected to vest as of December 31, 2015, based on the unvested options outstanding at December 31, 2015, adjusted for the estimated forfeiture.

At December 31, 2015 there were 2,999,199 options outstanding with a weighted average exercise price of $31.37 and a weighted average remaining contractual life of 8.4 years. At December 31, 2015 there were 947,909 options exercisable with a weighted average exercise price of $27.91 and a weighted average remaining contractual life of 6.9 years.

Employee stock-based compensation expense related to stock options in the years ended December 31, 2015, 2014 and 2013 was $9.2 million, $7.7 million and $4.6 million, respectively, and was based on awards ultimately expected to vest. At December 31, 2015, the Company had $20.7 million of total unrecognized compensation expense related to stock options that will be recognized over a weighted average vesting period of 1.4 years.

### *Employee Stock Purchase Plan*

The Employee Stock Purchase Plan ("ESPP") authorizes the issuance of up to a total of 380,000 shares of common stock to participating employees.

All employees who are employed by the Company 20 days prior to the first day of the offering period and whose customary employment is for more than 20 hours a week are eligible to participate in the ESPP. Any employee who owns 5% or more of the voting power or value of shares of the Company's common stock is not eligible to purchase shares under the ESPP.

The Company will make one or more offerings each year to employees to purchase stock under the ESPP. Offerings usually begin on each January 1 and July 1 and continue for six-month periods, referred to as offering periods.

Each employee who is a participant in the Company's ESPP may purchase shares by authorizing payroll deductions of up to 10% of his or her cash compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the common stock on the last day of the offering period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with the Company for any reason.

The ESPP may be terminated or amended by the Board of Directors at any time. An amendment to increase the number of shares of common stock that is authorized under the ESPP and certain other amendments require the approval of stockholders.

The Company issued 22,039 shares of common stock in 2015, 13,620 shares of common stock in 2014 and 12,970 shares of common stock in 2013 to employees participating in the ESPP. The Company recorded approximately $0.1 million of stock-based compensation expense related to the ESPP in each of the years ended December 31, 2015, 2014 and 2013.

### *Restricted Stock Units*

In the year ended December 31, 2015, the Company awarded 708,446 restricted stock units to certain employees and non-employee members of the Board of Directors, which included 114,287 restricted stock units subject to the achievement of performance conditions (performance-based restricted stock units). The Company recognized stock compensation expense of $1.4 million in 2015 as it expects a portion of the performance-based restricted stock units granted will be earned based on its evaluation of the performance criteria at December 31, 2015. The restricted stock units were granted under the 2007 Plan and vest annually over a three year period from the grant date.

The restricted stock units granted have a weighted average fair value of $30.37 per share based on the closing price of the Company's common stock on the date of grant. The restricted stock units granted during the year ended December 31, 2015 were valued at approximately $21.5 million on their grant date, and the Company is recognizing the compensation expense over the vesting period. Approximately $8.5 million, $14.7 million and $8.0 million of stock-based compensation expense related to the vesting of non-performance based restricted stock units was recognized in the years ended December 31, 2015, 2014 and 2013, respectively. Approximately $16.9 million of the fair value of the restricted stock units remained unrecognized as of December 31, 2015 and will be recognized over a weighted average period of 1.1 years. Under the terms of the awards, the Company will issue shares of common stock on each of the vesting dates.

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

| | Number of Shares (#) | Weighted Average Fair Value ($) |
|---|---|---|
| Balance, December 31, 2014 | 746,612 | $ 31.40 |
| Granted | 708,446 | 30.37 |
| Vested | (271,118) | 28.96 |
| Forfeited | (371,975) | 33.00 |
| Balance, December 31, 2015 | 811,965 | $ 30.58 |

### *Shareholder Rights Plan*

In November 2008, the Board of Directors of the Company adopted a shareholder rights plan (the "Shareholder Rights Plan"), as set forth in the Shareholder Rights Agreement between the Company and the rights agent, the purpose of which is, among other things, to enhance the ability of the Board of Directors to protect

shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of the Company is made in the future. The Shareholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring the Company or a large block of the Company's common stock.

