

INSULET CORP

FORM 10-K (Annual Report)

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016

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
(State or Other Jurisdiction of
Incorporation or Organization)

04-3523891
(I.R.S. Employer
Identification No.)

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

01821
(Zip Code)

Registrant's telephone number, including area code:
(978) 600-7000

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

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

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

None

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

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant computed by reference to the last reported sale price of the Common Stock as reported on The NASDAQ Global Market on June 30, 2016 was approximately \$1.7 billion .

The number of shares outstanding of each of the registrant's classes of common stock as of February 21, 2017 :

| <u>Title of Class</u> | <u>Shares Outstanding</u> |
|---|---------------------------|
| Common Stock, \$0.001 Par Value Per Share | 57,651,012 |
| 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, 2016 . Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 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 addition to using the Omnipod for insulin delivery, we also partner with global pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of subcutaneous drugs across 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 3 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, 2016.

Our Market

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

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

- Type 1 diabetes is characterized by the body's nearly complete inability to produce insulin. It is frequently diagnosed during childhood or adolescence. Individuals with Type 1 diabetes require daily insulin therapy, typically administered via injections or continuous infusion through pump therapy, to survive.
- Type 2 diabetes, the more common form of diabetes, is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Historically, Type 2 diabetes has occurred in later adulthood, but its incidence is increasing among the younger population, due primarily to increasing childhood obesity. Initially, many people with Type 2 diabetes attempt to manage their diabetes with improvements in diet, exercise and/or oral medications. As their diabetes advances, some patients progress to multiple drug therapy, which often includes insulin therapy.

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.

In addition to the diabetes market space, we have partnered with multiple pharmaceutical and biotechnology companies that utilize a customized form of the Omnipod System to deliver a drug over a specified interval of time, at a certain administered volume.

Managing Diabetes

Diabetes Management Challenges

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

Current Insulin Therapy

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

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

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

The Omnipod System

The Omnipod Insulin Management System is an innovative continuous insulin delivery system that provides all the proven benefits of CSII therapy in a way no conventional insulin pump can. The Omnipod 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 device ("Omnipod" or "Pod") and the PDM, that eliminates the need for the external tubing required with conventional pumps.

- The Pod is a small, lightweight, self-adhesive device that the patient fills with insulin and wears 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 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.

In 2016 there were three publications in peer-reviewed, scientific journals demonstrating the clinical and quality of life benefits associated with use of the Omnipod System. Two publications reported results of a retrospective study of patients with Type 1 and Type 2 diabetes. The study demonstrated clinically meaningful and statistically significant improvements in HbA1c (an important measure of blood glucose control), reduction in total daily dose of insulin and reduction in the frequency and severity of self-reported hypoglycemic episodes after three months of Omnipod System use compared to previous treatment with either multiple daily injections or traditional tubed insulin pumps. The third publication reported results of a second study that surveyed current adult Omnipod System users of which the majority reported positive changes in quality of life including perceived control over their diabetes, reduced diabetes distress, improved overall well-being and sense of hypoglycemic safety since initiating treatment with the Omnipod System. In addition, the majority of patients also reported significant improvement in glycemic control with more than one-third reporting a decrease in severe hypoglycemic episodes.

Research and Development

Our current research and development efforts are primarily focused on the development of mobile applications for the Omnipod System, including:

- Omnipod Dash Insulin Management System. Development of a secured Bluetooth Low Energy enabled Pod and PDM with a touch screen color user interface supported by web application and smart phone connectivity.
- Omnipod Horizon Automated Glucose Control. Development of a hybrid closed loop control system that will utilize the Dash mobile platform. Our Pod will communicate with a continuous glucose monitor and help control insulin delivery utilizing an algorithm located on the Pod.
- Concentrated Insulin Delivery. Development to support the use of concentrated insulins for Type 1 and Type 2 patients with higher insulin-requirements, utilizing the same form factor as our existing Pod.

In addition to insulin delivery, we continue to work with multiple pharmaceutical and biotechnology companies on alternative uses for our Omnipod System 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 our devices on varying degrees of semi-automated manufacturing lines at a facility in China, operated by a subsidiary of Flex Ltd. (formerly Flextronics International Ltd.) ("Flex"). We purchase our devices pursuant to our agreement with Flex. The current term of the agreement expires in September 2021 and is subject to an automatic renewal thereafter, unless otherwise canceled by the parties under the contract terms. The contract 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 continue to invest in our supply chain operations to increase manufacturing capacity and reduce the per-unit production cost for the Omnipod System. As part of our investment strategy, in 2016 we announced our plan to establish a highly automated manufacturing operation in the United States and expect to begin production through this operation in 2019. In December 2016, we entered into an agreement to purchase property for the planned facility in Acton, Massachusetts for a total purchase price of \$9.3 million. Of the total purchase price, \$0.5 million was paid as of December 31, 2016 and the remaining \$8.8 million was subsequently paid upon closing in February 2017. The new U.S. operation is intended to provide manufacturing redundancy and additional production capacity to support growth and new product launches. The new operation will enable further improvements of manufacturing reliability and the lowering of production costs.

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.

Our 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 Omnipod System. Our Quality Assurance Department also inspects and tests the Omnipod System 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 System 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 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, 2016, we had obtained 23 issued United States patents with expiration dates ranging from 2020 through 2034, and had 32 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 for the Omnipod System and next generation products;
- software for controlling the Omnipod System and next generation products; and
- various novel aspects of the Omnipod System, potential future generations of Omnipod Systems, and other mechanisms for the delivery of pharmaceuticals.

Trademarks. We have registered various trademarks associated with our business, including INSULET, OMNIPOD, DASH 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 represent approximately 40% of our total revenue in the United States. We sell the Omnipod System in certain countries in Europe through our independent distributor, Ypsomed Distribution AG ("Ypsomed"). Our exclusive distribution agreement with Ypsomed expires in mid-2018.

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 System technology. We have three areas of focus:

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

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

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

Competition

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

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

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

In addition to the established insulin pump competitors, several companies are working to develop and market new insulin "patch" pumps and other methods for the treatment of diabetes, such as inhaled insulin. These companies are at various stages of development and the number of such companies continuously change as they enter or exit the market on an ongoing basis.

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 and expect that PMA approval will be needed for some of our future products. We may be required to obtain a new 510(k) clearance or pre-market approval for significant post-market modifications to 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.

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

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

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

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

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. We cannot assure you that our facilities or our contract manufacturer or component suppliers' facilities would pass any future quality system inspection.

Our facility located at 600 Technology Park Drive, Suite 200, Billerica, MA 01821 was inspected by the FDA in March 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 FDA Form 483 and Warning Letter responses. Our facility located in Billerica, MA was re-inspected by the FDA in November to December 2015. This inspection also resulted in four inspectional observations. We responded to these inspectional observations on December 31, 2015. Our facility was again re-inspected in October 2016 and this FDA inspection focused on corrections to previous FDA inspections and resulted in one inspectional observation. In January 2017, the FDA officially closed the FDA inspection that was conducted in October 2016.

In July 2015 we implemented a field removal of certain lots of our product due to the possibility that some Omnipod Systems had a higher rate of failure than our current manufacturing standards. In January 2017, the FDA officially terminated this field action. In September 2015, as part of our product quality monitoring process, we identified that certain lots of the Omnipod System 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.

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 new 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. 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 System. We have been distributing the Omnipod System in certain countries in Europe, through Ypsomed, since 2010.

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 an individual;
- furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other federal health care programs; or
- the 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 federal health care programs.

The Federal Anti-Kickback Statute has been interpreted to apply to arrangements between drug and medical device manufacturers and suppliers on one hand and prescribers, purchasers and formulary managers on the other,

and liability may be established without a person or entity having actual knowledge of the statute or specific intent to violate it. In addition, claims resulting from a violation of the Federal Anti-Kickback Statute constitute false or fraudulent claims for purposes of the Federal False Claims Act, which is addressed below. 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 there are a number of statutory exemptions and regulatory safe harbors protecting certain common business practices from prosecution and administrative sanctions, and we have structured our arrangements with diabetes educators and other business practices to comply with these exemptions and safe harbors whenever possible, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be perceived as inducing the prescription, purchase, or recommendation of the Omnipod System may be subject to scrutiny under the law. 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 Statute 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 there are a number of statutory exemptions protecting certain common business practices from prosecution under the Stark Law, and we have structured our arrangements with physicians and other providers to comply with these exemptions whenever possible, these arrangements may not expressly meet the requirements for applicable exceptions from the 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 up to approximately \$22,000 per false claim or statement, 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. However, many drug and medical device manufacturers have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; or causing submission of false claims by providing inaccurate coding or billing information to actual or prospective purchasers, and our business practices could be subject to scrutiny and enforcement under the Federal False Claims Act. We also may be subject to other federal false claim laws, including federal criminal statutes that prohibit making a false statement to the federal government.

Civil Monetary Penalties Law. We are also subject to the Federal Civil Monetary Penalties Law, which prohibits, among other things, 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.

Federal Health Care Fraud Statutes. We are also subject to a federal health care fraud statute that, among other things, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program including non-governmental programs, and prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false or fraudulent statement or representation, or making or using any false writing or document with knowledge that it contains a materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

State Fraud and Abuse Provisions. Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act analogous to the Federal Anti-Kickback Statute and Federal False Claims Act, and in some cases these state laws apply regardless of the payer, including private payers. We believe that we are in conformance with such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

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

Patient Protection and Affordable Care Act. The Patient Protection and Affordable Care Act ("ACA") enacted significant changes to the provision of and payment for healthcare in the United States. Under the ACA and related laws and regulations, federal and state government initiatives are focused on limiting the growth of healthcare costs and implementing changes to healthcare delivery structures. These reforms are intended in part to put increased emphasis on the delivery to patients of more cost-effective therapies and could adversely affect our business. Legislative changes to the ACA remain possible and appear likely in the 115th United States Congress and under the Trump Administration, which could include changes that adversely affect our business. While some uncertainty exists regarding the future 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 in the near term.

Physician Payments Sunshine Act. The Physician Payments Sunshine Act, which is being implemented as the Open Payments program, requires manufacturers of drugs and devices for which Medicare or Medicaid payment is available to track and publicly report many types of payments made and items of value provided to physicians and teaching hospitals. Moreover, several states have imposed similar or more restrictive requirements, including requirements to disclose payments to HCPs, restrictions on marketing and other expenditures, and requirements to adopt a code of conduct or compliance program with specific elements. Our failure to adhere to these requirements could materially adversely impact our business and financial results.

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. Even if we are not found to have violated the law, responding to lawsuits, government investigations or enforcement actions, defending any claims raised, and paying any resulting settlement amounts would be expensive and time-consuming, and could have a material adverse effect on our reputation and business operations.

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. Reimbursement may also be declined by insurers based upon language in the contract between the insurer and the insured group. An example of this is certain employer self-insurance plans that may choose to decline coverage based on specific provisions within those individual plans.

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 or broad Medicaid coverage for the majority of the Omnipod System. However, we are continuing a dialogue with Centers for Medicare & Medicaid Services (“CMS”) about Medicare coverage and with other public payors for Medicaid coverage.

Employees

As of December 31, 2016 , we had 640 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe that our employee relations are good.

Item 1A. Risk Factors

This Annual Report on Form 10-K contains forward-looking statements. Forward-looking statements relate to future events or our future financial performance.

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

The outcomes of the events described in these forward-looking statements are subject to risks, uncertainties and other factors described in this Item 1A Risk Factors and elsewhere in this Annual Report on Form 10-K. Accordingly, you should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date of this report. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

Risks Relating to Our Business

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

Since our inception in 2000, we have incurred significant operating losses. We began commercial sales of the Omnipod System in 2005. For the year ended December 31, 2016 , our operating loss was \$10.7 million . Our net losses for the years ended December 31, 2016 , 2015 and 2014 were \$28.9 million , \$73.5 million and \$51.5 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, 2016 , we had an accumulated deficit of \$680.4 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;

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- 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 System 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 or capacity constraints;
- actual or perceived quality problems;
- changes in reimbursement rates or policies relating to the Omnipod System by third-party payors;
- claims that any portion of the Omnipod System infringes on patent rights or other intellectual property rights owned by other parties;
- adverse regulatory or legal actions relating to the Omnipod System;
- damage, destruction or loss of any of the facilities where our products are manufactured or stored or of the equipment therein or failure to successfully open or expand new facilities;
- 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 System by increasing customer orders, increasing manufacturing volume and productivity and reducing raw material and overhead costs per unit.

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 System. 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 System 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. 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 ongoing at the federal and state government levels. There are new provisions of law that provide for the creation of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities. For example, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute are publicly disseminated. It is difficult at this time to determine whether a comparative effectiveness analysis impacting our business will be done, and assuming one is, what impact that analysis will have on the Omnipod System or our future financial results.

Beginning in 2013, sales of certain medical devices became subject to a 2.3% federal excise tax, subject to a two-year suspension of the tax in 2016 and 2017. 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.

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.

Legislative and regulatory changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have an adverse effect on our industry generally and on our ability to maintain or increase sales of any of 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;

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- 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, cash equivalents and short-term investments, 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 2017.

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 and sold \$201.3 million in principal amount of 2% Convertible Senior Notes due in 2019 ("2% Notes"). In September 2016, we issued and sold \$345 million in principal amount of 1.25% Convertible Senior Notes due in 2021 ("1.25% Notes"). In connection with the issuance of the \$345 million in 1.25% Convertible Senior Notes, we repurchased \$134.2 million of our outstanding 2% Convertible Senior Notes. We may need to raise additional debt or equity financing to repay our outstanding convertible notes. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

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

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

We may not be able to generate sufficient cash to service our indebtedness represented by our 2% Convertible Senior Notes due June 15, 2019 and our 1.25% Convertible Senior Notes due September 15, 2021. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

In 2014, we issued and sold \$201.3 million in principal amount of 2% Convertible Senior Notes, due in 2019. In September 2016, we issued and sold \$345 million in principal amount of 1.25% Convertible Senior Notes due in 2021. In connection with the issuance of the \$345 million of 1.25% Convertible Senior Notes, we repurchased \$134.2 million of our outstanding 2% Convertible Senior Notes. Our ability to make scheduled payments or to refinance the 2% and 1.25% Convertible Senior Notes or other debt obligations depends on our financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness, including the outstanding 2% and 1.25% Convertible Senior Notes. We cannot assure you that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations when due.

We 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 for and perform assembly 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 we rely on NXP USA to manufacture and supply an application specific integrated circuit. In addition, a subsidiary of Flex in China performs assembly and supplies all finished Omnipod Systems. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we, or Flex on our behalf, make purchases on the basis of individual purchase orders. 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 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 announced that it will establish a competitive bidding program nationwide for conventional insulin pumps effective January 1, 2019. Since the Omnipod System is not currently covered or reimbursed by Medicare as durable medical equipment or as a prosthetic device, we would not be directly affected by this program. However, should this program commence in 2019 on a nationwide basis in 2019 as announced, it is expected that there would be a reduction in the amount reimbursed by CMS for conventional insulin pumps. This may negatively impact our ability to negotiate future pricing with private payors comparing the price of the Omnipod System to conventional insulin pumps.

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

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

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

Ypsomed is our exclusive distributor of the Omnipod System through June 2018 in multiple countries in Europe including France, Germany, the United Kingdom, the Netherlands, Switzerland, Austria, Italy, Norway, and Sweden. Our agreement with Ypsomed also covers China and a number of other countries. In addition to the Omnipod System, Ypsomed also markets and sells a suite of other products for the treatment of diabetes and has introduced and sells 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 or expand our current or future products in 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 Omnipod Systems are manufactured at a facility in China operated by Flex. As a result, our business is subject to risks associated with doing business internationally, including:

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

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

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

We expect that sales of the Omnipod System will be limited unless a substantial portion of the sales price of the Omnipod System is paid for by third-party payors, including private insurance companies, health maintenance organizations, preferred provider organizations, federal and state government healthcare agencies and other managed care providers. We currently have contracts establishing reimbursement for the Omnipod System with national and regional third-party payors that provide reimbursement for patients residing in all 50 states. While we anticipate entering into additional contracts with other third-party payors, we cannot assure that we will be successful in doing so. In addition, these contracts can generally be terminated by the third-party payor without cause. Also, healthcare market initiatives in the United States may lead third-party payors to decline or reduce reimbursement for the Omnipod System. Moreover, compliance with administrative procedures or requirements of third-party payors may result in delays in processing approvals by those payors for patients to obtain coverage for the use of the Omnipod System. We are an approved Medicare supplier and current Medicare coverage for continuous subcutaneous insulin infusion, or CSII therapy exists. However, existing Medicare and broad Medicaid coverage for CSII therapy is based on conventional insulin pumps. We have been in the process for several years of seeking appropriate Medicare and broad Medicaid coverage for the Omnipod System. No assurance can be provided that we will ever secure Medicare and broad Medicaid 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, many 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 introduced and sells its own branded conventional insulin pump. Ypsomed may have a greater financial incentive to sell its proprietary products rather than the Omnipod System.

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

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

We also compete with MDI therapy, which is substantially less expensive than CSII therapy. MDI therapy has been made more effective by the introduction of long-acting insulin analogs that can be used in combination with 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 and the number of such companies continuously change as they enter or exit the market on an ongoing basis.

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. The form and function of such systems may change over time as our business needs change. 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” or “hybrid 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 with reduced patient direction could have a material adverse effect on our revenue and future profitability. Medtronic has developed a “hybrid closed-loop” system with FDA-approval and has announced an anticipated commercial launch in 2017, which could negatively impact our business. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve the treatment of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could render the Omnipod System obsolete, which would have a material adverse effect on our business, financial condition and results of operations.

We also have ongoing 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 could 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 agreements or licenses to intellectual property or other rights in order to sell our current product or commercialize new products. If we cannot obtain these agreements, licenses, or other rights, we may not be able to sell, develop or commercialize these 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 rights.

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 System 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 System;
- our achievement of satisfactory development and pricing terms with the pharmaceutical companies that sell such drugs;
- our development of appropriate modifications to our Omnipod System technology to address the needs and parameters required for the respective drug-delivery opportunities;
- manufacturing issues relating to the modified Omnipod System;
- long lead-times associated with the development, regulatory approvals and ramp up applicable to the use of modified Omnipod Systems for the delivery of such drugs;
- relatively small number of modified Omnipod Systems needed to address each drug-delivery opportunity;

- uncertainties regarding the market acceptance of such drugs and the modified Omnipod Systems as appropriate delivery devices;
- uncertainties relating to the success of the pharmaceutical companies in marketing and selling such drugs as well as the modified Omnipod Systems 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; 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 our products 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 our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to ours without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

We rely on patents to protect a portion of our intellectual property and our competitive position. The patent laws that relate to the scope of claims in the technology fields in which we operate are still evolving and, consequently, certain 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. 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 our products and could cause us to incur significant costs.

