

INSULET CORP
Form 10-K
February 29, 2016
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x 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

(I.R.S. Employer

Incorporation or Organization)

Identification No.)

600 Technology Park Drive, Suite 200

01821

Billerica, Massachusetts

(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 x 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 x

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

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

Indicate by check mark 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 x Accelerated filer o Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

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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.

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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.

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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.

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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.

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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.

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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;

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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).

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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.

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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.

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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.

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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 “con” 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

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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;

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- 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.

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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.

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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.

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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.

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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.

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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

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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;

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- 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.

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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;

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- 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.

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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.

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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. T