In connection with the adoption of the Shareholder Rights Plan, the Board of Directors of the Company declared a dividend distribution of one preferred stock purchase right (a "Right") for each outstanding share of common stock to stockholders of record as of the close of business on November 15, 2008. In addition, one Right will automatically attach to each share of common stock issued between November 15, 2008 and the distribution date. The Rights currently are not exercisable and are attached to and trade with the outstanding shares of common stock. Under the Shareholder Rights Plan, the Rights become exercisable if a person or group becomes an "acquiring person" by acquiring 15% or more of the outstanding shares of common stock or if a person or group commences a tender offer that would result in that person or group owning 15% or more of the common stock. If a person or group becomes an "acquiring person," each holder of a Right (other than the acquiring person) would be entitled to purchase, at the then-current exercise price, such number of shares of the Company's preferred stock which are equivalent to shares of common stock having a value of twice the exercise price of the Right. If the Company is acquired in a merger or other business combination transaction after any such event, each holder of a Right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the Right.

## Note 15. Defined Contribution Plan

The Insulet 401(k) Retirement Plan (the "401(k) Plan") is a defined contribution plan in the form of a qualified 401(k) plan, in which substantially all employees are eligible to participate upon hire. Eligible employees may elect to contribute 100% of their eligible compensation up to the IRS maximum. The Company has the option of making both matching contributions and discretionary profit-sharing contributions to the 401(k) Plan. Since 2011, the Company has offered a discretionary match of 50% for the first 6% of an employee's salary that was contributed to the 401(k) Plan. The Company match vests after the employee attains one year of service. The total amount contributed by the Company under the 401(k) Plan was $1.8 million, $1.2 million and $1.0 million for the years ended December 31, 2015, 2014 and 2013, respectively.

## Note 16. Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect in the years in which the differences are expected to reverse. The Company reviews its deferred tax assets for recoverability considering historical profitability, projected future taxable income, and the expected timing of the reversals of existing temporary differences and tax planning strategies. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company follows the provisions of FASB ASC 740-10, *Income Taxes* ("ASC 740-10") on accounting for uncertainty in income taxes recognized in its financial statements. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense.

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

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

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Current: | | | |
| Federal | **$ —** | $ — | $ (76) |
| State | **73** | 58 | 88 |
| Non-U.S. | **321** | 3 | 4 |
| Total current expense | **394** | 61 | 16 |
| Deferred: | | | |
| Federal | **76** | 76 | 76 |
| State | **2** | 5 | 8 |
| Non-U.S. | **(181)** | — | — |
| Total deferred expense | **(103)** | 81 | 84 |
| Total income tax expense | **$ 291** | $ 142 | 100 |

The following table reconciles the federal statutory income rate to the Company's effective income tax rate:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2015 | 2014 | 2013 |
| Tax at U.S. statutory rate | **34.00 %** | 34.00 % | 34.00 % |
| **Changes from statutory rate:** | | | |
| State taxes, net of federal benefit | **4.56** | 4.04 | (4.21) |
| Tax credits | **1.27** | 1.26 | 4.98 |
| Permanent items | **(1.77)** | 0.71 | (5.49) |
| Change in valuation allowance | **(38.77)** | (38.79) | (29.32) |
| Other | **0.31** | (1.50) | (0.18) |
| Effective income tax rate | **(0.40)%** | (0.28)% | (0.22)% |

Pre-tax income attributable to the Company's operations located outside the U.S. was approximately $0.3 million, $0.1 million and $0.1 million for 2015, 2014 and 2013, respectively. In general, it is the Company's practice and intention to reinvest the earnings of its non-U.S. subsidiaries in those operations. As of December 31, 2015, the Company has chosen to indefinitely reinvest approximately $0.1 million of earnings of certain of its non-U.S. subsidiaries. Generally, such amounts become subject to U.S taxation upon the remittance of dividends and under certain other circumstances. No provision has been recorded for U.S. income taxes that could be incurred upon repatriation. It is not practical to estimate the amount of deferred tax liability related to such earnings.