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

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

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- 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 PMA 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 have since obtained clearance for modified versions of this device. We may be required to obtain a new 510(k) clearance or pre-market approval for significant further 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. We expect that some of our future products will require PMA approval. In addition, the FDA may demand that we obtain a PMA prior to marketing future changes of our existing Omnipod System. 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. The last of these regulations requires us to report to the FDA if our devices cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following sanctions:

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, as part of the 21st Century Act passed in 2016, Congress enacted several reforms that further affect medical device regulation both pre- and post-approval. While those changes are still being implemented by FDA, this serves as an example of the rapidly changing regulatory environment in which we operate. In addition, 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 ("QSR"), which is a complex regulatory framework that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic, sometimes unannounced, inspections by the FDA. We cannot assure you that our facilities or our contract manufacturer or component suppliers' facilities would pass any future quality system inspection. If our or any of our contract manufacturer or component suppliers' facilities fails a quality system inspection, the manufacturing or distribution of our devices could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could force a suspension or shutdown of our labeling operations or the manufacturing operations of our contract manufacturer, or a recall of our devices.

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

Our facility located at 600 Technology Park Drive, Suite 200, Billerica, MA 01821 was inspected by the FDA in March 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 FDA Form 483 and Warning Letter responses. Our facility located in Billerica, MA was re-inspected by the FDA in November to December 2015. This ins

pection also resulted in four inspectional observations. We responded to these inspectional observations on December 31, 2015. Our facility was again re-inspected in October 2016 and this FDA inspection focused on corrections to previous FDA inspections and resulted in one inspectional observation. In January 2017, the FDA officially closed the FDA inspection that was conducted in October 2016.

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

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

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

The FDA and similar governmental bodies in other countries have the authority to require the recall of our current or future products if we or our contract manufacturers fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of these products. For example, under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. A government-mandated recall could occur if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death. A voluntary recall by us could occur as a result of any material deficiency in a device, such as manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. In general, if we decide to make a change to our product, we are responsible for determining whether to classify the change as a recall. It is possible that the FDA could disagree with our initial classification. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. In general if any change or group of changes to a device addresses a violation of the Federal Food, Drug, and Cosmetic Act, that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

In July 2015 we implemented a field removal of certain lots of our product due to the possibility that some Omnipod Systems had a higher rate of failure than our current manufacturing standards. In January 2017, the FDA officially terminated this field action. In September 2015, as part of our product quality monitoring process, we identified that certain lots of the Omnipod System 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.

Further, under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious

injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDR regulations. In addition, in October 2014, the FDA issued guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the Federal Food, Drug, and Cosmetic Act, that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

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

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

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

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

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

Our relationships with customers and third-party payers are subject to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians, patients or other potential purchasers of medical devices. These laws include the Federal Anti-Kickback Statute, the Federal False Claims Act, other federal health care false statement and fraud statutes, the Open Payments program, the Civil Monetary Penalties Law, and analogous fraud and abuse and transparency laws in most states, as described in greater detail in the section above entitled "Government Regulation".

We conduct various marketing and product training activities that involve making payments to healthcare providers and entities. While we believe and make every effort to ensure that our business arrangements with third parties and other activities comply with all applicable laws, these laws are complex and our activities may be found not to be compliant with one of these laws, which may result in significant civil, criminal and/or administrative penalties. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations. Our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the United States Department of Health and Human Services' Office of the Inspector General ("OIG"), CMS, and the Department of Justice. To ensure compliance with Medicare, Medicaid and other regulations, government agencies conduct periodic audits of us to ensure compliance with various supplier standards and billing requirements.

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

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

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

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

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

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

Under our distribution model, we depend on a small number of customers, including distributors, for a large portion of our business, and changes in orders from such customers could have a significant impact on our operating results. If a major customer, either in our insulin or non-insulin drug delivery businesses significantly reduces the amount of business it does with us, there would be an adverse impact on our operating results.

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

| | Twelve Months Ended December 31, | | |
|-------------------------|----------------------------------|------|------|
| | 2016 | 2015 | 2014 |
| Amgen, Inc. | 17% | 10% | * |
| Ypsomed Distribution AG | 16% | 12% | 19% |
| RGH Enterprises, Inc. | 10% | 13% | 14% |

* Customer represents less than 10% of revenue for the period.

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

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

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

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

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

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

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

If we do not effectively manage the construction of our planned manufacturing facility in the U.S., our results of operations may be adversely affected.

To lower our manufacturing costs, increase supply redundancy and add capacity to support growth, we intend to construct a highly-automated manufacturing facility in the U.S. As of December 31, 2016 we had outstanding purchase commitments with various suppliers for the construction of the facility, including \$22.8 million with ATS Automation Tooling Systems Inc. for equipment purchases. Also, in December 2016, we entered into an agreement to purchase property for the planned manufacturing facility in Acton, Massachusetts for a total purchase price of \$9.3 million. Of the total purchase price, \$0.5 million was paid as of December 31, 2016 and the remaining \$8.8

million was subsequently paid upon closing in February 2017. The cost of construction for our planned manufacturing facility in the U.S. could increase significantly and there is no assurance that the final cost of the facility will not be materially higher than anticipated. There may be design changes, material cost escalations or budgetary overruns associated with the construction.

We may experience delays in the construction of our planned manufacturing facility in the U.S. We may also encounter defects in materials and/or workmanship in connection with construction which could lead to a failure to adhere to compliance requirements. Any defects could delay the commencement of operations of the facility, lead to fines from non-compliance of regulatory requirements, or, if such defects are discovered after operations have commenced, could halt or discontinue the facility indefinitely.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The price of our common stock may be volatile.

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

- failure to maintain and increase production capacity and reduce per unit production costs;
- changes in the availability of third-party reimbursement in the United States or other countries;
- volume and timing of orders for the Omnipod System;
- developments in administrative proceedings or litigation related to intellectual property rights;
- issuance of patents to us or our competitors;
- the announcement of new products or product enhancements by us or our competitors;
- the announcement of technological or medical innovations in the treatment or diagnosis of diabetes;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- developments in our industry;
- publication of clinical studies relating to the Omnipod System or a competitor's product;
- quarterly variations in our or our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

Conversion of any of our 2% and 1.25% Convertible Senior Notes may dilute the ownership interest of existing stockholders or depress our stock price.

The conversion of some or all of the 2% and 1.25% Convertible Senior Notes may dilute the ownership interests of existing stockholders. Any sales in the public market of any of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the anticipated conversion of the Convertible Senior Notes into a combination of cash and shares of our common stock could depress the price of our common stock.

Furthermore, the price of our common stock also could be affected by possible sales of our common stock by investors who view the 2% and 1.25% Convertible Senior Notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect will develop involving our common stock. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

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

In February 2016, we sold Neighborhood Diabetes to Liberty Medical for \$6.2 million in cash, which included \$1.2 million of closing adjustments finalized in June 2016 and paid by Liberty Medical. Under the terms of the sale, we agreed to indemnify Liberty Medical for certain customary matters primarily related to our pre-closing operation of the business. Although we currently do not expect any material indemnification obligations to arise, we could be required to reimburse Liberty Medical for such claims in the event that they were to arise.

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease a total of approximately 133,000 square feet of office space, laboratory, warehousing and other related facilities. Approximately 100,000 of the total square footage consists of laboratory and office space for our corporate headquarters in Billerica, Massachusetts under leases expiring in November 2022.

Additionally, we lease approximately 29,000 square feet of warehousing space in Billerica, Massachusetts under a lease expiring in September 2019. We lease other facilities in Canada, China, California and Tennessee containing a total of approximately 4,000 square feet under leases expiring from May 2017 to May 2018.

In December 2016, we entered into an agreement to purchase property for the planned manufacturing facility in Acton, Massachusetts. The property includes 195,000 square feet of manufacturing and office space.

Item 3. Legal Proceedings

The information required by this Item is provided under "Legal Proceedings" in note 15 to the consolidated financial statements included under Item 8 of this Form 10-K, and is incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

MARKET FOR REGISTRANT'S COMMON EQUITY

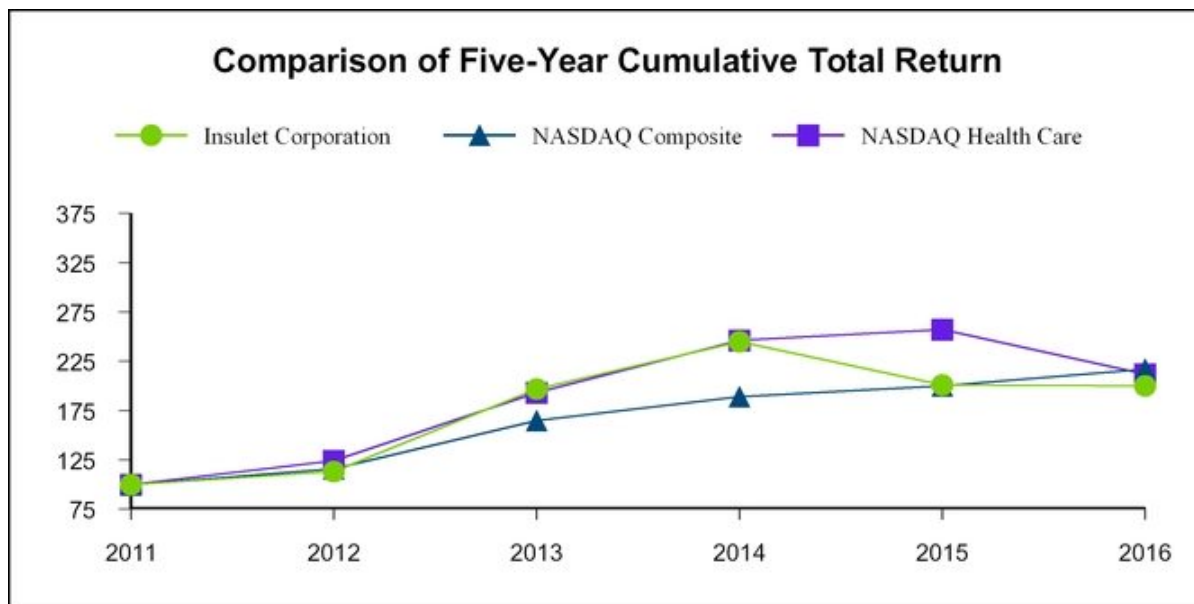
Our common stock has been listed on The NASDAQ Global Market under the trading symbol "PODD" since our initial public offering on May 15, 2007. The following table sets forth the high and low closing sales prices of our common stock, as reported by The NASDAQ Global Market, for each of the periods listed.

| | High | Low |
|-------------------------|----------|----------|
| Fiscal Year 2015 | | |
| First Quarter | \$ 45.18 | \$ 29.39 |
| Second Quarter | \$ 31.85 | \$ 26.23 |
| Third Quarter | \$ 34.39 | \$ 25.64 |
| Fourth Quarter | \$ 39.32 | \$ 26.36 |
| Fiscal Year 2016 | | |
| First Quarter | \$ 37.54 | \$ 24.68 |
| Second Quarter | \$ 35.15 | \$ 26.89 |
| Third Quarter | \$ 45.07 | \$ 30.46 |
| Fourth Quarter | \$ 40.72 | \$ 30.73 |

As of February 21, 2017, there were approximately 10 registered holders of record of our common stock. The number of beneficial stockholders of our shares is greater than the number of stockholders of record.

Performance Graph

The chart set forth below shows the value of an investment of \$100 on December 31, 2011 in each of Insulet Corporation common stock, the NASDAQ Composite Index, and the NASDAQ Health Care Index. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices and are calculated as of December 31, 2016. The historical stock price performance of our common stock shown in the performance graph below is not necessarily indicative of future stock price performance.



| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---------------------|--------|--------|--------|--------|--------|--------|
| Insulet Corporation | \$ 100 | \$ 113 | \$ 197 | \$ 245 | \$ 201 | \$ 200 |
| NASDAQ Composite | 100 | 116 | 165 | 189 | 200 | 217 |
| NASDAQ Health Care | 100 | 124 | 193 | 246 | 257 | 212 |

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

Dividend Policy

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

Securities Authorized For Issuance Under Equity Compensation Plans

The following table sets forth information regarding securities authorized for issuance under our equity compensation plans as of December 31, 2016 .

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|--|--|--|
| Equity compensation plans approved by security holders ⁽¹⁾ | 3,576,322 | \$ 24.45 | 4,487,991 |
| Equity compensation plans not approved by security holders ⁽²⁾ | 827,200 | \$ 28.54 | — |
| Total ⁽⁴⁾ | 4,403,522 | \$ 25.22 | 4,487,991 ⁽³⁾ |

⁽¹⁾ Includes our Amended and Restated 2007 Stock Option and Incentive Plan. Outstanding restricted stock units convert to common stock without the payment of consideration. As of December 31, 2016 , 860,123 restricted stock units were outstanding. The weighted-average exercise price of outstanding options as of such date issued under these Plans (excluding restricted stock units) was \$32.76.

⁽²⁾ Consists of the following inducement grants made to certain executive officers upon their initial hire by us: one inducement grant of 499,468 shares of non-qualified stock option awards made to Patrick J. Sullivan upon being hired by us in September 2014; one inducement grant of 26,756 non-qualified stock options and 18,182 restricted stock units (6,060 and 6,061 of which vested during the years ended December 31, 2015 and 2016, respectively) made to Bradley Thomas upon being hired by us in November 2014; one inducement grant of 79,936 non-qualified stock options and 56,965 restricted stock units (18,988 of which vested during the year ended December 31, 2016) made to Shacey Petrovic upon being hired by us in February 2015; one inducement grant of 58,852 non-qualified stock options and 43,028 restricted stock units (14,342 of which vested during the year ended December 31, 2016) made to Michael Levitz upon being hired by us in May 2015; one inducement grant of 29,581 non-qualified stock options and 21,627 restricted stock units (7,209 of which vested during the year ended December 31, 2016) made to David Collieran upon being hired by us in June 2015; and one inducement grant of 30,511 non-qualified stock options and 22,431 restricted stock units (7,477 of which vested during the year ended December 31, 2016) made to Michael Spears upon being hired by us in July 2015. These non-qualified stock option awards and restricted stock units were granted outside of our Amended and Restated 2007 Stock Option and Incentive Plan in compliance with Nasdaq Listing Rule 5635.

⁽³⁾ The maximum number of shares of our common stock that remain available for future issuance under our 2007 Stock Option and Incentive Plan as of December 31, 2016 is 4,487,991 shares.

⁽⁴⁾ As of December 31, 2016 , 962,219 restricted stock units were outstanding. The weighted-average exercise price of outstanding options as of such date issued as inducement grants (excluding restricted stock units) was \$35.08.

For more information relating to our equity compensation plans, see footnote 16 to our consolidated financial statements.

Issuer Repurchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended December 31, 2016 , nor issue any securities that were not registered under Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data

Years Ended December 31,

| (In thousands, except share and per share data) | Years Ended December 31, | | | | |
|---|---------------------------------|-------------|-------------|-------------|-------------|
| Consolidated Statements of Operations Data: | 2016 | 2015 | 2014 | 2013 | 2012 |
| Revenue | \$ 366,989 | \$ 263,893 | \$ 231,321 | \$ 185,139 | \$ 148,898 |
| Cost of revenue | 155,903 | 130,622 | 104,195 | 95,364 | 80,430 |
| Gross profit | 211,086 | 133,271 | 127,126 | 89,775 | 68,468 |
| Operating expenses: | | | | | |
| Research and development | 55,710 | 43,208 | 27,900 | 21,765 | 24,359 |
| Sales and marketing | 94,483 | 78,407 | 50,552 | 45,176 | 40,436 |
| General and administrative ⁽¹⁾ | 71,597 | 60,392 | 57,548 | 49,509 | 34,642 |
| Total operating expenses | 221,790 | 182,007 | 136,000 | 116,450 | 99,437 |
| Operating loss | (10,704) | (48,736) | (8,874) | (26,675) | (30,969) |
| Interest and other income (loss), net | (16,114) | (12,654) | (39,006) | (15,783) | (15,702) |
| Loss from continuing operations before income taxes | (26,818) | (61,390) | (47,880) | (42,458) | (46,671) |
| Income tax expense (benefit) | 392 | 212 | 60 | 22 | (9) |
| Net loss from continuing operations | (27,210) | (61,602) | (47,940) | (42,480) | (46,662) |
| Loss from discontinued operations, net of tax ⁽²⁾ | (1,669) | (11,918) | (3,560) | (2,494) | (5,205) |
| Net loss | \$ (28,879) | \$ (73,520) | \$ (51,500) | \$ (44,974) | \$ (51,867) |
| Net loss per share basic and diluted: | | | | | |
| Net loss from continuing operations per share | (0.48) | (1.08) | (0.86) | (0.78) | (0.97) |
| Net loss from discontinued operations per share | (0.03) | (0.21) | (0.06) | (0.05) | (0.11) |
| Weighted-average number of shares used in calculating net loss per share ⁽³⁾ | 57,251,377 | 56,785,646 | 55,628,542 | 54,010,887 | 47,924,324 |

As of December 31,

| (In thousands) | As of December 31, | | | | |
|---|---------------------------|-------------|-------------|-------------|-------------|
| Consolidated Balance Sheets Data: | 2016 | 2015 | 2014 | 2013 | 2012 |
| Cash and cash equivalents | \$ 137,174 | \$ 122,672 | \$ 151,193 | \$ 149,727 | \$ 57,293 |
| Short-term investments ⁽⁴⁾ | \$ 161,396 | \$ — | \$ — | \$ — | \$ — |
| Working capital | \$ 314,263 | \$ 125,605 | \$ 163,900 | \$ 155,824 | \$ 61,650 |
| Total assets | \$ 456,647 | \$ 275,126 | \$ 297,182 | \$ 286,541 | \$ 196,055 |
| Current portion of long-term debt and capital lease obligations | \$ 269 | \$ 5,519 | \$ 3,380 | \$ 2,637 | \$ 14,429 |
| Long-term debt and capital lease obligations ⁽⁵⁾ | \$ 332,768 | \$ 171,967 | \$ 166,283 | \$ 117,627 | \$ 101,726 |
| Other long-term liabilities | \$ 5,032 | \$ 3,952 | \$ 2,774 | \$ 1,943 | \$ 1,867 |
| Total stockholders' equity | \$ 63,150 | \$ 34,051 | \$ 83,829 | \$ 124,597 | \$ 44,176 |

⁽¹⁾ Included a charge of \$6.1 million related to in-process internally developed software in 2016. See note 12 to our consolidated financial statements included in this Annual Report on Form 10-K.

⁽²⁾ Included an impairment charge of \$9.0 million in 2015 related to the impairment of the Neighborhood Diabetes asset group. See note 13 to our consolidated financial statements included in this Annual Report on Form 10-K.

⁽³⁾ In January 2013, we issued and sold 4.7 million shares of common stock to the public. In July 2014, we issued 0.3 million shares of common stock in connection with the repurchase of the 3.75% Senior Convertible Notes. See note 7 to our consolidated financial statements included in this Annual Report on Form 10-K.

⁽⁴⁾ We invested in short-term investments beginning in 2016. See note 6 to our consolidated financial statements included in this Annual Report on Form 10-K.

⁽⁵⁾ In June 2008, we issued and sold \$85.0 million principal amount of 5.375% Convertible Senior Notes due June 2013. In June 2011, we issued and sold \$143.8 million of 3.75% Convertible Notes due June 2016 and repurchased \$70 million in principal of the 5.375% Notes. In June 2014, we issued and sold \$201.3 million of 2% Convertible Notes due June 2019 and repurchased \$114.9 million in 3.75% Notes. In July 2014, the remaining principal balance of the 3.75% Notes were converted and the principal was settled in cash. In September 2016, we issued \$345.0 million of 1.25% Convertible Notes due September 2021 and repurchased \$134.2 million in principal of the 2% Notes. In 2013 and 2014 we acquired \$9.0 million and \$1.5 million, respectively, of manufacturing equipment under capital leases. See notes 7 and 8 to our consolidated financial statements included in this Annual Report on Form 10-K.

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

Executive Level Overview

We are primarily engaged in the development, manufacturing and sale of our proprietary Omnipod System, an innovative, discreet and easy-to-use continuous insulin delivery system for people with insulin-dependent diabetes. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod device which is worn on the body for approximately three days at a time and its wireless companion, the handheld PDM. Conventional insulin pumps require people with insulin-dependent diabetes to learn to use, manage and wear a number of cumbersome components, including up to 42 inches of tubing. In contrast, the Omnipod System features only two discreet, easy-to-use devices that eliminate the need for a bulky pump, tubing and separate blood glucose meter, provides for virtually pain-free automated cannula insertion, communicates wirelessly and integrates a blood glucose meter. We believe that the Omnipod System's unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience, and ease.

We began commercial sale of the Omnipod System in the United States in 2005. We sell the Omnipod System 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 4 to the consolidated financial statements included under Item 8 of this Form 10-K.

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

In June 2011, we acquired Neighborhood Diabetes. Through Neighborhood Diabetes, we provided customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and had the ability to process claims as either durable medical equipment or through pharmacy benefits. In February 2016, we sold Neighborhood Diabetes to Liberty Medical. Additional information regarding the sale of Neighborhood Diabetes is provided in note 3 to the consolidated financial statements included under Item 8 of this Form 10-K.

Highlights and Recent Developments:

- Strengthened leadership team with appointment of key executives across the Company.
- Evidence demonstrating Omnipod's improved glycemic control and quality of life published in the Journal of Diabetes Technology & Therapeutics and the Journal of Diabetes Science and Technology.
- Completed private placement of \$345.0 million in principal amount of 1.25% Convertible Senior Notes due in 2021 and the repurchase of \$134.2 million in principal amount of the existing 2.00% Convertible Senior Notes due in 2019.
- Divested Neighborhood Diabetes medical supplies distribution business to focus on growth opportunities in insulin and drug delivery.
- Expanded development partnership with Eli Lilly and Company for Omnipod delivery of Humalog 200 concentrated insulin, in addition to the Company's already-existing partnership for Humalog U500.
- Partnered with Joslin Diabetes Center to implement a unique training certification for Insulet's clinical team.

2016 Revenue Results:

- Total revenue of \$367.0 million
 - U.S. Omnipod revenue of \$229.8 million
 - International Omnipod revenue of \$71.9 million
 - Drug Delivery revenue of \$65.3 million

Our long-term financial objective is to achieve and sustain profitable growth. We expect our efforts in 2017 to focus primarily on the expansion of our customer base in the United States and internationally, increasing our gross profit and product development. Achieving these objectives is expected to require additional investments in certain personnel and initiatives, as well as enhancements to our supply chain operation capacity, efficiency and effectiveness. We believe that we will continue to incur net losses in the near term in order to achieve these

objectives. However, we believe that the accomplishment of our near term objectives will have a positive impact on our financial condition in the future.

Components of Financial Operations

Revenue. We derive most of our revenue from global sales of the Omnipod System. Our revenue also includes sales of devices based on the Omnipod System technology platform to global pharmaceutical and biotechnology companies for the delivery of subcutaneous drugs across multiple therapeutic areas.

Cost of revenue. Cost of revenue consists primarily of raw material, labor, warranty, inventory reserve and overhead costs such as freight-in and depreciation and the cost of products we acquire from third party suppliers.

Research and development. Research and development expenses consist primarily of personnel costs and outside services within our product development, regulatory and clinical functions, and product development projects. We generally expense research and development costs as incurred.

Sales and marketing. Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support, customer care and training functions, sales commissions paid to our sales representatives, costs associated with promotional activities and participation in industry trade shows.

General and administrative. General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, finance, legal, information technology and human resource functions, as well as legal fees, accounting fees, insurance costs, bad debt expenses, shipping, handling and facilities-related costs.

Results of Operations

This section discusses our consolidated results of operations for 2016 compared to 2015, as well as 2015 compared to 2014, and should be read in conjunction with the consolidated financial statements and accompanying notes included under Item 8 of this Form 10-K.

TABLE 1: RESULTS OF OPERATIONS

| (In Thousands) | Years Ended December 31, | | | | Years Ended December 31, | | | |
|---|--------------------------|-------------|-------------|----------|--------------------------|-------------|-------------|----------|
| | 2016 | 2015 | \$ Change | % Change | 2015 | 2014 | \$ Change | % Change |
| Revenue | | | | | | | | |
| U.S. Omnipod | \$ 229,785 | \$ 189,604 | \$ 40,181 | 21 % | \$ 189,604 | \$ 175,950 | \$ 13,654 | 8 % |
| International Omnipod | 71,889 | 40,339 | 31,550 | 78 % | 40,339 | 50,025 | (9,686) | (19)% |
| Drug Delivery | 65,315 | 33,950 | 31,365 | 92 % | 33,950 | 5,346 | 28,604 | 535 % |
| Total Revenue | 366,989 | 263,893 | 103,096 | 39 % | 263,893 | 231,321 | 32,572 | 14 % |
| Cost of revenue | 155,903 | 130,622 | 25,281 | 19 % | 130,622 | 104,195 | 26,427 | 25 % |
| Gross profit | 211,086 | 133,271 | 77,815 | 58 % | 133,271 | 127,126 | 6,145 | 5 % |
| Gross margin | 57.5% | 50.5% | | 7 | 50.5% | 55.0% | | -4.5 |
| Operating expenses: | | | | | | | | |
| Research and development | 55,710 | 43,208 | 12,502 | 29 % | 43,208 | 27,900 | 15,308 | 55 % |
| Sales and marketing | 94,483 | 78,407 | 16,076 | 21 % | 78,407 | 50,552 | 27,855 | 55 % |
| General and administrative | 71,597 | 60,392 | 11,205 | 19 % | 60,392 | 57,548 | 2,844 | 5 % |
| Total operating expenses | 221,790 | 182,007 | 39,783 | 22 % | 182,007 | 136,000 | 46,007 | 34 % |
| Operating loss | (10,704) | (48,736) | (38,032) | (78)% | (48,736) | (8,874) | 39,862 | 449 % |
| Interest and other income (loss), net | (16,114) | (12,654) | (3,460) | (27)% | (12,654) | (39,006) | 26,352 | (68)% |
| Loss from continuing operations before income taxes | (26,818) | (61,390) | (34,572) | (56)% | (61,390) | (47,880) | 13,510 | 28 % |
| Income tax expense | 392 | 212 | 180 | 85 % | 212 | 60 | 152 | 253 % |
| Net loss from continuing operations | (27,210) | (61,602) | (34,392) | (56)% | (61,602) | (47,940) | 13,662 | 28 % |
| Loss from discontinued operations, net of tax | (1,669) | (11,918) | (10,249) | (86)% | (11,918) | (3,560) | 8,358 | 235 % |
| Net loss | \$ (28,879) | \$ (73,520) | \$ (44,641) | 61 % | \$ (73,520) | \$ (51,500) | \$ (22,020) | 43 % |

Comparison of the Years Ended December 31, 2016 and December 31, 2015

Revenue

Our total revenue increased to \$367.0 million, up \$103.1 million, or 39%, in 2016 compared to 2015, primarily due to strong growth in our U.S. Omnipod revenue, International Omnipod revenue and our on-body injection device for drug delivery. Our U.S. Omnipod revenue increased to \$229.8 million, up \$40.2 million, or 21%, primarily due to growth in our installed base of Omnipod users which was greatly driven by the expansion in 2015 and 2016 of our sales force and customer support personnel and strategic initiatives introduced in mid-2015 to expand awareness of the Omnipod System. The results for 2015 were also partially impacted by unfavorable distributor ordering patterns in the first quarter of 2015 which stabilized thereafter. Our International Omnipod revenue increased to \$71.9 million, up \$31.6 million, or 78%, primarily due to growth in distributor sales from continued adoption in existing markets and to a lesser extent from entry into new markets. The results for 2015 included lower International Omnipod sales which partially resulted from unfavorable distributor ordering patterns in the first and second quarters of 2015 which stabilized thereafter. Our drug delivery revenue increased to \$65.3 million, up \$31.4 million, or 92%, due to strong growth in demand for our primary drug delivery device following regulatory approval in December 2014.

For 2017 we expect strong revenue growth across all of our product lines as we continue our expansion in the U.S. and internationally. We expect strong growth of approximately 20% in our worldwide Omnipod installed base.

Cost of Revenue

Cost of revenue increased to \$155.9 million , up \$25.3 million , or 19% , in 2016 compared to 2015 , primarily due to an increase in sales volumes, partially offset by \$11.5 million of costs incurred during 2015 that were considered non-recurring in nature, along with supply chain operation efficiency and effectiveness improvements made in 2016.

Gross Margin

Gross margin increased to 57.5% , up approximately 7 points, in 2016 compared to 2015 , primarily due to \$11.5 million of costs incurred in 2015 that were considered non-recurring in nature, along with supply chain operation efficiency and effectiveness improvements made in 2016.

For 2017 , we expect gross margin to increase primarily from improvements to our supply chain operation efficiency and effectiveness as demonstrated in 2016.

Research and Development

Research and development expenses increased to \$55.7 million , up \$12.5 million , or 29% , in 2016 compared to 2015 , primarily due to an increase in expenses related to our development projects, including our mobile application development which involves interaction with continuous glucose monitoring technology, artificial pancreas program, development efforts with Eli Lilly and Company for the use of concentrated insulin for patients with higher insulin-resistance and other Omnipod product improvement initiatives.

For 2017 , we expect overall research and development spending to increase due to the development efforts on our ongoing projects described above.

Sales and Marketing

Sales and marketing expenses increased to \$94.5 million , up \$16.1 million , or 21% , for 2016 , compared to 2015 , primarily due to an increase of \$16.0 million in personnel-related expenses, including increased incentive compensation costs resulting from growth in the business, as well as costs associated with the expansion in 2015 of our sales force and customer support personnel.

We expect sales and marketing expenses in 2017 to increase due to the expansion of our sales force and customer support personnel.

General and Administrative

General and administrative expenses increased to \$71.6 million , up \$11.2 million , or 19% , for 2016 , compared to 2015 . This increase includes a charge of \$6.1 million related to in-process internally developed software recorded in the fourth quarter of 2016 due to a change in our longer-term enterprise resource planning ("ERP") system requirements. In addition, the increase was also due to a \$4.6 million increase that was primarily attributable to personnel-related costs on higher incentive compensation associated with growth in our business, as well as additional staff to support our growth expectations and fees paid for external consultants.

For 2017 , we expect overall general and administrative expenses to increase as compared to 2016 as we continue to grow the business and make investments in our operating structure to support this continued growth.

Interest and Other Income (Loss), Net

Interest and other income (loss), net increased to \$16.1 million , up \$3.5 million , or 27% , for 2016 , compared to 2015 , primarily due to \$3.0 million of net additional interest expense associated with the issuance of the 1.25% Notes and a \$2.6 million charge recorded for the extinguishment of debt related to the repurchase of \$134.2 million in principal of the 2% Notes. This was partially offset from a slight decrease in capital lease interest expense.

Income Tax Expense

In 2016 and 2015, income tax expense was \$0.4 million and \$0.2 million , respectively. The increase in tax expense is due to foreign taxes due to our acquisition in mid-2015 of the Canadian distribution business. Additional information regarding income tax expense is provided in note 18 to the consolidated financial statements

Loss from Discontinued Operations, Net of Tax

The loss from discontinued operations decreased by approximately \$10.2 million in 2016, compared to the year ended December 31, 2015. This decrease was primarily the result of a \$9.1 million impairment charge recorded in the fourth quarter of 2015 for the long-lived assets of Neighborhood Diabetes which we sold in February 2016. As the Neighborhood Diabetes business was sold in February 2016, 2016 includes less than two months of full operations compared to a full year for 2015.

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

Revenue

Our total revenue increased to \$263.9 million , up \$32.6 million , or 14% , in 2015 , compared to 2014 , led by growth in our U.S. Omnipod revenue and our on-body injection device for drug delivery, offset by lower international Omnipod revenue. Our U.S. Omnipod revenue increased to \$189.6 million , up \$13.7 million , or 8% , due to growth in our installed base of Omnipod users offset in part by unfavorable distributor ordering patterns and a reduction in royalty revenues of \$3.2 million. Our drug delivery revenue increased to \$34.0 million , up \$28.6 million due to strong growth in demand for our on-body injection device following regulatory approval in December 2014. Our International Omnipod revenue decreased to \$40.3 million , down \$9.7 million , or 19% , primarily reflecting lower distributor sales due to changes in distributor ordering patterns despite continued growth in our installed base of Omnipod users. This decrease internationally was partially offset by growth in Canada (we acquired our Canadian distributor in July 2015).

Cost of Revenue

Cost of revenue increased to \$130.6 million , up \$26.4 million , or 25% , in 2015 compared to 2014 , due to an increase in sales volumes, as well as \$11.5 million of costs directly and indirectly attributable to a voluntary Field Safety Notification that we initiated in November 2015 after identifying certain lots of Omnipod product which had a slight increase in the reported cases in which the needle mechanism failed to deploy or there was a delay in the deployment of the needle mechanism. The product manufactured in this condition was contained prior to distribution and was ultimately scrapped.

Gross Margin

Gross margin decreased to 50.5% , down approximately 4.5 points in 2015 compared to 2014 , primarily due to approximately \$11.5 million of costs directly and indirectly attributable to the voluntary field safety notification. The decrease in gross margin also reflects an increased investment in product quality and related policies and procedures to stand behind our products, which contributed to a \$3.3 million increase in warranty expense year over year, of which \$0.4 million related to the voluntary field safety notification.

Research and Development

Research and development expenses increased to \$43.2 million , up \$15.3 million , or 55% , in 2015 compared to 2014 , due to expenses related to our development projects, including a new PDM, the use of concentrated insulin for patients with higher insulin-resistance and investment in our artificial pancreas program, as well as expenses related to software development costs of \$10.5 million.

Sales and Marketing

Sales and marketing expenses increased to \$78.4 million , up \$27.9 million , or 55% , for 2015 compared to 2014 , primarily due to a \$19.5 million increase in employee related expenses associated with the expansion of our sales force and customer support personnel. Additionally, there was a \$6.9 million increase in costs associated with marketing campaigns, new market opportunities and other strategic initiatives.

General and Administrative

General and administrative expenses increased to \$60.4 million , up \$2.8 million , or 5% , for 2015 compared to 2014 , mainly the result of an increase of \$1.7 million in audit, professional services and consulting fees and an increase of \$1.6 million in technology license fees and consulting services. Additionally, there was an increase in shipping costs of \$1.4 million, an increase in employee related expenses of \$0.9 million, a \$0.9 million increase in expenses associated with claims and settlements and a \$0.9 million increase in occupancy and depreciation expense. This increase was partially offset by a decrease in legal fees of approximately \$6.2 million, mainly related to the Becton, Dickinson and Company litigation settlement in 2014.

Interest and Other Income (Loss), Net

Interest and other income (loss), net decreased to \$12.7 million , down \$26.4 million , or 68% for 2015 compared to 2014 , due to the loss from extinguishment of long-term debt of \$23.2 million in 2014 as well as the change in interest rate on our long-term debt to 2% in mid-2014 from 3.75%.

Income Tax Expense

In 2015 and 2014, income tax expense was \$0.2 million and \$0.1 million, respectively. Income tax expense is comprised of a current portion for 2015 and 2014 and deferred portion for 2015. The current portion primarily related to state and foreign taxes and the deferred portion primarily related to federal and state tax amounts. The increase in tax expense was due to foreign taxes due to our acquisition in 2015 of the Canadian distribution assets. Additional information regarding income tax expenses is provided in note 18 to the consolidated financial statements.

Loss from Discontinued Operations, Net of Tax

The loss from discontinued operations increased by approximately \$8.4 million in 2015 compared to 2014. This increase was primarily the result of a \$9.1 million impairment charge recorded in the fourth quarter of 2015 for the long-lived assets of Neighborhood Diabetes.

Liquidity and Capital Resources

As of December 31, 2016, we had \$137.2 million in cash and cash equivalents and \$161.4 million in short-term investments. We believe that our current liquidity, together with the cash expected to be generated from sales, will be sufficient to meet our projected operating and debt service requirements for at least the next twelve months.

To lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base and support growth, we intend to construct a highly-automated manufacturing facility in the U.S., with planned production out of the facility beginning in 2019. We expect capital expenditures to increase above historic levels to fund the construction of the manufacturing facility and related equipment purchases. We believe that our current liquidity will be sufficient to meet our projected expenditures associated with this project.

Convertible Debt

In September 2016, we issued and sold \$345.0 million in principal amount of 1.25% Convertible Senior Notes due September 2021 ("1.25% Notes"). The interest rate on the notes is 1.25% per annum, payable semi-annually in arrears in cash on March 15 and September 15 of each year. Interest began accruing on September 13, 2016; the first interest payment is due on March 15, 2017. The 1.25% Notes are convertible into our common stock at an initial conversion rate of 17.1332 shares of common stock per \$1,000 principal amount of the 1.25% Notes, which is equivalent to a conversion price of approximately \$58.37 per share, subject to adjustment under certain circumstances. The 1.25% Notes will be convertible prior to the close of business on the business day immediately preceding June 15, 2021 only under certain circumstances and during certain periods, and will be convertible on or after June 15, 2021 until the close of business on the second scheduled trading day immediately preceding September 15, 2021, regardless of those circumstances.