Significant components of the Company's deferred tax assets (liabilities) consists of the following (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | **2015** | **2014** |
| Deferred tax assets: | | |
| Net operating loss carryforwards | **$ 178,048** | $ 161,888 |
| Start up expenditures | **1,168** | 1,416 |
| Tax credits | **8,173** | 6,968 |
| Provision for bad debts | **1,981** | 2,174 |
| Depreciation and amortization | **2,528** | 897 |
| Other | **13,102** | 9,777 |
| Total deferred tax assets | **$ 205,000** | $ 183,120 |
| Deferred tax liabilities: | | |
| Prepaids | **$ (1,249)** | $ (935) |
| Amortization of acquired intangibles | **(662)** | (5,218) |
| Amortization of debt discount | **(9,503)** | (11,947) |
| Goodwill | **(383)** | (304) |
| Total deferred tax liabilities | **$ (11,797)** | $ (18,404) |
| Valuation allowance | **$ (193,405)** | $ (165,020) |
| Net deferred tax liabilities | **$ (202)** | $ (304) |

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

A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of the available evidence, both positive and negative, the Company has determined that a $193.4 million valuation allowance at December 31, 2015 is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The Company provided a valuation allowance for the full amount of its net deferred tax asset for the years ended December 31, 2015 and 2014 because it is not more likely than not that the future tax benefit will be realized. In the year ended December 31, 2015, the Company's valuation allowance increased by $28.4 million to $193.4 million from the balance at December 31, 2014 of $165.0 million. The change in the valuation allowance is primarily attributable to an increase in net operating loss carryforwards along with a decrease in deferred tax liabilities related to acquired intangibles as a result of an impairment charge recorded during the period.

At December 31, 2015, the Company had approximately $546.7 million, $289.6 million and $8.2 million of federal net operating loss carryforwards, state net operating loss carryforwards and research and development and other tax credits, respectively. If not utilized, these federal carryforwards will begin to expire in 2020 and will continue to expire through 2035, and the state carryforwards will continue to expire through 2035. At December 31, 2014, the Company had approximately $500.6 million, $246.7 million and $7.0 million of federal net operating loss carryforwards, state net operating loss carryforwards and research and development and other tax credits, respectively. The utilization of such net operating loss carryforwards and the realization of tax benefits in future years depends predominantly upon having taxable income. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss carryforwards which may be used in future years. There will be a yearly limitation placed on the amount of net operating loss available for use in future years. Additionally, it is probable that a portion of the research and development tax credit carryforward may not be available to offset future income.

As a result of certain realization requirements of ASC 718, the table of deferred tax assets and liabilities does not include certain deferred tax assets as of December 31, 2015 and December 31, 2014, that arose directly from tax deductions related to equity compensation greater than compensation recognized for financial reporting. Equity will be increased by $22.6 million if and when such deferred tax assets are ultimately realized. The Company utilizes ASC 740 ordering when excess tax benefits have been realized.

The Company had no unrecognized tax benefits at December 31, 2015.

## Note 17. Change in Accounting Estimate

The Company capitalizes eligible software development costs, including salaries and payroll-related costs of employees who devote time to the development. Capitalization begins when a detail program design is completed and technological feasibility has been established. These costs are amortized on a straight-line basis over the estimated useful life. In the second quarter of 2015, based on changes in one of the Company's ongoing projects, the Company determined that the detailed program designs were no longer sufficiently complete to establish technological feasibility of this project. As such, all costs previously capitalized for this project, approximately $1.3 million, and all subsequent costs incurred through December 31, 2015, approximately $9.2 million, have been recorded to research and development expense.

The Company records inventory at cost according to ASU No. 330, *Inventory* ("ASU 330"). In the third quarter of 2015, the Company identified that certain lots of OmniPods had increased complaints relating to the deployment of the needle mechanism. The Company believes that all goods produced with the specific tooling changes of needle mechanism components are subject to replacement, including certain OmniPod lots that were held as inventory. As such, the Company has determined that it will not recover any amounts related to this inventory. Accordingly, this change in estimate increased our cost of revenue in the year ended December 31, 2015 by approximately $7.3 million.

## 18. Subsequent Events

In February 2016, the Company sold Neighborhood Diabetes to Liberty Medical for approximately $5 million in cash, subject to certain customary closing adjustments. Neighborhood Diabetes did not meet the held for sale criteria and was not presented in discontinued operations as of December 31, 2015 as a sale was not approved by the Board of Directors as of December 31, 2015.

The major classes of assets and liabilities for Neighborhood Diabetes consists of the following (in thousands):

| | December 31, 2015 |
|---|---|
| **ASSETS** [1] | |
| Current assets | **$ 9,252** |
| Total assets | **11,208** |
| **LIABILITIES** [1] | |
| Current liabilities | **$ 5,319** |
| Total liabilities | **5,703** |

(1) These amounts represent the direct assets and liabilities, including intangible assets, that are that are expected to be transferred as part of the sale.