Cash interest expense related to the 1.25% Notes in the year ended December 31, 2016 was \$1.3 million. Non-cash interest expense related to the 1.25% Notes was comprised of the amortization of the debt discount and debt issuance costs and in the year ended December 31, 2016 was \$3.8 million.

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

In September 2016, in connection with the issuance of \$345.0 million in principal amount of 1.25% Notes discussed above, we repurchased approximately \$134.2 million in principal amount of the 2% Notes for \$153.6 million. The \$154.3 million paid to extinguish the debt was allocated to debt and equity based on their respective fair values immediately prior to the transaction. We allocated \$121.4 million of the payment to the debt and \$32.9 million to equity.

Cash interest expense related to the 2% Notes in the years ended December 31, 2016, 2015 and 2014 was \$3.2 million, \$4.0 million and \$2.3 million, respectively. Non-cash interest expense related to the 2% Notes was comprised of the amortization of the debt discount and debt issuance costs and in the years ended December 31, 2016, 2015 and 2014 was \$6.3 million, \$7.7 million and \$4.0 million, respectively.

Additional information regarding our debt issuances is provided in note 7 to the consolidated financial statements included under Item 8 of this Form 10-K.

Capital Leases

As of December 31, 2016 and December 31, 2015, we had approximately \$13.7 million of manufacturing equipment acquired under capital leases. As of December 31, 2016, one capital lease remained outstanding and is being repaid in equal monthly installments over a 24 month term, ending in the first quarter of 2017, and includes principal and interest payments with an effective interest rate of 13%.

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

Summary of Cash Flows

| (In thousands) | Years Ended December 31, | | |
|--|--------------------------|-------------|----------|
| | 2016 | 2015 | 2014 |
| Cash provided by (used in): | | | |
| Operating activities | \$ 15,911 | \$ (12,552) | \$ 8,920 |
| Investing activities | (178,010) | (15,323) | (11,486) |
| Financing activities | 176,567 | (371) | 4,032 |
| Effect of exchange rate changes on cash | 34 | (275) | — |
| Net increase (decrease) in cash and cash equivalents | \$ 14,502 | \$ (28,521) | \$ 1,466 |

Included in our summary of cash flows are the results of our discontinued operations. Refer to note 3 in the consolidated financial statements for further information.

Operating Activities

Our net cash provided by operating activities for the year ended December 31, 2016 was \$15.9 million compared to net cash used in operating activities of \$12.6 million in the same period of 2015. The increase was primarily due to a lower net loss recorded for the year and improved customer collections, partially offset by timing of cash disbursements and additional inventory purchases in order to support customer demand and to allow for alternative shipping methods which in turn is expected to lower our distribution costs.

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

Investing Activities

Our net cash used in investing activities in the year ended December 31, 2016 was \$178.0 million compared to \$15.3 million in the same period of 2015. In the year ended December 31, 2016, we invested \$161.6 million into short-term investments (net of proceeds from redemptions and sales), driven by the net proceeds from the issuance of the 1.25% Notes. There were no such investments in 2015. In addition, the increase in investing activities relates to higher capital purchases of \$22.1 million in 2016 compared to \$10.6 million in 2015, primarily associated with investments in supply chain operations including \$10.7 million for equipment in process of construction to support our U.S. manufacturing initiatives.

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

Financing Activities

Our net cash provided by financing activities for the year ended December 31, 2016 was \$176.6 million compared to \$0.4 million in net cash used in financing activities in the same period of 2015. The increase was primarily attributable to net proceeds of \$333.7 million in September 2016 from the issuance of the 1.25% Notes, offset by repayments of \$153.6 million to extinguish \$134.2 million or approximately 67% of our outstanding 2% Notes.

Net cash used in financing activities in the year ended December 31, 2015 was \$0.4 million compared to \$4.0 million in net cash provided by financing activities in the same period of 2014. The \$4.4 million decrease was primarily attributable to the increase in capital lease property and equipment in 2015 as well as a \$5.0 million net decrease in proceeds related to the 2014 issuance of the 2% Notes.

Commitments and Contingencies

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

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

The following table summarizes our principal obligations as of December 31, 2016 :

(In thousands)

| Contractual Obligations | Total | 2017 | 2018 | 2019 | 2020 | 2021 | Later |
|--------------------------------------|-------------------|------------------|------------------|------------------|-----------------|-------------------|-----------------|
| Operating lease obligations | \$ 14,380 | \$ 2,560 | \$ 2,468 | \$ 2,455 | \$ 2,383 | \$ 2,383 | \$ 2,131 |
| Debt obligations (1) | 435,687 | 5,654 | 5,654 | 72,011 | 4,313 | 348,055 | — |
| Capital lease obligations (2) | 269 | 269 | — | — | — | — | — |
| Purchase obligations (3) | 78,102 | 67,928 | 10,174 | — | — | — | — |
| Total contractual obligations | \$ 528,438 | \$ 76,411 | \$ 18,296 | \$ 74,466 | \$ 6,696 | \$ 350,438 | \$ 2,131 |

(1) Debt obligations include principal and interest. Our senior convertible notes incur interest of 2% and 1.25% per annum.

(2) The effective interest rate on our capital lease obligation is 13%.

(3) Our purchase obligations include commitments with certain of our suppliers, primarily for the purchase of Omnipod System components and manufacturing equipment along with other commitments to purchase goods or services in the normal course of business. We make such commitments through a combination of purchase orders, supplier contracts, and open orders based on projected demand information. These amounts include an \$8.8 million commitment for the purchase of property located in Acton, Massachusetts that will be used for our manufacturing facility in the U.S. and was subsequently paid in February 2017. Total purchase price for the property was \$9.3 million. These amounts also include outstanding purchase commitments with various suppliers for the construction and retrofit of the manufacturing facility and the establishment of highly-automated manufacturing operations, including \$22.8 million with ATS Automation Tooling Systems Inc for equipment purchases.

Legal Proceedings

The significant estimates and judgments related with establishing litigation reserves are discussed under "Legal Proceedings" in note 15 of the consolidated financial statements included under Item 8 of this Form 10-K.

Off-Balance Sheet Arrangements

As of December 31, 2016, we did not have any off-balance sheet financing arrangements.

Critical Accounting Policies and Estimates

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying notes. Future events and their effects cannot be determined with certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results could differ from those estimates, and any such differences may be material to our financial statements.

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

- Revenue recognition
- Stock-based compensation and equity instruments
- Business Combinations
- Goodwill
- Intangibles and other long-lived assets
- Accounts receivable and allowance for doubtful accounts
- Warranty
- Contingencies
- Income Taxes
- Convertible Debt

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

Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

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

As of December 31, 2016, we had outstanding debt recorded on our consolidated balance sheet of \$332.8 million, net of our deferred financing costs and unamortized debt discount totaling \$79.3 million, related to our 2% and 1.25% Notes. As the interest rates are fixed, changes in interest rates do not affect the value of our debt.

Foreign Currency Exchange Risk. Our business is subject to risks, including, but not limited to: unique economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. We are primarily exposed to currency exchange rate fluctuations related to our subsidiary operation in Canada. The majority of our sales outside of the U.S. are transacted in U.S. dollars and are not subject to material foreign currency fluctuations.

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

Item 8. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2016 and 2015 and for each of the three years in the period ended December 31, 2016, and the Reports of the Registered Independent Public Accounting Firms are included in this report as listed in the index.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Insulet Corporation

We have audited the accompanying consolidated balance sheet of Insulet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2016 , and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2016 . Our audit of the basic consolidated financial statements included the financial statement schedule listed in the index appearing under Item 15(a). These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Insulet Corporation and subsidiaries as of December 31, 2016 , and the results of their operations and their cash flows for the year ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2016 , based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2017 expressed an unqualified opinion.

/s/ GRANT THORNTON LLP

Boston, Massachusetts
February 27, 2017

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of
Insulet Corporation

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

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

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

/s/ Ernst & Young LLP

Boston, Massachusetts

February 29, 2016

(except for the effects of discontinued operations as discussed in Notes 2 and 3 as to which the date is September 6, 2016)

INSULET CORPORATION
CONSOLIDATED BALANCE SHEETS

| | December 31, 2016 | December 31, 2015 |
|--|----------------------|----------------------|
| (In thousands, except share and per share data) | | |
| ASSETS | | |
| Current Assets | | |
| Cash and cash equivalents | \$ 137,174 | \$ 122,672 |
| Short-term investments | 161,396 | — |
| Accounts receivable, net | 28,803 | 42,530 |
| Inventories, net | 35,514 | 12,024 |
| Prepaid expenses and other current assets | 7,073 | 4,283 |
| Current assets from discontinued operations | — | 9,252 |
| Total current assets | 369,960 | 190,761 |
| Property and equipment, net | 46,266 | 41,793 |
| Other intangible assets, net | 528 | 933 |
| Goodwill | 39,677 | 39,607 |
| Other assets | 216 | 76 |
| Long-term assets from discontinued operations | — | 1,956 |
| Total assets | \$ 456,647 | \$ 275,126 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities | | |
| Accounts payable | \$ 13,160 | \$ 15,213 |
| Accrued expenses and other current liabilities | 40,959 | 36,744 |
| Deferred revenue | 1,309 | 2,361 |
| Current portion of capital lease obligations | 269 | 5,519 |
| Current liabilities from discontinued operations | — | 5,319 |
| Total current liabilities | 55,697 | 65,156 |
| Capital lease obligations | — | 269 |
| Long-term debt, net of discount | 332,768 | 171,698 |
| Other long-term liabilities | 5,032 | 3,952 |
| Total liabilities | 393,497 | 241,075 |
| Commitments and contingencies (Note 15) | | |
| Stockholders' Equity | | |
| Preferred stock, \$.001 par value: | | |
| Authorized: 5,000,000 shares at December 31, 2016 and 2015. | | |
| Issued and outstanding: zero shares at December 31, 2016 and 2015 | — | — |
| Common stock, \$.001 par value: | | |
| Authorized: 100,000,000 shares at December 31, 2016 and 2015. | | |
| Issued and outstanding: 57,457,967 and 56,954,830 shares at December 31, 2016 and 2015, respectively | 57 | 57 |
| Additional paid-in capital | 744,243 | 686,193 |
| Accumulated other comprehensive loss | (726) | (654) |
| Accumulated deficit | (680,424) | (651,545) |
| Total stockholders' equity | 63,150 | 34,051 |
| Total liabilities and stockholders' equity | \$ 456,647 | \$ 275,126 |

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

| (In thousands, except share and per share data) | Years Ended December 31, | | |
|---|--------------------------|-------------|-------------|
| | 2016 | 2015 | 2014 |
| Revenue | \$ 366,989 | \$ 263,893 | \$ 231,321 |
| Cost of revenue | 155,903 | 130,622 | 104,195 |
| Gross profit | 211,086 | 133,271 | 127,126 |
| Operating expenses: | | | |
| Research and development | 55,710 | 43,208 | 27,900 |
| Sales and marketing | 94,483 | 78,407 | 50,552 |
| General and administrative | 71,597 | 60,392 | 57,548 |
| Total operating expenses | 221,790 | 182,007 | 136,000 |
| Operating loss | (10,704) | (48,736) | (8,874) |
| Interest expense | 14,388 | 12,712 | 14,578 |
| Other income (expense), net | 825 | 58 | (1,225) |
| Loss on extinguishment of long-term debt | 2,551 | — | 23,203 |
| Interest and other income (loss), net | (16,114) | (12,654) | (39,006) |
| Loss from continuing operations before income taxes | (26,818) | (61,390) | (47,880) |
| Income tax expense | 392 | 212 | 60 |
| Net loss from continuing operations | (27,210) | (61,602) | (47,940) |
| Loss from discontinued operations, net of tax (\$408, \$79 and \$82 for the years ended December 31, 2016, 2015 and 2014, respectively) | (1,669) | (11,918) | (3,560) |
| Net loss | \$ (28,879) | \$ (73,520) | \$ (51,500) |
| Net loss from continuing operations per share basic and diluted | \$ (0.48) | \$ (1.08) | \$ (0.86) |
| Net loss from discontinued operations per share basic and diluted | \$ (0.03) | \$ (0.21) | \$ (0.06) |
| Weighted-average number of shares used in calculating net loss per share | 57,251,377 | 56,785,646 | 55,628,542 |

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

| (In thousands) | Years Ended December 31, | | |
|--|--------------------------|-------------|-------------|
| | 2016 | 2015 | 2014 |
| Net loss | \$ (28,879) | \$ (73,520) | \$ (51,500) |
| Other comprehensive loss, net of tax | | | |
| Foreign currency translation adjustment, net of tax | 135 | (641) | 6 |
| Unrealized loss on available-for-sale securities, net of tax | (207) | | |
| Total other comprehensive (loss) income, net of tax | (72) | (641) | 6 |
| Total comprehensive loss | \$ (28,951) | \$ (74,161) | \$ (51,494) |

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| (In thousands, except share data) | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total Stockholders' Equity |
|---|-------------------|--------------|----------------------------------|------------------------|---|----------------------------------|
| | Shares | Amount | | | | |
| Balance, December 31, 2013 | 54,870,424 | \$ 55 | \$ 651,086 | \$ (526,525) | \$ (19) | \$ 124,597 |
| Exercise of options to purchase common stock | 754,522 | 1 | 11,084 | — | — | 11,085 |
| Issuance for employee stock purchase plan | 13,620 | — | 583 | — | — | 583 |
| Stock-based compensation expense | — | — | 22,432 | — | — | 22,432 |
| Restricted stock units vested, net of shares withheld for taxes | 311,921 | — | (8,665) | — | — | (8,665) |
| Net impact of conversion of 3.75% Notes | — | — | (61,728) | — | — | (61,728) |
| Allocation to equity for conversion feature on 2% Notes, net of issuance costs | — | — | 34,455 | — | — | 34,455 |
| Issuance of common stock pursuant to conversion of debt | 348,535 | — | 12,564 | — | — | 12,564 |
| Net loss | — | — | — | (51,500) | — | (51,500) |
| Other comprehensive income | — | — | — | — | 6 | 6 |
| Balance, December 31, 2014 | 56,299,022 | 56 | 661,811 | (578,025) | (13) | 83,829 |
| Exercise of options to purchase common stock | 449,149 | 1 | 7,198 | — | — | 7,199 |
| Issuance for employee stock purchase plan | 22,039 | — | 652 | — | — | 652 |
| Stock-based compensation expense | — | — | 19,178 | — | — | 19,178 |
| Restricted stock units vested, net of shares withheld for taxes | 184,620 | — | (2,646) | — | — | (2,646) |
| Net loss | — | — | — | (73,520) | — | (73,520) |
| Other comprehensive loss | — | — | — | — | (641) | (641) |
| Balance, December 31, 2015 | 56,954,830 | 57 | 686,193 | (651,545) | (654) | 34,051 |
| Exercise of options to purchase common stock | 242,962 | — | 4,832 | — | — | 4,832 |
| Issuance for employee stock purchase plan | 30,949 | — | 802 | — | — | 802 |
| Stock-based compensation expense | — | — | 23,638 | — | — | 23,638 |
| Restricted stock units vested, net of shares withheld for taxes | 229,226 | — | (2,866) | — | — | (2,866) |
| Allocation to equity for conversion feature on 1.25% Notes, net of issuance costs | — | — | 64,509 | — | — | 64,509 |
| Extinguishment of conversion feature on 2% Notes, net of issuance costs | — | — | (32,865) | — | — | (32,865) |
| Net loss | — | — | — | (28,879) | — | (28,879) |
| Other comprehensive loss | — | — | — | — | (72) | (72) |
| Balance, December 31, 2016 | 57,457,967 | \$ 57 | \$ 744,243 | \$ (680,424) | \$ (726) | \$ 63,150 |

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

INSULET CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

| (In thousands) | Years Ended December 31, | | |
|--|--------------------------|-------------|-------------|
| | 2016 | 2015 | 2014 |
| Cash flows from operating activities | | | |
| Net loss | \$ (28,879) | \$ (73,520) | \$ (51,500) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities | | | |
| Depreciation and amortization | 13,833 | 15,838 | 12,223 |
| Non-cash interest and other expense | 10,068 | 7,678 | 10,253 |
| Stock-based compensation expense | 23,617 | 19,178 | 22,519 |
| Loss on extinguishment of long-term debt | 2,551 | — | 23,203 |
| Provision for bad debts | 2,070 | 1,184 | 3,254 |
| Impairment and other charges | 6,234 | 9,086 | — |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 12,551 | (9,793) | (10,069) |
| Inventories | (24,103) | (722) | (3,635) |
| Deferred revenue | (849) | 809 | 654 |
| Prepaid expenses and other assets | (2,621) | (1,460) | 662 |
| Accounts payable, accrued expenses and other current liabilities | 639 | 17,986 | 525 |
| Other long-term liabilities | 800 | 1,184 | 831 |
| Net cash provided by (used in) operating activities ⁽¹⁾ | 15,911 | (12,552) | 8,920 |
| Cash flows from investing activities | | | |
| Purchases of property and equipment | (22,115) | (10,608) | (11,486) |
| Purchases of short-term investments | (177,654) | — | — |
| Receipts from the maturity or sale of short-term investments | 16,045 | — | — |
| Proceeds from divestiture of business, net | 5,714 | — | — |
| Acquisition of Canadian distribution business | — | (4,715) | — |
| Net cash used in investing activities | (178,010) | (15,323) | (11,486) |
| Cash flows from financing activities | | | |
| Principal payments of capital lease obligations | (5,518) | (5,576) | (3,858) |
| Proceeds from issuance of convertible notes, net of issuance costs | 333,725 | — | 194,490 |
| Repayment of convertible notes | (153,628) | — | (189,521) |
| Proceeds from issuance of common stock, net of offering costs | 4,854 | 7,851 | 11,586 |
| Payment of withholding taxes in connection with vesting of restricted stock units | (2,866) | (2,646) | (8,665) |
| Net cash provided by (used in) financing activities | 176,567 | (371) | 4,032 |
| Effect of exchange rate changes on cash | 34 | (275) | — |
| Net increase (decrease) in cash and cash equivalents | 14,502 | (28,521) | 1,466 |
| Cash and cash equivalents, beginning of period | 122,672 | 151,193 | 149,727 |
| Cash and cash equivalents, end of period | \$ 137,174 | \$ 122,672 | \$ 151,193 |
| Supplemental disclosure of cash flow information | | | |
| Cash paid for interest | \$ 3,687 | \$ 4,025 | \$ 4,657 |
| Cash paid for taxes | \$ 932 | \$ 109 | \$ 124 |
| Non-cash investing and financing activities | | | |
| Allocation to equity for conversion feature for issuance of 2% convertible notes | \$ — | \$ — | \$ 35,638 |
| Allocation to equity for conversion feature for issuance of 1.25% convertible notes | \$ 66,689 | \$ — | \$ — |
| Allocation to equity for conversion feature for the repurchase of 2% convertible notes | \$ (32,865) | \$ — | \$ — |
| Common stock issued in exchange for 3.75% convertible notes | \$ — | \$ — | \$ 12,564 |
| Purchases of property and equipment under capital lease | \$ — | \$ 5,721 | \$ 1,474 |

⁽¹⁾ Includes activity related to discontinued operations. See note 3 to the consolidated financial statements for discussion of discontinued operations.

INSULET CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Nature of the Business

Insulet Corporation, the "Company," is primarily engaged in the development, manufacturing and sale of its proprietary Omnipod Insulin Management System (the "Omnipod System"), an innovative, discreet and easy-to-use 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. The Company believes that the Omnipod System's unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience, and ease.

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

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

The Company acquired Neighborhood Holdings, Inc. and its wholly-owned subsidiaries (collectively, "Neighborhood Diabetes") in June 2011. Through Neighborhood Diabetes, the Company provided customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals and had the ability to process claims as either durable medical equipment or through pharmacy benefits. In February 2016, the Company sold Neighborhood Diabetes to Liberty Medical LLC ("Liberty Medical"). Additional information regarding the disposition and treatment of the Neighborhood Diabetes business as discontinued operations is provided in note 3 to these consolidated financial statements.

Note 2 . Summary of Significant Accounting Policies

Use of Estimates in Preparation of Financial Statements

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions in the application of certain of its significant accounting policies that may materially affect the reported amounts of assets, liabilities, equity, revenue and expenses. The most significant estimates used in these financial statements include the valuation of stock-based compensation expense, acquired businesses, accounts receivable, inventories, goodwill, deferred revenue, equity instruments, convertible debt, the lives of property and equipment and intangible assets, as well as warranty and doubtful accounts allowance reserve calculations. Actual results may differ from those estimates.

Foreign Currency Translation

For foreign operations, asset and liability accounts are translated at exchange rates as of the balance sheet date; income and expenses are translated using weighted average exchange rates for the reporting period. Resulting translation adjustments are reported in accumulated other comprehensive loss, a separate component of stockholders' equity. Gains and losses arising from transactions and translation of period-end balances denominated in currencies other than the functional currency, primarily the Canadian dollar, are included in other income (expense), net, and were not material for fiscal years 2016, 2015 and 2014.

Principles of Consolidation

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

Cash and Cash Equivalents

For the purpose of the financial statement classification, the Company considers all highly-liquid investment instruments with original maturities of 90 days or less, when purchased, to be cash equivalents. Cash equivalents

include money market mutual funds, corporate bonds, and certificates of deposit which are carried at cost which approximates their fair value. Included in the Company's cash and cash equivalents are amounts set aside for collateral on outstanding letters of credit, related to security deposits for lease obligations, totaling \$1.2 million as of December 31, 2016 and December 31, 2015 .

Short-term Investments

Short-term investment securities consist of available-for-sale marketable securities and are carried at fair value with unrealized gains or losses included as a component of other comprehensive loss in stockholders' equity. Investments, exclusive of cash equivalents, with a stated maturity date of one year or less from the balance sheet date or that are expected to be used in current operations, are classified as short-term investments. Short-term investments include U.S. government and agency bonds, corporate bonds, and certificates of deposit.

The Company reviews investments for other-than-temporary impairment when the fair value of an investment is less than its amortized cost. If an available-for-sale security is other than temporarily impaired, the loss is charged to earnings.

Property and Equipment

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

Business Combinations

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

Segment Reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company has concluded that their Chief Executive Officer is the CODM as he is the ultimate decision maker for key operating decisions, determining the allocation of resources and assessing the financial performance of the Company. These decisions, allocations and assessments are performed by the CODM using consolidated financial information. Consolidated financial information is utilized by the CODM as the Company's current product offering primarily consists of drug delivery and the Omnipod System. The Company's products are relatively consistent and manufacturing is centralized and consistent across product offerings. Based on these factors, key operating decisions and resource allocations are made by the CODM using consolidated financial data and as such the Company has concluded that they operate as one segment.

Goodwill

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

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

As the Company operates in one segment, the Company has considered whether that segment contains multiple reporting units. The Company has concluded that there is a single reporting unit as the Company does not

have segment managers and discrete financial information below consolidated results is not reviewed on a regular basis. Based on this conclusion, goodwill was tested for impairment at the enterprise level. The Company performs an annual goodwill impairment test unless interim indicators of impairment exist. The Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of its sole reporting unit is less than its carrying amount. This qualitative analysis is used as a basis for determining whether it is necessary to perform the two-step goodwill impairment analysis. If the Company determines that it is more likely than not that its fair value is less than its carrying amount, then the two-step goodwill impairment test will be performed. The first step compares the carrying value of the reporting unit to its fair value using a discounted cash flow analysis. If the reporting unit's carrying value exceeds its fair value, the Company would record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. There was no impairment of goodwill during the years ended December 31, 2016, 2015 or 2014. As a result of the sale of Neighborhood Diabetes, goodwill totaling \$0.1 million was allocated to the discontinued business on the disposition date using the relative fair value approach and was included in long-term assets from discontinued operations as of December 31, 2015.

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

| (In thousands) | Years Ended December 31, | |
|-------------------------------------|--------------------------|-----------|
| | 2016 | 2015 |
| Goodwill: | | |
| Beginning balance | \$ 39,607 | \$ 37,396 |
| Goodwill as a result of acquisition | — | 2,403 |
| Foreign currency adjustment | 70 | (192) |
| Ending balance | \$ 39,677 | \$ 39,607 |

Revenue Recognition

The Company generates the majority of its revenue from sales of its Omnipod System to customers and third-party distributors who resell the products to patients with diabetes.

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

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

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

In June 2011, the Company entered into a development agreement with a U.S. based pharmaceutical company (the "Development Agreement"). Under the Development Agreement, the Company was required to perform design, development, regulatory, and other services to support the pharmaceutical company as it worked to obtain regulatory approval to use the Company's drug delivery technology as a delivery method for its pharmaceutical. Over the term of the Development Agreement, the Company has invoiced amounts based upon meeting certain deliverable milestones. Revenue on the Development Agreement was recognized using a

proportional performance methodology based on efforts incurred and total payments under the agreement. The impact of changes in the expected total effort or contract payments was recognized as a change in estimate using the cumulative catch-up method. The pharmaceutical company received regulatory approval and now purchases product from the Company for use with its pharmaceutical under a supply agreement. Product revenue under this arrangement is recognized at the time that all of the revenue recognition criteria are met, typically upon shipment.

The Company had deferred revenue of \$1.9 million and \$2.5 million as of December 31, 2016 and 2015, respectively. Deferred revenue included \$0.6 million and \$0.2 million classified in other long-term liabilities as of December 31, 2016 and 2015, respectively. Deferred revenue primarily relates to undelivered elements within certain of the Company's developmental arrangements and other instances where the Company has not yet met the revenue recognition criteria.

Collaborative Arrangements

The Company enters into collaborative arrangements for ongoing initiatives to develop products. Although the Company does not consider any individual alliance to be material, certain of the more notable alliances are described below.

Eli Lilly and Concentrated insulins : In May 2013, the Company entered into an agreement with Eli Lilly and Company (Eli Lilly) to develop a new version of the Omnipod insulin pump specifically designed to deliver Humulin R U-500 insulin, a concentrated form of insulin used by people with highly insulin resistant Type 2 diabetes. In January 2016, the Company entered into a development agreement with Eli Lilly to develop a new version of Insulet's Omnipod tubeless insulin delivery system, specifically designed to deliver Lilly's Humalog 200 units/mL insulin, a concentrated form of insulin used by higher insulin-requiring patients with diabetes that provides the same dose of insulin in half the volume of Lilly's Humalog U100 insulin. Under the terms of these arrangements, the parties share the responsibility of the permissible costs that are incurred. Any amounts incurred in excess of the permissible shared costs that are the responsibility of one party becomes due and payable by the other party. Consideration received and payments made by the Company under the terms of the arrangements are recorded within research and development expense.

Shipping and Handling Costs

The Company does not typically charge its customers for shipping and handling costs associated with shipping its product to its customers unless non-standard shipping and handling services are requested. These shipping and handling costs are included in general and administrative expenses and were \$4.1 million, \$3.7 million and \$2.3 million in the years ended December 31, 2016, 2015 and 2014, respectively.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, short-term investments and accounts receivable. The Company maintains the majority of its cash and short-term investments with one financial institution. Accounts are partially insured up to various amounts mandated by the Federal Deposit Insurance Corporation or by the foreign country where the account is held.

The Company purchases Omnipod Systems from Flex Ltd., its single source supplier. As of December 31, 2016 and December 31, 2015, liabilities to this vendor represented approximately 16% and 28% of the combined balance of accounts payable, accrued expenses and other current liabilities, respectively.

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

| | Twelve Months Ended December 31, | | |
|-------------------------|----------------------------------|------|------|
| | 2016 | 2015 | 2014 |
| Amgen, Inc. | 17% | 10% | * |
| Ypsomed Distribution AG | 16% | 12% | 19% |
| RGH Enterprises, Inc. | 10% | 13% | 14% |

* Customer represents less than 10% of revenue for the period.

Reclassification of Prior Period Balances

Certain reclassifications have been made to prior period amounts to conform to the current period financial statement presentation including adjusting footnotes to reflect the presentation of discontinued operations as further discussed in note 3 . These reclassifications have no effect on the previously reported net loss.

Subsequent Events

Events occurring subsequent to December 31, 2016 have been evaluated for potential recognition or disclosure in the consolidated financial statements.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). ASU 2014-09 requires that a company recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. Under this guidance, a company makes additional estimates regarding performance conditions and the allocation of variable consideration and must evaluate whether revenue derived from a contract should be recognized at a point in time or over time. The guidance is effective in fiscal years beginning January 1, 2018, with early adoption permitted. The Company plans to adopt the standard as of the required effective date. The Company is currently evaluating the impact of ASU 2014-09. As part of the Company's assessment work to-date, the Company has formed an implementation work team, completed training on the new ASU's revenue recognition model and is continuing its contract review and documentation, for which to date the Company has made significant progress. Over the course of 2017, the Company plans to finalize its evaluation and implement any required policy, process, and internal control changes required as a result of that evaluation. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective method). The Company has not yet selected a transition method nor has it determined the full effect of the standard on its consolidated financial position and results of operations.

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

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

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory* ("ASU 2015-11"). ASU 2015-11 amends existing guidance and requires entities to measure most inventory at the lower of cost and net realizable value. The guidance is effective prospectively for annual reporting periods beginning after December 15, 2016. Early adoption is permitted. Upon adoption, entities must disclose the nature of and reason for the accounting change. The Company is currently evaluating the impact of ASU 2015-11 but does not expect it to be material to the consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations, Simplifying the Accounting for Measurement Period Adjustments* ("ASU 2015-16"). ASU 2015-16 eliminates the requirement that an acquirer in a business combination account for measurement-period adjustments retrospectively. Instead, an acquirer will recognize a measurement period adjustment during the period in which it determines the amount of the adjustment, including the effect on earnings of any amounts it would have recorded in previous periods if the accounting had been completed at the acquisition date. The guidance is effective in 2016 for calendar year-end public entities. Early adoption is permitted. The Company has adopted ASU 2015-16 on January 1, 2016 and its adoption did not have an impact on the consolidated financial statements.

In January 2016, the FASB issued Accounting Standards Update 2016-01 ("ASU 2016-01"), *Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-01 changes the current GAAP model for the accounting of equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. All equity investments in unconsolidated entities (other than those accounted for using the equity method of accounting) will generally be measured at fair value through earnings. There will no longer be an available-for-sale classification (changes in fair value reported in other comprehensive income (loss)) for equity securities with readily determinable fair values. In addition, the FASB clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The classification and measurement guidance will be effective in fiscal years beginning after December 15, 2017, and interim periods within those years. The Company is currently evaluating the impact of ASU 2016-01.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires lessees to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and continue to recognize expenses on their income statements over the lease term. It will also require disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash flows arising from leases. The guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. The Company is currently evaluating the impact of ASU 2016-02.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those years. Early adoption is permitted for all entities. Had the standard been adopted as of December 31, 2016, the Company's deferred tax assets (tax effected) would have increased by approximately \$23.8 million, which would have been offset by a full valuation allowance. Overall, the Company does not expect adoption of the standard to have a material impact on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force)* ("ASU 2016-15"). ASU 2016-15 clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows. The guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. The guidance is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years. Early adoption is permitted for all entities. The Company is currently evaluating the impact of ASU 2016-15 but does not expect it to be material to the consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash (a consensus of the Emerging Issues Task Force)* ("ASU 2016-18"). ASU 2016-18 requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The guidance is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years. Early adoption is permitted for all entities. The Company is currently evaluating the impact of ASU 2016-18 but does not expect it to be material to the consolidated financial statements.

In December 2016, the FASB issued ASU 2016-19, *Technical Corrections and Improvements ("ASU 2016-19")*. ASU 2016-19 includes numerous technical corrections and clarifications to GAAP that are designed to remove inconsistencies in the board's accounting guidance. Several provisions in this accounting guidance are effective immediately which did not have an impact on the Company's consolidated financial statements. Additional provisions in this accounting guidance are effective for the Company in annual financial reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact that the adoption of the additional provisions in this accounting guidance may have on its consolidated financial statements.

Other Significant Policies:

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

| | | | | |
|--|------|----|------|----|
| Fair Value Measurements | Note | 5 | Page | 64 |
| Convertible Debt | Note | 7 | Page | 66 |
| Accounts Receivable and Allowance for Doubtful Accounts | Note | 10 | Page | 71 |
| Inventories | Note | 11 | Page | 71 |
| Other Intangible Assets | Note | 13 | Page | 73 |
| Accrued Expenses and Other Current Liabilities- Product Warranty Costs | Note | 14 | Page | 74 |
| Commitments and Contingencies | Note | 15 | Page | 75 |
| Equity - Stock-Based Compensation | Note | 16 | Page | 76 |
| Income Taxes | Note | 18 | Page | 80 |

Note 3 . Discontinued Operations

In February 2016, the Company sold Neighborhood Diabetes to Liberty Medical for approximately \$6.2 million in cash, which included \$1.2 million of closing adjustments finalized in June 2016 and paid by Liberty Medical. The results of operations, assets, and liabilities of Neighborhood Diabetes, are classified as discontinued operations for all periods presented, except for certain corporate overhead costs which remain in continuing operations.

In connection with the 2016 disposition, the Company entered into a transition services agreement pursuant to which Insulet is providing various services to Liberty Medical on an interim transitional basis. The services generally commenced on the closing date and terminated six months following the closing. Services provided by Insulet included certain information technology and back office support. The charges for such services were generally intended to allow the service provider to recover all out-of-pocket costs. Billings by Insulet under the transition services agreement were recorded as a reduction of the costs to provide the respective service in the applicable expense category in the consolidated statements of operations. This transitional support is to provide Liberty Medical the time required to establish its stand-alone processes for such activities that were previously provided by Insulet as described above and does not constitute significant continuing support of Liberty Medical's operations. Total expenses incurred for such transition services, which are reimbursed in full, were \$0.9 million for the year ended December 31, 2016.

Following the disposition, the Company entered into a distribution agreement with the Neighborhood Diabetes subsidiary of Liberty Medical to continue to act as a distributor for the Company's products. Omnipod sales transacted through Neighborhood Diabetes prior to the divestiture that were previously eliminated in consolidation were \$0.3 million, \$2.8 million and \$2.3 million for the years ended December 31, 2016, 2015 and 2014, respectively. These amounts were historically reported in the Neighborhood Diabetes revenue results and are being presented based on current market terms of products sold to the Neighborhood Diabetes subsidiary of Liberty Medical.

Post divestiture, Omnipod System sales to the Neighborhood Diabetes subsidiary of Liberty Medical were \$0.4 million for the year ended December 31, 2016.

The following is a summary of the operating results of Neighborhood Diabetes included in discontinued operations for the year ended December 31, 2016, 2015 and 2014 :

| (In thousands) | Years Ended December 31, | | |
|--|--------------------------|--------------------|-------------------|
| | 2016 | 2015 | 2014 |
| Discontinued operations: | | | |
| Revenue ⁽¹⁾ | \$ 7,730 | \$ 60,332 | \$ 57,399 |
| Cost of revenue | 5,468 | 45,449 | 41,237 |
| Gross profit | 2,262 | 14,883 | 16,162 |
| Operating expenses: | | | |
| Sales and marketing | 1,542 | 9,945 | 10,292 |
| General and administrative ⁽²⁾ | 1,853 | 16,967 | 9,293 |
| Total operating expenses | 3,395 | 26,912 | 19,585 |
| Operating Loss | (1,133) | (12,029) | (3,423) |
| Interest and other income (expense), net | (128) | 190 | (55) |
| Loss from discontinued operations before taxes | (1,261) | (11,839) | (3,478) |
| Income tax expense | 408 | 79 | 82 |
| Net loss from discontinued operations | \$ (1,669) | \$ (11,918) | \$ (3,560) |

⁽¹⁾ Revenue for the year ended December 31, 2016 includes revenue from operations of Neighborhood Diabetes through the date of sale in February 2016.

⁽²⁾ Included in general and administration expenses for the year ended December 31, 2015 was a charge of \$9.1 million related to the impairment of Neighborhood Diabetes asset group.

Depreciation and amortization expense included in discontinued operations was \$0.1 million , \$3.3 million and \$4.5 million for the years ended December 31, 2016 , 2015 and 2014 , respectively.

The following is a summary of the Neighborhood Diabetes assets and liabilities presented as discontinued operations:

| (in thousands) | December 31, 2015 | |
|---|----------------------|--------|
| ASSETS | | |
| Accounts receivable, net | \$ | 5,857 |
| Inventories, net | | 2,019 |
| Prepaid expenses and other current assets | | 1,376 |
| Total current assets of discontinued operations | | 9,252 |
| Intangible assets, net | | 1,788 |
| Goodwill | | 140 |
| Other non-current assets | | 28 |
| Total long-term assets of discontinued operations | | 1,956 |
| Total assets of discontinued operations | \$ | 11,208 |
| LIABILITIES | | |
| Accounts payable | \$ | 3,436 |
| Accrued expenses and other current liabilities | | 1,883 |
| Current liabilities of discontinued operations | | 5,319 |
| Total liabilities of discontinued operations | \$ | 5,319 |

Net operating cash flows used in discontinued operations in the years ended December 31, 2016 and 2015 were \$2.0 million and \$3.2 million , respectively. Net operating cash flows provided by discontinued operations in the year ended December 31, 2014 was \$0.2 million .

4. Business Combination

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

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

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

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

The table below details the consideration transferred to acquire GSK.