## 19. Quarterly Data (Unaudited)

| | 2015 Quarters ended | | | |
|---|---|---|---|---|
| | December 31[1] | September 30 | June 30 | March 31 |
| | (In thousands, except per share data) | | | |
| Revenue | $ 100,119 | $ 87,303 | $ 75,588 | $ 61,215 |
| Gross profit | $ 45,321 | $ 35,651 | $ 34,375 | $ 32,807 |
| Net loss | $ (27,327) | $ (18,927) | $ (15,432) | $ (11,834) |
| Net loss per share | $ (0.48) | $ (0.33) | $ (0.27) | $ (0.21) |

(1) Included in net loss for the fourth quarter of 2015 was a charge of $9.1 million related to the impairment of the Neighborhood Diabetes asset group.

| | 2014 Quarters ended | | | |
|---|---|---|---|---|
| | December 31 | September 30 | June 30[2] | March 31 |
| | (In thousands, except per share data) | | | |
| Revenue | $ 72,561 | $ 74,985 | $ 72,013 | $ 69,161 |
| Gross profit | $ 36,673 | $ 38,042 | $ 35,765 | $ 32,808 |
| Net loss | $ (5,400) | $ (10,845) | $ (29,111) | $ (6,144) |
| Net loss per share | $ (0.10) | $ (0.19) | $ (0.53) | $ (0.11) |

(2) Included in net loss for the second and third quarters of 2014 was a charge of $18.9 million and $4.3 million, respectively, related to the loss from extinguishment of long-term debt.

## SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

The following table sets forth activities in our accounts receivable reserve and deferred tax valuation allowance accounts:

| Description | Balance at Beginning of Period | Additions Charged to Costs and Expenses | Deductions | Balance at End of Period |
|---|---|---|---|---|
| | | (In thousands) | | |
| **Year Ended December 31, 2015** | | | | |
| Allowance for doubtful accounts | **$ 5,837** | **$ 1,184** | **$ 2,567** | **$ 4,454** |
| Deferred tax valuation allowance | **165,020** | **28,418** | **33** | **193,405** |
| **Year Ended December 31, 2014** | | | | |
| Allowance for doubtful accounts | $ 7,133 | $ 3,254 | $ 4,550 | $ 5,837 |
| Deferred tax valuation allowance | 158,323 | 21,070 | 14,373 | 165,020 |
| **Year Ended December 31, 2013** | | | | |
| Allowance for doubtful accounts | $ 6,627 | $ 4,741 | $ 4,235 | $ 7,133 |
| Deferred tax valuation allowance | 145,927 | 32,050 | 19,654 | 158,323 |

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## Item 9A. 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 December 31, 2015. 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 December 31, 2015, 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 during the three months ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### *Management's Annual Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a — 15(f). Our internal control system was designed to provide reasonable assurance to our management and the Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 2013 (“COSO”) in Internal Control — Integrated Framework (the COSO criteria).

The scope of management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2015 excluded an assessment of the internal control over financial reporting of Insulet Canada. Insulet Canada is the Company’s wholly owned subsidiary which is comprised of the assets and operations of GSK's Canadian distribution business which was acquired during the current year. The results of this acquired company are included in our 2015 consolidated financial statements and represent approximately 3% of consolidated total assets as of December 31, 2015 and 2% (for a partial year) of consolidated revenue for Insulet Corporation for the year then ended.

Based on our assessment we believe that, as of December 31, 2015, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which appears below.

## Report of Independent Registered Public Accounting Firm

**The Board of Directors and Stockholders of**

**Insulet Corporation**

We have audited Insulet Corporation's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework (the COSO criteria). Insulet Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Insulet Canada. Insulet Canada is the Company's wholly owned subsidiary which is comprised of the assets and operations of GSK's Canadian distribution business which was acquired during the current year. Insulet Canada is included in the 2015 consolidated financial statements of Insulet Corporation and represents approximately 3% of consolidated total assets as of December 31, 2015 and 2% (for a partial year) of consolidated revenue for Insulet Corporation for the year then ended. Our audit of internal control over financial reporting of Insulet Corporation also did not include an evaluation of the internal control over financial reporting of Insulet Canada.

In our opinion, Insulet Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015 of Insulet Corporation and our report dated February 29, 2016 expressed an unqualified opinion.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 29, 2016

## ITEM 9B. OTHER INFORMATION

None.