(in thousands)

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

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

(in thousands)

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

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

Note 5 . Fair Value Measurements

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

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

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

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

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

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

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

The following table provides a summary of assets that are measured at fair value as of December 31, 2016 and 2015, aggregated by the level in the fair value hierarchy within which those measurements fall:

| (in thousands) | Fair Value Measurements | | | |
|--|-------------------------|------------------|-------------------|-------------|
| | Total | Level 1 | Level 2 | Level 3 |
| December 31, 2016 | | | | |
| Recurring fair value measurements: | | | | |
| Cash equivalents: | | | | |
| Money market mutual funds | \$ 93,467 | \$ 93,467 | \$ — | \$ — |
| Corporate bonds | \$ 4,203 | \$ — | \$ 4,203 | \$ — |
| Certificates of deposit | \$ 735 | \$ — | \$ 735 | \$ — |
| Total cash equivalents | \$ 98,405 | \$ 93,467 | \$ 4,938 | \$ — |
| Short-term investments: | | | | |
| U.S. government and agency bonds | \$ 79,093 | \$ 49,963 | \$ 29,130 | \$ — |
| Corporate bonds | \$ 56,653 | \$ — | \$ 56,653 | \$ — |
| Certificates of deposit | \$ 25,650 | \$ — | \$ 25,650 | \$ — |
| Total short-term investments | \$ 161,396 | \$ 49,963 | \$ 111,433 | \$ — |
| December 31, 2015 | | | | |
| Recurring fair value measurements: | | | | |
| Cash equivalents: | | | | |
| Money market mutual funds | \$ 98,223 | \$ 98,223 | \$ — | \$ — |
| Non-recurring fair value measurements: | | | | |
| Long-term assets of discontinued operations ⁽¹⁾ | \$ 1,800 | \$ — | \$ — | \$ 1,800 |

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

Debt

The estimated fair value of debt is based on the Level 2 quoted market prices for the same or similar issues and included the impact of the conversion features.

The carrying amounts, net of unamortized discounts and issuance costs, and the estimated fair values of the Company's convertible debt as of December 31, 2016 and 2015 are as follows:

| (in thousands) | December 31, 2016 | | December 31, 2015 | |
|--------------------------------|-------------------|----------------------|-------------------|----------------------|
| | Carrying Value | Estimated Fair Value | Carrying Value | Estimated Fair Value |
| 2% Convertible Senior Notes | \$ 59,737 | \$ 71,909 | \$ 171,698 | \$ 207,882 |
| 1.25% Convertible Senior Notes | \$ 273,031 | \$ 320,969 | \$ — | \$ — |

Note 6 . Short-term Investments

The Company's short-term investments are classified as available-for-sale and have maturity dates that range from zero months to 19 months as of December 31, 2016. The investments are all classified as short-term as they are available for current operations. Amortized costs, gross unrealized holding gains and losses, and fair values at December 31, 2016 are as follows:

| (in thousands) | Amortized cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|----------------------------------|-------------------|---------------------------|-------------------------------|-------------------|
| December 31, 2016 | | | | |
| U.S. government and agency bonds | \$ 79,211 | \$ — | \$ (118) | \$ 79,093 |
| Corporate bonds | 56,742 | — | (89) | 56,653 |
| Certificates of deposit | 25,650 | — | — | 25,650 |
| Total short-term investments | <u>\$ 161,603</u> | <u>\$ —</u> | <u>\$ (207)</u> | <u>\$ 161,396</u> |

The Company had no realized gains or losses in 2016. The Company had no short-term investments at December 31, 2015.

Note 7 . Convertible Debt

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

| (in thousands) | As of | |
|--|-------------------|-------------------|
| | December 31, 2016 | December 31, 2015 |
| Principal amount of the 2% Convertible Senior Notes | \$ 67,084 | \$ 201,250 |
| Principal amount of the 1.25% Convertible Senior Notes | 345,000 | — |
| Unamortized debt discount | (69,684) | (25,704) |
| Deferred financing costs | (9,632) | (3,848) |
| Long-term debt, net of discount | <u>\$ 332,768</u> | <u>\$ 171,698</u> |

Interest expense related to the convertible notes is as follows:

| (in thousands) | Years Ended December 31, | | |
|---|--------------------------|------------------|------------------|
| | 2016 | 2015 | 2014 |
| Contractual coupon interest | 4,467 | 4,025 | 4,657 |
| Accretion of debt discount | 8,800 | 6,552 | 8,007 |
| Amortization of debt issuance costs | 1,270 | 1,126 | 895 |
| Loss on extinguishment of long-term debt | 2,551 | — | 23,203 |
| Total interest and loss on extinguishment | <u>\$ 17,088</u> | <u>\$ 11,703</u> | <u>\$ 36,762</u> |

1.25% Convertible Senior Notes

In September 2016, the Company issued and sold \$345.0 million in principal amount of 1.25% Convertible Senior Notes, due September 15, 2021 (the "1.25% Notes"). The interest rate on the notes is 1.25% per annum, payable semi-annually in arrears in cash on March 15 and September 15 of each year. Interest began accruing on September 13, 2016; the first interest payment is due on March 15, 2017. The 1.25% Notes are convertible into the Company's common stock at an initial conversion rate of 17.1332 shares of common stock per \$1,000 principal amount of the 1.25% Notes, which is equivalent to a conversion price of approximately \$58.37 per share, subject to adjustment under certain circumstances. The 1.25% Notes will be convertible prior to the close of business on the business day immediately preceding June 15, 2021 only under certain circumstances and during certain periods, and will be convertible on or after June 15, 2021 until the close of business on the second scheduled trading day immediately preceding September 15, 2021, regardless of those circumstances.

The Company recorded a debt discount of \$66.7 million related to the 1.25% Notes which results from allocating a portion of the proceeds to the fair value of the conversion feature. The fair value of the debt discount was estimated using a trinomial lattice model based on the following inputs: Company's stock price, expected volatility, term to maturity, risk-free interest rate, and dividend yield. The debt discount was recorded as additional paid-in capital and the remaining liability reflects the value of the Company's nonconvertible debt borrowing rate of 5.8% per annum. This debt discount is being amortized as non-cash interest expense over the five year term of the 1.25% Notes. The Company incurred debt issuance costs and other expenses related to this offering of approximately \$11.3 million, of which \$2.2 million has been reclassified as a reduction to the value of the amount

allocated to equity. The remainder is presented as a reduction of debt in the consolidated balance sheet, is being amortized using the effective interest method, and is recorded as non-cash interest expense over the five year term of the 1.25% Notes.

The 1.25% Notes contain provisions that allow for additional interest to holders of the notes upon failure to timely file documents or reports that the Company is required to file with the SEC. The additional interest is at a rate of 0.50% per annum of the principal amounts of the notes outstanding for a period of 360 days.

If the Company merges or consolidates with a foreign entity, then additional taxes may be required to be paid by the Company under the terms of the 1.25% Notes.

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

Cash interest expense related to the 1.25% Notes in the year ended December 31, 2016 was \$1.3 million. Non-cash interest expense related to the 1.25% Notes was comprised of the amortization of the debt discount and debt issuance costs and in the year ended December 31, 2016 was \$3.8 million.

As of December 31, 2016, the Company included \$273.0 million on its balance sheet in long-term debt related to the 1.25% Notes.

2% Convertible Senior Notes

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

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

In September 2016, in connection with the issuance of \$345 million in principal amount of the 1.25% Notes, the Company repurchased approximately \$134.2 million in principal amount of the 2% Notes for \$153.6 million. The extinguishment of the 2% Notes was accounted for separately from the issuance of the 1.25% Notes as both transactions were viewed as arm's-length in nature and were not contingent upon one another. The \$153.6 million paid to extinguish the debt was allocated to debt and equity based on their respective fair values immediately prior to the transaction. The fair value of the debt was estimated using a trinomial lattice model based on the following inputs: Company's stock price, expected volatility, term to maturity, risk-free interest rate, and dividend yield. The Company allocated \$121.4 million of the payment to the debt and \$32.9 million to equity.

The Company recorded a loss on extinguishment of debt of \$2.6 million in connection with the repurchase and redemption of the 2% Notes during the year ended December 31, 2016, representing the excess of the \$121.4 million allocated to the debt over its carrying value, net of unamortized debt discount, deferred financing costs and accrued interest.

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

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

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

Cash interest expense related to the 2% Notes in the years ended December 31, 2016, 2015 and 2014 was \$3.2 million, \$4.0 million and \$2.3 million, respectively.

Non-cash interest expense related to the 2% Notes was comprised of the amortization of the debt discount and debt issuance costs and in the years ended December 31, 2016, 2015 and 2014 was \$6.3 million, \$7.7 million and \$4.0 million, respectively.

As of December 31, 2016, the Company included \$59.7 million on its balance sheet in long-term debt related to the 2% Notes.

3.75% Convertible Senior Notes

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

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

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

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

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

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

Beginning on June 20, 2014, the Company had the right to redeem the 3.75% Notes, at its option, in whole or in part, if the last reported sale price per share of the Company's common stock was at least 130% of the conversion price then in effect for at least 20 trading days during a period of 30 consecutive trading days. In June 2014, the Company met the redemption requirements and notified holders of its intent to redeem the outstanding

\$28.8 million in principal amount of 3.75% Notes in July 2014. Prior to the redemption date, holders of \$28.5 million in principal amount of 3.75% Notes exercised their right to convert their outstanding 3.75% Notes. The Company settled this conversion of the 3.75% Notes in July 2014 by providing cash of \$28.5 million for the principal amount of the outstanding 3.75% Notes converted and issuing 348,535 shares of common stock for the conversion premium totaling \$12.6 million, for a total consideration paid of \$41.1 million. The Company settled the redemption of the remaining \$0.3 million in principal amount in exchange for a cash payment of \$0.3 million representing principal and accrued and unpaid interest. The Company allocated \$27.9 million of the total consideration paid to the debt and \$13.5 million to equity.

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

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

No cash interest expense was recorded related to the 3.75% Notes in the years ended December 31, 2016 and 2015. Cash interest expense related to the 3.75% Notes in the year ended December 31, 2014 was \$2.4 million.

No non-cash interest expense was recorded in the years ended December 31, 2016 and 2015 related to the 3.75% Notes. Non-cash interest expense related to the 3.75% Notes in the year ended December 31, 2014 was \$4.9 million.

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

Note 8 . Capital Lease Obligations

As of December 31, 2016 and 2015 , the Company had approximately \$13.7 million of manufacturing equipment acquired under capital leases, included in property and equipment. As of December 31, 2016 , one capital lease remained outstanding and is being repaid in equal monthly installments over a 24 month term, ending in the first quarter of 2017, and includes principal and interest payments with an effective interest rate of 13% .

The assets acquired under capital leases are being amortized on a straight-line basis over 5 years in accordance with the Company's policy for depreciation of manufacturing equipment. Amortization expense on assets acquired under capital leases is included with depreciation expense. Amortization expense related to these capital leased assets was \$2.7 million , \$2.5 million and \$1.3 million in the years ended December 31, 2016 , 2015 and 2014 , respectively.

Assets acquired under capital leases consist of the following:

| (in thousands) | As of | |
|--------------------------------|-------------------|-------------------|
| | December 31, 2016 | December 31, 2015 |
| Manufacturing equipment | \$ 13,705 | \$ 13,705 |
| Less: Accumulated amortization | (7,086) | (4,346) |
| Total | \$ 6,619 | \$ 9,359 |

The aggregate future minimum lease payments related to these capital leases as of December 31, 2016 are as follows:

| (in thousands) | Minimum Lease Payments | |
|-------------------------------------|------------------------|-----|
| Years Ending December 31, | | |
| 2017 | \$ | 269 |
| Total future minimum lease payments | \$ | 269 |
| Interest expense | | — |
| Total capital lease obligations | \$ | 269 |

The Company recorded \$0.4 million , \$1.2 million and \$1.2 million of interest expense on capital leases in the years ended December 31, 2016 , 2015 , and 2014 , respectively.

Note 9. Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, excluding unvested restricted common shares. Diluted net loss per share is computed using the weighted average number of common shares outstanding and, when dilutive, potential common share equivalents from options, restricted stock units and warrants (using the treasury-stock method), and potential common shares from convertible securities (using the if-converted method). Because the Company reported a net loss for the years ended December 31, 2016 , 2015 and 2014 , all potential dilutive common shares have been excluded from the computation of the diluted net loss per share for all periods presented, as the effect would have been anti-dilutive.

Potential dilutive common share equivalents consist of the following:

| | Years Ended December 31, | | |
|---------------------------------|--------------------------|-----------|-----------|
| | 2016 | 2015 | 2014 |
| 2.00% Convertible Senior Notes | 1,442,433 | 4,327,257 | 4,327,257 |
| 1.25% Convertible Senior Notes | 5,910,954 | — | — |
| Unvested restricted stock units | 962,219 | 811,965 | 746,612 |
| Outstanding stock options | 3,441,303 | 2,999,199 | 1,847,669 |
| Total dilutive common shares | 11,756,909 | 8,138,421 | 6,921,538 |

Note 10 . Accounts Receivable, Net

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

Customers that represented greater than 10% of gross accounts receivable as of December 31, 2016 , and 2015 were as follows:

| | As of | |
|-------------------------|-------------------|-------------------|
| | December 31, 2016 | December 31, 2015 |
| Amgen, Inc. | 16% | 22% |
| Ypsomed Distribution AG | 19% | 19% |

The components of accounts receivable from continuing operations are as follows:

| (in thousands) | As of | |
|---------------------------------|-------------------|-------------------|
| | December 31, 2016 | December 31, 2015 |
| Trade receivables | \$ 31,714 | \$ 46,668 |
| Allowance for doubtful accounts | (2,911) | (4,138) |
| Total accounts receivable | \$ 28,803 | \$ 42,530 |

Refer to note 3 for accounts receivable related to discontinued operations.

Note 11 . Inventories, Net

Inventories are held at the lower of cost or market, determined under the first-in, first-out method, and include the costs of material, labor and overhead. Inventory has been recorded at cost, or net realizable value as appropriate, as of December 31, 2016 and 2015 . The Company reviews inventories for net realizable value based on quantities on hand and expectations of future use. Work in process is calculated based upon a buildup in the stage of completion using estimated labor inputs for each stage in production.

The components of inventories from continuing operations are as follows:

| (in thousands) | As of | |
|---------------------|-------------------|-------------------|
| | December 31, 2016 | December 31, 2015 |
| Raw materials | \$ 1,911 | \$ 632 |
| Work-in-process | 15,681 | 1,960 |
| Finished goods, net | 17,922 | 9,432 |
| Total inventories | \$ 35,514 | \$ 12,024 |

Refer to note 3 for inventories related to discontinued operations, which were fully comprised of finished goods as of December 31, 2015.

In the third quarter of 2015, the Company identified that certain lots of Omnipods had increased complaints relating to the deployment of the needle mechanism. Omnipods produced with the specific tooling changes of needle mechanism components were subject to replacement, including certain Omnipod lots that were held as inventory. As such, the Company determined that it would not recover any amounts related to this inventory. Accordingly, this change in estimate increased the Company's cost of revenue in the year ended December 31, 2015 by approximately \$7.3 million .

Note 12 . Property and Equipment, Net

Property and equipment related to continuing operations consist of the following:

| (in thousands) | Estimated Useful Life (Years) | As of | |
|-----------------------------------|-------------------------------|-------------------|-------------------|
| | | December 31, 2016 | December 31, 2015 |
| Machinery and equipment | 2-5 | \$ 53,246 | \$ 49,059 |
| Lab equipment | 2-3 | 694 | 1,615 |
| Computers | 3 | 2,833 | 2,067 |
| Software | 3 | 3,786 | 2,566 |
| Office furniture and fixtures | 3-5 | 1,960 | 1,468 |
| Leasehold improvement | * | 1,126 | 927 |
| Construction in process | — | 24,137 | 12,275 |
| Total property and equipment | | \$ 87,782 | \$ 69,977 |
| Less: accumulated depreciation | | (41,516) | (28,184) |
| Total property and equipment, net | | \$ 46,266 | \$ 41,793 |

* Lesser of lease term or useful life of asset.

Property and equipment from discontinued operations were not significant as of December 31, 2015 .

Depreciation expense related to property and equipment from continuing operations was \$13.3 million , \$11.4 million and \$7.7 million for the years ended December 31, 2016 , 2015 and 2014 , respectively. Depreciation expense from discontinued operations was not significant during those same periods. The Company recorded \$0.5 million , \$0.2 million and \$0.2 million of capitalized interest in the years ended December 31, 2016 , 2015 and 2014 .

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

During the year ended December 31, 2015 , the Company wrote-off \$5.4 million of fully depreciated assets, as the assets were no longer in use. No gain or loss was recognized in the year ended December 31, 2015 related to the write-off of these assets. During the year ended December 31, 2016 , the Company wrote-off no fully depreciated assets.

During 2016, the Company restructured its plan for an internally developed ERP system to leverage current third-party software available and scale conversion based on the Company's evolving ERP needs. As a result, the Company recorded a charge of \$6.1 million included in general and administrative expenses related to in-process internally developed software.

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

Note 13 . Other Intangible Assets

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

The Company recorded \$32.9 million of other intangible assets as a result of the acquisition of Neighborhood Diabetes in 2011. In December 2015, the Company completed a long-lived asset impairment test for Neighborhood Diabetes and determined that the carrying value of the long-lived asset group, which included intangible assets, exceeded the undiscounted cash flows expected to be generated from the asset group. The Company compared the fair value of the intangible assets and the related asset group, which was estimated based on the subsequent sales price of the asset group as of February 2016. As a result, an impairment charge of \$9.0 million was recorded within loss from discontinued operations for the year ended December 31, 2015. The impairment charge was allocated on a pro-rata basis based on the carrying value of the assets within the asset group. As a result, impairment charges of approximately \$7.4 million and \$1.6 million, respectively, were recorded on the customer relationship and trade name intangible assets which are included within long-term assets from discontinued operations on the balance sheet. During the three months ended March 31, 2016, the remaining balance of the other intangible assets associated with the acquisition of Neighborhood Diabetes was removed from the balance sheet as part of the divestiture and included in the calculated loss of disposal. No further impairment was recorded upon the sale.

The Company recorded \$2.1 million of other intangible assets in the year ended December 31, 2015 as a result of the July 2015 acquisition of its Canadian distribution business (see note 4 for further description). The Company determined that the estimated useful life of the contractual relationship asset is 5 years and is amortizing the asset over the estimated lives, based on the expected cash flows of the assets, accordingly.

Other intangible assets consist of the following:

| (in thousands) | As of | | | | | |
|---|-----------------------|--------------------------|----------------|-----------------------|--------------------------|-----------------|
| | December 31, 2016 | | | December 31, 2015 | | |
| | Gross Carrying Amount | Accumulated Amortization | Net Book Value | Gross Carrying Amount | Accumulated Amortization | Net Book Value |
| Customer and contractual relationships, net ⁽¹⁾⁽²⁾ | \$ 1,994 | \$ (1,466) | \$ 528 | \$ 3,399 | \$ (1,000) | \$ 2,399 |
| Tradenam e ⁽³⁾ | — | — | — | 322 | — | 322 |
| Total intangible assets ⁽⁴⁾ | \$ 1,994 | \$ (1,466) | \$ 528 | \$ 3,721 | \$ (1,000) | \$ 2,721 |

⁽¹⁾ Includes foreign currency translation loss of approximately \$0.1 million .

⁽²⁾ The customer relationships asset includes \$1.5 million of both the gross carrying amount and net book value, respectively, that are included in long-term assets from discontinued operations on the balance sheet as of December 31, 2015.

⁽³⁾ The tradenam e asset is included in long-term assets from discontinued operations on the balance sheet as of December 31, 2015.

⁽⁴⁾ As a result of the impairment recorded on the Neighborhood Diabetes asset group, the Company recorded an impairment charge of approximately \$9.0 million on the related Neighborhood Diabetes intangible assets, which was recorded through discontinued operations. This resulted in the gross carrying value and accumulated amortization of the Neighborhood Diabetes intangibles being reduced by \$31.1 million and \$22.1 million, respectively, at December 31, 2015.

Amortization expense from continuing operations was approximately \$0.4 million and \$1.0 million for the years ended December 31, 2016 and 2015, respectively. There was no amortization expense from continuing operations in the year ended December 31, 2014. Amortization expense from discontinued operations was approximately \$0.1 million, \$3.3 million and \$4.0 million for the years ending December 31, 2016, 2015 and 2014 respectively. Amortization expense is recorded in general and administration expenses in the consolidated statements of operations.

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

(in thousands)

| Years Ending December 31, | Customer and Contractual Relationships | |
|---------------------------|--|-----|
| 2017 | \$ | 181 |
| 2018 | | 154 |
| 2019 | | 129 |
| 2020 | | 64 |
| Total | \$ | 528 |

As of December 31, 2016, the weighted average amortization period of the Company's intangible assets is approximately 4 years.

Note 14 . Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities related to continuing operations consist of the following:

| (in thousands) | Years Ended December 31, | | | |
|--|--------------------------|--------|------|--------|
| | 2016 | | 2015 | |
| Employee compensation and related costs | \$ | 21,999 | \$ | 16,856 |
| Professional and consulting services | | 6,753 | | 5,654 |
| Sales and use tax | | 299 | | 1,163 |
| Supplier charges | | 2,886 | | 4,981 |
| Warranty | | 1,642 | | 1,592 |
| Other | | 7,380 | | 6,498 |
| Total accrued expenses and other current liabilities | \$ | 40,959 | \$ | 36,744 |

Product Warranty Costs

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

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

| (in thousands) | Years Ended December 31, | |
|--|--------------------------|----------|
| | 2016 | 2015 |
| Balance at the beginning of the period | \$ 4,152 | \$ 2,614 |
| Warranty expense | 4,602 | 4,964 |
| Warranty claims settled | (4,366) | (3,426) |
| Balance at the end of the period | \$ 4,388 | \$ 4,152 |

| (in thousands) | As of | |
|-------------------------|-------------------|-------------------|
| | December 31, 2016 | December 31, 2015 |
| Composition of balance: | | |
| Short-term | \$ 1,642 | \$ 1,592 |
| Long-term | 2,746 | 2,560 |
| | \$ 4,388 | \$ 4,152 |

Note 15 . Commitments and Contingencies

The Company records a liability in the consolidated financial statements for loss contingencies when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed.

As of December 31, 2016, the Company had a commitment of \$8.8 million for the purchase of property that will be used for the Company's manufacturing facility in the United States and was subsequently paid in February 2017. Total purchase price for the property was \$9.3 million .

Operating Leases

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

The Company leases approximately 100,000 square feet of laboratory and office space for its corporate headquarters in Billerica, Massachusetts. The leases expire in November 2022 and contain escalating payments over the life of the lease. Additionally, the Company leases approximately 29,000 square feet of warehousing space in Billerica, Massachusetts under a lease expiring in September 2019. The Company leases other facilities in Canada, China, California and Tennessee containing a total of approximately 4,000 square feet under leases expiring from May 2017 to May 2018.

Certain of the Company's operating lease agreements contain scheduled rent increases. Rent expense is recorded using the straight-line method and deferred rent is included in other liabilities in the accompanying balance sheets. The Company has considered FASB ASC 840-20, *Leases* in accounting for these lease provisions. Rental expense from continuing operations under operating leases was \$2.5 million , \$1.9 million and \$1.4 million in the years ended December 31, 2016 , 2015 and 2014 , respectively.

The aggregate future minimum lease payments related to these leases from continuing operations as of December 31, 2016 are as follows:

(in thousands)

| Years Ending December 31, | Minimum Lease Payments |
|---------------------------|------------------------|
| 2017 | 2,560 |
| 2018 | 2,468 |
| 2019 | 2,455 |
| 2020 | 2,383 |
| 2021 | 2,383 |
| Thereafter | 2,131 |
| Total | \$ 14,380 |

Legal Proceedings

The Company is in the process of responding to a revised audit report received in December 2015 on behalf of the Centers for Medicare and Medicaid Services and the State of New York alleging overpayment of certain Medicaid claims to Neighborhood Diabetes. As of December 31, 2015, the Company had determined that it was probable that a loss had been incurred and recorded an aggregate liability of \$0.4 million recorded within loss from discontinued operations, which was reduced to \$0.3 million during 2016 (which remains the Company's current estimate of such liability). The change in the liability was recorded in discontinued operations.

In May 2016, the Company reached a settlement agreement for \$0.5 million with the Connecticut Department of Social Services Office of Quality Assurance relating to an audit alleging overpayment of certain Medicaid claims to Neighborhood Diabetes. The settlement amount for this audit was consistent with the amount previously accrued.

In April 2016, the Company reached a settlement agreement for \$0.5 million with the Massachusetts Department of Revenue for sales and use tax audits related to Insulet Corporation, which resulted in a \$0.2 million reduction of the previously recorded liability and a credit to general and administrative expenses during 2016.

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

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

Note 16 . Equity

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

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

The Company grants share-based awards to employees in the form of options to purchase the Company's common stock, the ability to purchase stock at a discounted price under the employee stock purchase plan and restricted stock units. The Company uses the Black-Scholes option pricing model to determine the weighted-average fair value of options granted and determines the intrinsic value of restricted stock units based on the closing price of its common stock on the date of grant. The Company recognizes the compensation expense of

share-based awards on a straight-line basis for awards with only service conditions and on an accelerated basis for awards with performance conditions. Compensation expense is recognized over the vesting period of the awards.

Stock-based compensation expense from continuing operations related to share-based awards recognized in the years ended December 31, 2016, 2015 and 2014 was \$23.8 million, \$18.7 million and \$22.0 million, respectively, and was calculated on awards ultimately expected to vest. Stock-based compensation expense from discontinued operations related to share-based awards was not significant for the year ended December 31, 2016. Stock-based compensation expense from discontinued operations related to share-based awards for the years ended December 31, 2015 and 2014 was \$0.5 million and \$0.5 million, respectively. At December 31, 2016, the Company had \$41.5 million of total unrecognized compensation expense related to unvested stock options and restricted stock units.

Stock Options

In May 2007, in conjunction with the Company's initial public offering, the Company adopted its 2007 Stock Option and Incentive Plan (the "2007 Plan"). The 2007 Plan was amended and restated in November 2008, May 2012 and May 2015 to provide for the issuance of additional shares and to amend certain other provisions. Under the 2007 Plan, awards may be granted to persons who are, at the time of grant, employees, officers, non-employee directors or key persons (including consultants and prospective employees) of the Company. The 2007 Plan provides for the granting of stock options, restricted stock units, stock appreciation rights, deferred stock awards, restricted stock, unrestricted stock, cash-based awards, performance share awards or dividend equivalent rights. Options granted under the 2007 Plan generally vest over a period of four years and expire ten years from the date of grant. As of December 31, 2016, 4,487,991 shares remain available for future issuance under the 2007 Plan.

In the year ended December 31, 2015 the Company awarded 194,500 shares of performance-based incentive stock options. In the year ended December 31, 2016 the Company awarded 65,000 shares of performance-based incentive stock options. The stock options were granted under the 2007 Plan and vest over a four year period from the grant date with the potential of an accelerated vesting period pursuant to the achievement of certain performance conditions.

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

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

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

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

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

| | Years Ended December 31, | | |
|--------------------------|--------------------------|---------------|---------------|
| | 2016 | 2015 | 2014 |
| Risk-free interest rate | 0.99% - 1.91% | 1.16% - 1.75% | 0.12% - 1.98% |
| Expected term (in years) | 5.07 - 5.38 | 4.86 - 5.25 | 1.0 - 6.25 |
| Dividend yield | — | — | — |
| Expected volatility | 38% - 40% | 37% - 38% | 37% - 63% |

The weighted average grant date fair value of options granted for the years ended December 31, 2016, 2015 and 2014 was \$11.60, \$11.09 and \$15.88, respectively.

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

| | Number of Options (#) | Weighted Average Exercise Price (\$) | Aggregate Intrinsic Value (\$) |
|--|-----------------------|--------------------------------------|--------------------------------|
| (In thousands) | | | |
| Balance, December 31, 2015 | 2,999,199 | \$ 31.37 | — |
| Granted | 1,049,862 | 31.85 | — |
| Exercised ⁽¹⁾ | (242,962) | 19.89 | \$ 4,646 |
| Canceled | (364,796) | 31.92 | — |
| Balance, December 31, 2016 | <u>3,441,303</u> | \$ 32.27 | \$ 20,196 |
| Vested, December 31, 2016 ⁽²⁾ | 1,503,811 | \$ 31.89 | \$ 9,325 |
| Vested and expected to vest, December 31, 2016 ⁽²⁾⁽³⁾ | 3,167,755 | | \$ 18,648 |

⁽¹⁾ The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of the date of exercise and the exercise price of the underlying options. The aggregate intrinsic value of options exercised in the years ended December 31, 2016, 2015 and 2014 was \$4.6 million, \$8.6 million and \$20.4 million, respectively.

⁽²⁾ The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock as of December 31, 2016, and the exercise price of the underlying options.

⁽³⁾ Represents the number of vested options as of December 31, 2016, plus the number of unvested options expected to vest as of December 31, 2016, based on the unvested options outstanding at December 31, 2016 adjusted for the estimated forfeiture.

At December 31, 2016 there were 3,441,303 options outstanding (vested and unvested) with a weighted average exercise price of \$32.27 and a weighted average remaining contractual life of 7.9 years. Of this amount, at December 31, 2016, there were 1,503,811 vested options exercisable with a weighted average exercise price of \$31.89 and a weighted average remaining contractual life of 6.6 years and 1,663,944 options expected to vest with a weighted average exercise price of \$32.57 and a weighted average remaining contractual life of 8.8 years.

Employee stock-based compensation expense from continuing operations related to stock options in the years ended December 31, 2016, 2015 and 2014 was \$9.9 million, \$9.1 million and \$7.6 million, respectively, and was based on awards ultimately expected to vest. Employee stock-based compensation expense from discontinued operations related to stock options was not significant for the year ended December 31, 2016. Employee stock-based compensation expense from discontinued operations related to stock options for the years ended December 31, 2015 and 2014 was \$0.1 million and \$0.1 million. At December 31, 2016, the Company had \$19.0 million of total unrecognized compensation expense related to stock options that will be recognized over a weighted average vesting period of 2.5 years.

Restricted Stock Units

In the year ended December 31, 2016, the Company awarded 592,783 restricted stock units to certain employees and non-employee members of the Board of Directors, which included 154,991 restricted stock units subject to the achievement of performance conditions (performance-based restricted stock units). For performance-based restricted stock units for which the performance criteria has not yet been achieved, the Company recognized stock compensation expense of \$2.4 million in 2016 as it expects a portion of the performance-based restricted

stock units granted will be earned based on its evaluation of the performance criteria at December 31, 2016 . An additional \$1.0 million of stock compensation expense was recognized in 2016 for performance-based restricted stock units for which the performance criteria has been achieved as of December 31, 2016. The restricted stock units were granted under the 2007 Plan and generally vest annually over a one or three year period from the grant date, except for the performance-based restricted stock units, which follow different vesting patterns.

The restricted stock units granted have a weighted average fair value of \$29.85 per share based on the closing price of the Company's common stock on the date of grant. The restricted stock units granted during the year ended December 31, 2016 were valued at approximately \$17.7 million on their grant date, and the Company is recognizing the compensation expense over the vesting period. Approximately \$10.2 million , \$8.1 million and \$14.3 million of stock-based compensation expense from continuing operations related to the vesting of non-performance based restricted stock units was recognized in the years ended December 31, 2016 , 2015 and 2014 , respectively. Employee stock-based compensation expense recognized from discontinued operations related to the vesting of non-performance based restricted stock units was not significant for the year ended December 31, 2016. Employee stock-based compensation expense from discontinued operations related to the vesting of non-performance based restricted stock for the years ended December 31, 2015 and 2014 was \$0.4 million and \$0.4 million , respectively. Approximately \$22.4 million of the fair value of the restricted stock units remained unrecognized as of December 31, 2016 and will be recognized over a weighted average period of 1.8 years. Under the terms of the awards, the Company will issue shares of common stock on each of the vesting dates.

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

| | Number of Shares (#) | Weighted Average Fair Value (\$) |
|----------------------------|-------------------------|--|
| Balance, December 31, 2015 | 811,965 | \$ 30.58 |
| Granted | 592,783 | 29.85 |
| Vested | (317,470) | 31.01 |
| Forfeited | (125,059) | 33.02 |
| Balance, December 31, 2016 | 962,219 | \$ 31.14 |

Employee Stock Purchase Plan

The Employee Stock Purchase Plan ("ESPP") authorizes the issuance of up to a total of 380,000 shares of common stock to participating employees. The Company will make one or more offerings each year to eligible employees to purchase stock under the ESPP. Between January 1, 2008 and June 30, 2016, offering periods began on the first business day occurring on or after each January 1 and July 1 and ended on the last business day occurring on or before the following June 30 and December 31, respectively. Beginning as of July 1, 2016, offering periods begin on the first business day occurring on or after each December 1 and June 1 and will end on the last business day occurring on or before the following May 31 and November 30, respectively. In order to permit a transition to the new offering cycle, a one-time offering period began on July 1, 2016 and ended on November 30, 2016.

Each employee who is a participant in the Company's ESPP may purchase up to a maximum of 800 shares per offering period or \$25,000 worth of common stock, valued at the start of the purchase period, per year by authorizing payroll deductions of up to 10% of his or her base salary. Unless the participating employee withdraws from the offering period, his or her accumulated payroll deductions will be used to purchase common stock.

For all offering periods ending on or before June 30, 2016, the purchase price for each share purchased was 85% of the fair market value of the common stock on the last day of the offering period. For all offering periods beginning on or after July 1, 2016, the purchase price for each share purchased will be 85% of the lower of (i) the fair market value of the common stock on the first day of the offering period or (ii) the fair market value of the common stock on the last day of the offering period.

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

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

The Company issued 30,949 shares of common stock in 2016 , 22,039 shares of common stock in 2015 and 13,620 shares of common stock in 2014 to employees participating in the ESPP. The Company recorded approximately \$0.2 million , \$0.1 million and \$0.1 million of stock-based compensation expense related to the ESPP in each of the years ended December 31, 2016 , 2015 and 2014 .

Shareholder Rights Plan

In November 2008, the Board of Directors of the Company adopted a shareholder rights plan (the "Shareholder Rights Plan"), as set forth in the Shareholder Rights Agreement between the Company and the rights agent, the purpose of which is, among other things, to enhance the ability of the Board of Directors to protect shareholder interests and to ensure that shareholders receive fair treatment in the event any coercive takeover attempt of the Company is made in the future. The Shareholder Rights Plan could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, the Company or a large block of the Company's common stock.

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

Note 17. Defined Contribution Plan

The Insulet 401(k) Retirement Plan (the "401(k) Plan") is a defined contribution plan in the form of a qualified 401(k) plan, in which substantially all employees are eligible to participate upon hire. Eligible employees may elect to contribute 100% of their eligible compensation up to the IRS maximum. The Company has the option of making both matching contributions and discretionary profit-sharing contributions to the 401(k) Plan. Since 2011, the Company has offered a discretionary match of 50% for the first 6% of an employee's salary that was contributed to the 401(k) Plan. The Company match vests after the employee attains one year of service. The total amount contributed by the Company under the 401(k) Plan in continuing operations was \$1.6 million , \$1.6 million and \$1.1 million for the years ended December 31, 2016 , 2015 and 2014 , respectively. Contributions in discontinued operations were not significant during those same periods.

Note 18 . Income Taxes

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

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

interest and penalties, accounting in interim periods, disclosure and transition. The Company recognizes estimated interest and penalties for uncertain tax positions in income tax expense.

The Company files federal, state and foreign tax returns. These returns are generally open to examination by the relevant tax authorities from three to four years from the date they are filed. The tax filings relating to the Company's federal and state tax returns are currently open to examination for tax years 2013 through 2015 and 2012 through 2015, respectively. In addition, the Company has generated tax losses since its inception in 2000. These years may be subject to examination if the losses are carried forward and utilized in future years.

At December 31, 2016 and December 31, 2015, the Company provided a full valuation allowance against its domestic net deferred tax asset because it is not more likely than not that the future tax benefit will be realized. In addition, the Company has a net deferred tax asset in foreign jurisdictions where no valuation allowance is recorded, because it is more likely than not that the future tax benefit will be realized.

Income tax expense from continuing operations consists of the following:

| (in thousands) | Years Ended December 31, | | |
|--------------------------|--------------------------|--------|------|
| | 2016 | 2015 | 2014 |
| Current: | | | |
| Federal | \$ — | \$ — | \$ — |
| State | 52 | 72 | 57 |
| Non-U.S. | 539 | 321 | 3 |
| Total current expense | 591 | 393 | 60 |
| Deferred: | | | |
| Federal | — | — | — |
| State | — | — | — |
| Non-U.S. | (199) | (181) | — |
| Total deferred expense | (199) | (181) | — |
| Total income tax expense | \$ 392 | \$ 212 | 60 |

Income tax expense from discontinued operations was \$0.4 million for the year ended 2016 and was primarily generated from federal deferred taxes. Income tax expense from discontinued operations was not significant for the years ended December 31, 2015 and 2014.