## PART III

### *Item 10. Directors, Executive Officers and Corporate Governance*

Certain information required by this Item 10 relating to our directors, executive officers and corporate governance is incorporated by reference herein from our proxy statement in connection with our 2016 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission (the "SEC") not later than 120 days after the close of our year ended December 31, 2015.

**Audit Committee Financial Expert**

As of December 31, 2015, the audit committee of our board of directors consisted of Steven Sobieski (Chairman), Regina Sommer, Joseph Zakrzewski and Dr. Jessica Hopfield. In February 2016, David A. Lemoine joined the board of directors and the audit committee of the board of directors. Our board of directors has determined that each member of the audit committee is "independent" as that term is defined in the rules of the SEC and the applicable Nasdaq rules. Our board of directors has determined that Mr. Sobieski, Ms. Sommer, and Mr. Lemoine all qualify as an "audit committee financial expert" as such term is defined in the rules of the SEC. In making its determination, our board of directors considered the nature and scope of the experiences and responsibilities these members have previously had with reporting companies. Stockholders should understand that this designation is a disclosure requirement of the SEC related to the experience and understanding of the members of the audit committee with respect to certain accounting and auditing matters. The designation does not impose upon any duties, obligations or liability upon the members of the audit committee that are greater than are generally imposed on other members of the audit committee and our board of directors and designation as an audit committee financial expert pursuant to this SEC requirement does not affect the duties, obligations or liability of any other member of the audit committee or the board of directors.

**Code of Ethics**

We have adopted a "code of ethics," as defined by regulations promulgated under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934 as amended, that applies to all of our directors and employees worldwide, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the Code of Business Conduct and Ethics is available at the Corporate Governance section of our website at http://www.insulet.com. A copy of the Code of Business Conduct and Ethics may also be obtained, free of charge, upon a request directed to: 600 Technology Park Drive, Suite 200, Billerica, Massachusetts 01821, Attention: Secretary. We intend to disclose any amendment to or waiver of a provision of the Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, by posting such information on our website available at http://www.insulet.com.

For more corporate governance information, you are invited to access the Corporate Governance section of our website available at http://www.insulet.com.

### *Item 11. Executive Compensation*

Certain information required by this Item 11 relating to remuneration of directors and executive officers and other transactions involving management is incorporated by reference herein from our proxy statement in connection with our 2016 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2015.

### *Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

Certain information required by this Item 12 relating to security ownership of certain beneficial owners and management is incorporated by reference herein from our proxy statement in connection with our 2016 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2015. For information on securities authorized for issuance under equity compensation plans, see the section entitled "Market for Registrant's Common Equity, Related Stockholders Matters, and Issuer Purchases of Equity Securities " in Part II, Item 5. in this Annual Report on Form 10-K.

### *Item 13. Certain Relationships and Related Transactions, and Director Independence*

Certain information required by this Item 13 relating to certain relationships and related transactions, and director independence is incorporated by reference herein from our proxy statement in connection with our 2016 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2015.

### *Item 14. Principal Accounting Fees and Services*

Certain information required by this Item 14 regarding principal accounting fees and services is set forth under "Principal Accounting Fees and Services" in our proxy statement in connection with our 2016 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2015.

## Item 15. Exhibits, Financial Statement Schedules

(A)(1) FINANCIAL STATEMENTS

The following consolidated financial statements of Insulet Corporation are included in Item 8 hereof:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets - Years ended December 31, 2015 and 2014

Consolidated Statements of Operations - Years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Comprehensive Loss - Years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Stockholders' Equity - Years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Cash Flows - Years ended December 31, 2015, 2014 and 2013

Notes to Consolidated Financial Statements

(A)(2) FINANCIAL STATEMENT SCHEDULES

Certain schedules to the consolidated financial statements have been omitted if they were not required by Article 9 of Regulation S-X or if, under the related instructions, they were inapplicable, or the information was contained elsewhere herein.

(A)(3) EXHIBITS

The exhibits listed in the Exhibit Index following the signature page of this Form 10-K are filed herewith or are incorporated herein by reference to other SEC filings.

### 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: February 29, 2016

/s/ Patrick J. Sullivan

Patrick J. Sullivan

President and Chief Executive Officer
(Principal Executive Officer)

Date: February 29, 2016

/s/ Michael L. Levitz

Michael L. Levitz

Chief Financial Officer
(Principal Financial and Accounting Officer)

## POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Insulet Corporation, hereby severally constitute and appoint Patrick J. Sullivan and Michael L. Levitz, and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us in our names in the capacities indicated below, on all amendments to this Report, and generally to do all things in our names and on our behalf in such capacities to enable Insulet Corporation to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities on February 29, 2016.

| Signature | Title |
|---|---|
| /s/ Patrick J. Sullivan<br>Patrick J. Sullivan | President, Chief Executive Officer and Director<br>(Principal Executive Officer) |
| /s/ Michael L. Levitz<br>Michael L. Levitz | Chief Financial Officer<br>(Principal Financial and Accounting Officer) |
| /s/ Sally Crawford<br>Sally Crawford | Director |
| /s/ John Fallon, M.D.<br>John Fallon, M.D. | Director |
| /s/ Dr. Jessica Hopfield<br>Dr. Jessica Hopfield | Director |
| /s/ David A. Lemoine<br>David Lemoine | Director |
| /s/ Timothy J. Scannell<br>Timothy J. Scannell | Director |
| /s/ Steven Sobieski<br>Steven Sobieski | Director |
| /s/ Regina Sommer<br>Regina Sommer | Director |
| /s/ Joseph Zakrzewski<br>Joseph Zakrzewski | Director |

## EXHIBIT INDEX

Listed and indexed below are all Exhibits filed as part of this report.

| Number | Description |
|---|---|
| 3.1(4) | Eighth Amended and Restated Certificate of Incorporation of the Registrant |
| 3.2(40) | Amended and Restated By-laws of the Registrant |
| 4.1(4) | Specimen Stock Certificate |
| 4.2(9) | Certificate of Designations, Preferences and Rights of a Series of Preferred Stock of Insulet Corporation classifying and designating the Series A Junior Participating Cumulative Preferred Stock |
| 4.3(9) | Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Registrar and Transfer Company, as Rights Agent |
| 4.4(11) | Amendment, dated September 25, 2009, to Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Computershare Trust Company, As Rights Agent |
| 4.5(27) | Indenture, dated as of June 9, 2014, between Insulet Corporation and Wells Fargo Bank, National Association, as Trustee |
| 4.6(27) | Form of 2.00% Convertible Senior Notes due 2019 (included in Exhibit 33.3) |
| 10.1(2)+ | Development and License Agreement between TheraSense, Inc. and Insulet Corporation, dated January 23, 2002 |
| 10.2(1) | Insulet Corporation 2000 Stock Option and Incentive Plan |
| 10.3(31) | Form of Non-Qualified Stock Option Agreement for Company Employees under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.4(31) | Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.5(31) | Form of Time Vesting Restricted Stock Unit Agreement for Employees under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.6(31) | Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.7(1) | Employment Agreement between Duane DeSisto and Insulet Corporation, dated May 4, 2005 |
| 10.8(3) | Form of Employee Non-Competition and Non-Solicitation Agreement by and between Insulet Corporation and each of its executive officers |
| 10.9(5)+ | Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated January 3, 2007 |
| 10.10(5)+ | Addendum to Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated October 4, 2007 |
| 10.11(6)+ | Amendment No. 1 to Development and License Agreement, dated as of March 3, 2008, by and between Abbott Diabetes Care, Inc. (ADC), formerly known as TheraSense, Inc., and Insulet Corporation. |
| 10.12(31) | Amended and Restated Executive Severance Plan |
| 10.13(8) | Seconded Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.14(12) | Offer Letter by and between Insulet Corporation and Brian Roberts, dated March 2, 2009 |
| 10.15(14) | Offer Letter by and between Insulet Corporation and Peter Devlin, dated July 16, 2009 |
| 10.16(32) | Insulet Corporation Second Amended and Restated 2007 Employee Stock Purchase Plan |
| 10.17(16)+ | Distribution Agreement dated January 4, 2010 by and between Insulet Corporation and Ypsomed Distribution AG |
| 10.18(17)+ | Amendment No. 2 to Development and License Agreement, dated as of June 30, 2010, by and between ADC formerly known as TheraSense, Inc., and Insulet Corporation |
| 10.19(20) | Offer Letter by and between Insulet Corporation and Paul Lucidi, dated May 11, 2010 |
| 10.20(21) | Offer Letter by and between Insulet Corporation and Charles Liamos |

| Number | Description |
|---|---|
| 10.21(22) | Amendment No. 1 to Distribution Agreement dated April 10, 2012 by and between Insulet Corporation and Ypsomed Distribution AG |
| 10.22(22) | Amendment No. 3 to Development and License Agreement, dated as of April 5, 2011 by and between ADC and Insulet Corporation |
| 10.23(22) | Amendment No. 4 to Development and License Agreement, dated as of March 29, 2012 by and between ADC and Insulet Corporation |
| 10.24(23) | Amendment No. 5 to Development and License Agreement, dated as of June 21, 2012 by and between ADC and Insulet Corporation |
| 10.25(24)+ | Settlement and Cross-License Agreement, dated September 18, 2013, by and among the Company and Medtronic Inc., Medtronic MiniMed Inc., and Medtronic Puerto Rico Operations Co. |
| 10.26(31) | Form of Time Vesting Restricted Stock Unit Agreement for Singapore Employees under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.27(31) | Form of Time Vesting Restricted Stock Unit Agreement for Non-Employee Directors under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.28(31) | Form of Incentive Stock Option Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.29(31) | Form of Non-Qualified Stock Option Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.30(31) | Form of Time Vesting Restricted Stock Unit Agreement for Employees at the Vice President Level and Above under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.31(31) | Form of Time Vesting Restricted Stock Unit Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.32(26) | Convertible Notes Underwriting Agreement dated June 4, 2014 between Insulet Corporation and J.P. Morgan Securities LLC, as underwriter. |
| 10.33(28) | Third Addendum to Manufacturing Services Agreement between Insulet Corporation and Flextronics Marketing (L) Ltd., dated May 29, 2014 |
| 10.34(28) | Four Addendum to Manufacturing Services Agreement between Insulet Corporation and Flextronics Marketing (L) Ltd., dated July 15, 2014 |
| 10.35(28) | Fifth Addendum to Manufacturing Services Agreement between Insulet Corporation and Flextronics Marketing (L) Ltd., dated July 15, 2014 |
| 10.36(29) | Retirement Agreement by and between Insulet Corporation and Duane DeSisto dated September 16, 2014 |
| 10.37(29) | Employment Agreement by and between Insulet Corporation and Patrick J. Sullivan dated September 16, 2014 |
| 10.38(30) | Agreement by and between Insulet Corporation and Brian K. Roberts dated November 5, 2014 |
| 10.39(31) | Form of Non-Qualified Stock Option Agreement for Patrick J. Sullivan under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.40(31) | Form of Incentive Stock Option Agreement for Christopher Barber under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.41(31) | Form of Time Vesting Restricted Stock Unit Agreement for Christopher Barber under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.42(31) | Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan - October 2014 New Hires |
| 10.43(33) | Rules and Conditions for the Directors' Compensation Program |
| 10.44(33) | Form of UK Time Vesting Restricted Stock Unit Agreement for Employees at the Vice President Level and Above under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.45(33) | Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan - 2015 Sales Plan |
| 10.46(33) | Form of Non-Qualified Stock Option Agreement for Brad Thomas under the Second Amended and Restated 2007 Stock Option and Incentive Plan |

| Number | Description |
|---|---|
| 10.47(33) | Form of Non-Qualified Stock Option Agreement for Shacey Petrovic under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.48(33) | Form of Time Vesting Restricted Stock Unit Agreement for Brad Thomas under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.49(33) | Form of Time Vesting Restricted Stock Unit Agreement for Shacey Petrovic under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.50(33) | Form of UK Non-Qualified Stock Option Agreement for Employees at the Vice President Level and Above under the Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.51(34) | Agreement by and between Insulet Corporation and Michael Levitz dated March 23, 2015 |
| 10.52(34) | Agreement by and between Insulet Corporation and Allison Dorval dated April 1, 2015 |
| 10.53(35) | Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.54(36) | Agreement by and between Insulet Corporation and Patrick Ryan dated June 25, 2015 |
| 10.55(37) | Form of Canada Non-Qualified Stock Option Agreement for Company Employees under the Insulet Corporation Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.56(37) | Form of Canada Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.57(37) | Form of Performance Vesting Restricted Stock Unit Agreement under the Insulet Corporation Second Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.58(37) | Form of Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.59 | Form of Non-Executive Employee Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.60 | Form of Non-Executive Employee Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.61 | Form of Section 16 Officer Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.62 | Form of Section 16 Officer Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.63 | Form of Vice President Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.64 | Form of Vice President Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan |
| 10.65(38) | Agreement by and between Insulet Corporation and Peter J. Devlin dated January 6, 2015 |
| 10.66(39) | Form of Non-Qualified Stock Option Agreement for Michael Levitz, David Colleran and Michael Spears |
| 10.67(39) | Form of Time Vesting Restricted Stock Unit Agreement for Michael Levitz, David Colleran and Michael Spears |
| 12.1(25) | Insulet Corporation Statement Regarding Computation of Ratios of Earnings to Fixed Charges |
| 21.1 | Subsidiaries of the Registrant |
| 23.1 | Consent of Independent Registered Public Accounting Firm (Ernst & Young LLP) |
| 24.1 | Power of Attorney (included on signature page) |
| 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. |

| Number | Description |
|---|---|
| 101 | The following materials from Insulet Corporation's Annual Report on Form 10-K for the year ended December 31, 2015 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Loss; (iv) the Consolidated Statements of Changes in Stockholders' Equity; (v) the Consolidated Statements of Cash Flows |

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* 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 granted as to certain portions of this exhibit.

(1) Incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-140694) filed April 25, 2007

(2) Incorporated by reference to Amendment No. 3 to our Registration Statement on Form S-1 (File No. 333-140694) filed May 8, 2007

(3) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-140694) filed February 14, 2007

(4) Incorporated by reference to our Registration Statement on Form S-8 (No. 333-144636) filed July 17, 2007

(5) Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-146810) filed October 19, 2007

(6) Incorporated by reference to our Current Report on Form 8-K, filed March 5, 2008

(7) Incorporated by reference to our Current Report on Form 8-K, filed June 20, 2008

(8) Incorporated by reference to our Definitive Proxy Statement on Form DEF14A, filed April 2, 2012

(9) Incorporated by reference to our Form 8-A, filed November 20, 2008

(10) Incorporated by reference to our Current Report on Form 8-K, filed March 16, 2009

(11) Incorporated by reference to our Current Report on Form 8-A/A, filed September 28, 2009

(12) Incorporated by reference to our Current Report on Form 8-K, filed March 5, 2009

(13) Incorporated by reference to our Current Report on Form 8-K, filed September 28, 2009

(14) Incorporated by reference to our Annual Report on Form 10-K, filed March 9, 2010

(15) Incorporated by reference to our Current Report on Form 8-K, filed June 21, 2010

(16) Incorporated by reference to our Quarterly Report on Form 10-Q/A, filed November 19, 2010

(17) Incorporated by reference to our Quarterly Report on Form 10-Q/A, filed November 19, 2010

(18) Incorporated by reference to our Current Report on Form 8-K, filed June 7, 2011

(19) Incorporated by reference to our Current Report on Form 8-K, filed July 5, 2011

(20) Incorporated by reference to our Annual Report on Form 10-K, filed March 10, 2011

(21) Incorporated by reference to our Current Report on Form 8-K, filed January 10, 2011

(22) Incorporated by reference to our Quarterly Report on Form 10-Q, filed May 9, 2012

(23) Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 8, 2012

(24) Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 7, 2013

(25) Incorporated by reference to our Registration Statement on Form S-3, filed June 22, 2011

(26) Incorporated by reference to our Current Report on Form 8-K, filed June 6, 2014

(27) Incorporated by reference to our Current Report on Form 8-K, filed June 12, 2014

(28) Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 7, 2014

(29) Incorporated by reference to our Current Report on Form 8-K, filed September 16, 2014

(30) Incorporated by reference to our Current Report on Form 8-K, filed November 5, 2014

(31) Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014

(32) Incorporated by reference to our Annual Report on Form 10-K, filed February 28, 2014

(33) Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015

(34) Incorporated by reference to our Current Report on Form 8-K, filed April 1, 2015

(35) Incorporated by reference to our Definitive Proxy Statement on Form DEF14A, filed April 2, 2015

(36) Incorporated by reference to our Current Report on Form 8-K, filed June 30, 2015

(37) Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 12, 2015

(38) Incorporated by reference to our Current Report on Form 8-K, filed January 7, 2015

(39) Incorporated by reference to our Registration Statement on Form S-8 (No. 333-208387) filed December 8, 2015

(40) Incorporated by reference to our Current Report on Forn 8-K, filed February 26, 2016