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

| | Year Ended December 31, | | |
|-------------------------------------|-------------------------|---------|---------|
| | 2016 | 2015 | 2014 |
| Tax at U.S. statutory rate | 34.00 % | 34.00 % | 34.00 % |
| Changes from statutory rate: | | | |
| State taxes, net of federal benefit | (10.86) | 3.06 | 1.56 |
| Tax credits | 0.03 | 1.51 | 1.36 |
| Permanent items | (11.03) | (2.09) | (1.32) |
| Change in valuation allowance | (13.45) | (37.11) | (32.13) |
| Other | (0.15) | 0.28 | (3.60) |
| Effective income tax rate | (1.46)% | (0.35)% | (0.13)% |

Pre-tax income attributable to the Company's operations located outside the U.S. was approximately \$0.8 million, \$0.3 million and \$0.1 million for 2016, 2015 and 2014, respectively. In general, it is the Company's practice and intention to reinvest the earnings of its non-U.S. subsidiaries in those operations. As of December 31, 2016, the Company has chosen to indefinitely reinvest approximately \$0.8 million of earnings of certain of its non-U.S. subsidiaries. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. No provision has been recorded for U.S. income taxes that could be incurred upon repatriation. It is not practicable to estimate the amount of the deferred tax liability related to such earnings.

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

| (in thousands) | Year Ended December 31, | |
|--------------------------------------|-------------------------|--------------|
| | 2016 | 2015 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ 169,203 | \$ 172,815 |
| Start up expenditures | 929 | 1,168 |
| Tax credits | 8,007 | 8,173 |
| Provision for bad debts | 1,330 | 1,724 |
| Depreciation and amortization | 6,368 | 2,472 |
| Capital loss carryforward | 18,961 | — |
| Other | 15,060 | 13,022 |
| Total deferred tax assets | \$ 219,858 | \$ 199,374 |
| Deferred tax liabilities: | | |
| Prepays | \$ (1,173) | \$ (1,249) |
| Amortization of acquired intangibles | (33) | — |
| Amortization of debt discount | (25,977) | (9,503) |
| Goodwill | (855) | (383) |
| Other | (313) | — |
| Total deferred tax liabilities | \$ (28,351) | \$ (11,135) |
| Valuation allowance | \$ (191,922) | \$ (188,442) |
| Net deferred tax liabilities | \$ (415) | \$ (203) |

The Company has recorded a deferred tax liability related to the tax basis in an acquired intangible asset that is not amortized for financial reporting purposes. The deferred tax liability will only reverse at the time of ultimate sale or further impairment of the underlying intangible assets. Due to the uncertain timing of this reversal, the temporary difference cannot be considered as a source of future taxable income for purposes of determining a valuation allowance; therefore, the tax liability cannot be used to offset the deferred tax asset related to the net operating loss carryforward for tax purposes that will be generated by the same amortization.

A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of the available evidence, both positive and negative, the Company has determined that a \$191.9 million valuation allowance at December 31, 2016 is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The Company provided a valuation allowance for the full amount of its domestic net deferred tax asset for the years ended December 31, 2016 and 2015 because it is not more likely than not that the future tax benefit will be realized. In the year ended December 31, 2016, the Company's valuation allowance increased to \$191.9 million from the balance at December 31, 2015 of \$188.4 million. The change in the valuation allowance is primarily attributable to the capital loss carryforward generated in the current year that resulted from the sale of the Neighborhood Diabetes business, partially offset additional deferred tax liabilities recognized for the amortization of debt discount in the current year.

At December 31, 2016, the Company had approximately \$535.7 million, \$216.2 million and \$8.0 million of federal net operating loss carryforwards, state net operating loss carryforwards and research and development and other tax credits, respectively. If not utilized, these federal carryforwards will begin to expire in 2020 and will continue to expire through 2036, and the state carryforwards will continue to expire through 2036. At December 31, 2015, the Company had approximately \$532.0 million, \$285.6 million and \$8.2 million of federal net operating loss carryforwards, state net operating loss carryforwards and research and development and other tax credits, respectively from continuing operations. The utilization of such net operating loss carryforwards and the realization of tax benefits in future years depends predominantly upon having taxable income. Under the provisions of the Internal Revenue Code, certain substantial changes in the Company's ownership may result in a limitation on the amount of net operating loss carryforwards which may be used in future years. There will be a yearly limitation placed on the amount of net operating loss available for use in future years. Additionally, it is probable that a portion of the research and development tax credit carryforward may not be available to offset future income.

As a result of certain realization requirements of ASC 718, the table of deferred tax assets and liabilities does not include certain deferred tax assets as of December 31, 2016 and December 31, 2015 that arose directly from tax deductions related to equity compensation greater than compensation recognized for financial reporting. Equity will be increased by \$23.8 million if and when such deferred tax assets are ultimately realized. The Company utilizes ASC 740 ordering when excess tax benefits have been realized. Upon adoption of ASU 2016-09 in 2017, these deferred tax assets are expected to be added to the Company's table of deferred tax assets and liabilities, with an offsetting amount recorded to the valuation allowance.

The Company had no unrecognized tax benefits at December 31, 2016 .

19 . Segment Reporting

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company has concluded that their Chief Executive Officer is the CODM as he is the ultimate decision maker for key operating decisions, determining the allocation of resources and assessing the financial performance of the Company. These decisions, allocations and assessments are performed by the CODM using consolidated financial information. Consolidated financial information is utilized by the CODM as the Company's current product offerings and primarily consists of the Omnipod System and drug delivery. The Company's products are relatively consistent and manufacturing is centralized and consistent across product offerings. Based on these factors, key operating decisions and resource allocations are made by the CODM using consolidated financial data and as such the Company has concluded that it operates as one segment.

Worldwide revenue for the Company's products is categorized as follows:

| (in thousands) | Years Ended December 31, | | |
|-----------------------|--------------------------|------------|------------|
| | 2016 | 2015 | 2014 |
| U.S. Omnipod | \$ 229,785 | \$ 189,604 | \$ 175,950 |
| International Omnipod | 71,889 | 40,339 | 50,025 |
| Drug Delivery | 65,315 | 33,950 | 5,346 |
| Total | \$ 366,989 | \$ 263,893 | \$ 231,321 |

Geographic information about revenue, based on the region of the customer's shipping location, is as follows:

| (in thousands) | Years Ended December 31, | | |
|----------------|--------------------------|------------|------------|
| | 2016 | 2015 | 2014 |
| United States | \$ 295,100 | \$ 223,554 | \$ 181,296 |
| All other | 71,889 | 40,339 | 50,025 |
| Total | \$ 366,989 | \$ 263,893 | \$ 231,321 |

Geographic information about long-lived assets, net, excluding goodwill and other intangible assets is as follows:

| (in thousands) | December 31, 2016 | December 31, 2015 |
|----------------|-------------------|-------------------|
| United States | \$ 20,854 | \$ 13,018 |
| China | 25,431 | 28,638 |
| Other | 197 | 213 |
| Total | \$ 46,482 | \$ 41,869 |

20. Quarterly Data (Unaudited)

| | 2016 Quarters Ended | | | |
|--|----------------------------|--------------|------------|-------------|
| | December 31 ⁽¹⁾ | September 30 | June 30 | March 31 |
| (In thousands, except per share data) | | | | |
| Revenue | \$ 103,575 | \$ 94,871 | \$ 87,330 | \$ 81,213 |
| Gross profit | 60,937 | 55,641 | 50,457 | 44,051 |
| Operating income (loss) | (4,135) | 2,418 | (1,288) | (7,699) |
| Net loss from continuing operations, net of taxes | (9,153) | (3,017) | (4,351) | (10,689) |
| Income (loss) from discontinued operations, net of taxes | 34 | (64) | 153 | (1,792) |
| Net loss | \$ (9,119) | \$ (3,081) | \$ (4,198) | \$ (12,481) |
| Net loss per share from continuing operations | \$ (0.16) | \$ (0.05) | \$ (0.08) | \$ (0.19) |
| Net loss per share from discontinued operations | \$ — | \$ — | \$ — | \$ (0.03) |

⁽¹⁾ Included in net loss from continuing operations for the fourth quarter of 2016 was a charge of \$6.1 million related to in-process internally developed software.

| | 2015 Quarters Ended | | | |
|--|----------------------------|--------------|-------------|-------------|
| | December 31 ⁽²⁾ | September 30 | June 30 | March 31 |
| (In thousands, except per share data) | | | | |
| Revenue | \$ 83,801 | \$ 71,393 | \$ 60,551 | \$ 48,148 |
| Gross profit | 41,993 | 31,570 | 30,515 | 29,193 |
| Operating loss | (12,617) | (14,794) | (14,059) | (7,266) |
| Net loss from continuing operations, net of taxes | (15,909) | (17,984) | (17,267) | (10,442) |
| Income (loss) from discontinued operations, net of taxes | (11,418) | (943) | 1,835 | (1,392) |
| Net loss | \$ (27,327) | \$ (18,927) | \$ (15,432) | \$ (11,834) |
| Net loss per share from continuing operations | \$ (0.28) | \$ (0.31) | \$ (0.30) | \$ (0.18) |
| Net loss per share from discontinued operations | \$ (0.20) | \$ (0.02) | \$ 0.03 | \$ (0.03) |

⁽²⁾ Included in loss from discontinued operations for the fourth quarter of 2015 was a charge of \$9.1 million related to the impairment of the Neighborhood Diabetes asset group.

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

The following table sets forth activities in the Company's accounts receivable reserve and deferred tax valuation allowance accounts:

| Description | Balance at Beginning of Period | Additions Charged to Costs and Expenses | Deductions | Balance at End of Period |
|---|--------------------------------------|---|------------|--------------------------------|
| (In thousands) | | | | |
| Year Ended December 31, 2016 | | | | |
| Allowance for doubtful accounts ⁽¹⁾ | \$ 4,454 | \$ 2,069 | \$ 3,612 | \$ 2,911 |
| Deferred tax valuation allowance ⁽¹⁾ | 193,405 | 7,599 | 9,082 | 191,922 |
| Year Ended December 31, 2015 | | | | |
| Allowance for doubtful accounts ⁽¹⁾ | \$ 5,837 | \$ 1,184 | \$ 2,567 | \$ 4,454 |
| Deferred tax valuation allowance ⁽¹⁾ | 165,020 | 28,418 | 33 | 193,405 |
| Year Ended December 31, 2014 | | | | |
| Allowance for doubtful accounts ⁽¹⁾ | \$ 7,133 | \$ 3,254 | \$ 4,550 | \$ 5,837 |
| Deferred tax valuation allowance ⁽¹⁾ | 158,323 | 21,070 | 14,373 | 165,020 |

⁽¹⁾ Includes the amount classified as discontinued operations on the balance sheet and related activity.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2016, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a — 15(f). Our internal control system was designed to provide reasonable assurance to our management and the Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 2013 (“COSO”) in Internal Control — Integrated Framework (the COSO criteria).

Based on our assessment we believe that, as of December 31, 2016, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2016 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their report which appears below.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Insulet Corporation

We have audited the internal control over financial reporting of Insulet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2016, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Reporting on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in the 2013 *Internal Control-Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of the Company as of and for the year ended December 31, 2016, and our report dated February 27, 2017 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Boston, Massachusetts
February 27, 2017

ITEM 9B. OTHER INFORMATION

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Certain information required by this Item 10 relating to our directors, executive officers and corporate governance is incorporated by reference herein from our proxy statement in connection with our 2017 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission (the "SEC") not later than 120 days after the close of our year ended December 31, 2016 .

Item 11. Executive Compensation

Certain information required by this Item 11 relating to remuneration of directors and executive officers and other transactions involving management is incorporated by reference herein from our proxy statement in connection with our 2017 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2016 .

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

Certain information required by this Item 12 relating to security ownership of certain beneficial owners and management is incorporated by reference herein from our proxy statement in connection with our 2017 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2016 . For information on securities authorized for issuance under equity compensation plans, see the section entitled "Market for Registrant's Common Equity, Related Stockholders Matters, and Issuer Purchases of Equity Securities " in Part II, Item 5, in this Annual Report on Form 10-K.

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

Certain information required by this Item 13 relating to certain relationships and related transactions, and director independence is incorporated by reference herein from our proxy statement in connection with our 2017 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2016 .

Item 14. Principal Accounting Fees and Services

Certain information required by this Item 14 regarding principal accounting fees and services is set forth under "Principal Accounting Fees and Services" in our proxy statement in connection with our 2017 annual meeting of stockholders, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our year ended December 31, 2016 .

Item 15. Exhibits, Financial Statement Schedules

(A)(1) FINANCIAL STATEMENTS

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets - Years ended December 31, 2016 and 2015

Consolidated Statements of Operations - Years ended December 31, 2016, 2015 and 2014

Consolidated Statements of Comprehensive Loss - Years ended December 31, 2016, 2015 and 2014

Consolidated Statements of Stockholders' Equity - Years ended December 31, 2016, 2015 and 2014

Consolidated Statements of Cash Flows - Years ended December 31, 2016, 2015 and 2014

Notes to Consolidated Financial Statements

(A)(2) FINANCIAL STATEMENT SCHEDULES

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

(A)(3) EXHIBITS

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

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSULET CORPORATION

(Registrant)

February 27, 2017

/s/ Patrick J. Sullivan

Patrick J. Sullivan

Chief Executive Officer

(Principal Executive Officer)

February 27, 2017

/s/ Michael L. Levitz

Michael L. Levitz

Chief Financial Officer

(Principal Financial and Accounting Officer)

POWER OF ATTORNEY AND SIGNATURES

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities on February 27, 2017 .

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

EXHIBIT INDEX

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

| <u>Number</u> | <u>Description</u> |
|---------------|---|
| 3.1 | Eighth Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to our Registration Statement on Form S-8 (No. 333-144636) filed July 17, 2007) |
| 3.2 | Amended and Restated By-laws of the Registrant (Incorporated by reference to our Current Report on Form 8-K, filed February 26, 2016) |
| 4.1 | Specimen Stock Certificate (Incorporated by reference to our Registration Statement on Form S-8 (No. 333-144636) filed July 17, 2007) |
| 4.2 | Certificate of Designations, Preferences and Rights of a Series of Preferred Stock of Insulet Corporation classifying and designating the Series A Junior Participating Cumulative Preferred Stock (Incorporated by reference to our Form 8-A, filed November 20, 2008) |
| 4.3 | Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Registrar and Transfer Company, as Rights Agent (Incorporated by reference to our Form 8-A, filed November 20, 2008) |
| 4.4 | Amendment, dated September 25, 2009, to Shareholder Rights Agreement, dated as of November 14, 2008, between Insulet Corporation and Computershare Trust Company, As Rights Agent (Incorporated by reference to our Current Report on Form 8-A/A, filed September 28, 2009) |
| 4.5 | Amendment No. 2, dated August 30, 2016, to Shareholder Rights Agreement, dated as of November 18, 2008, between Insulet Corporation and Computershare Trust Company, As Rights Agent (Incorporated by reference to our Current Report on Form 8-K, filed August 31, 2016) |
| 4.6 | Indenture, dated as of June 9, 2014, between Insulet Corporation and Wells Fargo Bank, National Association, as Trustee (Incorporated by reference to our Current Report on Form 8-K, filed June 12, 2014) |
| 4.7 | Form of 2.00% Convertible Senior Notes due 2019 (included in Exhibit 33.3) (Incorporated by reference to our Current Report on Form 8-K, filed June 12, 2014) |
| 4.8 | Indenture, dated as of September 13, 2016, between Insulet Corporation and Wells Fargo Bank, National Association, as Trustee (Incorporated by reference to Exhibit 4.1 in our Current Report on Form 8-K, filed September 13, 2016) |
| 4.9 | Form of 1.25% Convertible Senior Notes due 2021 (included in Exhibit 4.8) (Incorporated by reference to Exhibit 4.1 in our Current Report on Form 8-K, filed September 13, 2016) |
| 10.1+ | Development and License Agreement between TheraSense, Inc. and Insulet Corporation, dated January 23, 2002 (Incorporated by reference to Amendment No. 3 to our Registration Statement on Form S-1 (File No. 333-140694) filed May 8, 2007) |
| 10.2+ | Amendment No. 1 to Development and License Agreement, dated as of March 3, 2008, by and between Abbott Diabetes Care, Inc. (ADC), formerly known as TheraSense, Inc., and Insulet Corporation. (Incorporated by reference to our Current Report on Form 8-K, filed March 5, 2008) |
| 10.3+ | Amendment No. 2 to Development and License Agreement, dated as of June 30, 2010, by and between ADC formerly known as TheraSense, Inc., and Insulet Corporation (Incorporated by reference to our Quarterly Report on Form 10-Q/A, filed November 19, 2010) |
| 10.4 | Amendment No. 3 to Development and License Agreement, dated as of April 5, 2011 by and between ADC and Insulet Corporation (Incorporated by reference to our Quarterly Report on Form 10-Q, filed May 9, 2012) |
| 10.5 | Amendment No. 4 to Development and License Agreement, dated as of March 29, 2012 by and between ADC and Insulet Corporation (Incorporated by reference to our Quarterly Report on Form 10-Q, filed May 9, 2012) |
| 10.6 | Amendment No. 5 to Development and License Agreement, dated as of June 21, 2012 by and between ADC and Insulet Corporation (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 8, 2012) |
| 10.7+ | Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated January 3, 2007 (Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-146810) filed October 19, 2007) |
| 10.8+ | Addendum to Master Supply Agreement between Insulet Corporation and Flextronic Marketing (L) Ltd., dated October 4, 2007 (Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-146810) filed October 19, 2007) |
| 10.9+ | Distribution Agreement dated January 4, 2010 by and between Insulet Corporation and Ypsomed Distribution AG (Incorporated by reference to our Quarterly Report on Form 10-Q/A, filed November 19, 2010) |

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| <u>Number</u> | <u>Description</u> |
|---------------|--|
| 10.10 | Amendment No. 1 to Distribution Agreement dated April 10, 2012 by and between Insulet Corporation and Ypsomed Distribution AG (Incorporated by reference to our Quarterly Report on Form 10-Q, filed May 9, 2012) |
| 10.11+ | Settlement and Cross-License Agreement, dated September 18, 2013, by and among the Company and Medtronic Inc., Medtronic MiniMed Inc., and Medtronic Puerto Rico Operations Co. (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 7, 2013) |
| 10.12+ | Master Equipment and Services Agreement between Insulet Corporation and ATS Automated Tooling Systems Inc., dated August 31, 2016 (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 4, 2016) |
| 10.13+ | Materials Supplier Agreement between Insulet Corporation and Flextronics Medical Sales and Marketing, Ltd, dated September 1, 2016 (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 4, 2016) |
| 10.14 | Third Addendum to Manufacturing Services Agreement between Insulet Corporation and Flextronics Marketing (L) Ltd., dated May 29, 2014 (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 7, 2014) |
| 10.15 | Fourth Addendum to Manufacturing Services Agreement between Insulet Corporation and Flextronics Marketing (L) Ltd., dated July 15, 2014 (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 7, 2014) |
| 10.16 | Fifth Addendum to Manufacturing Services Agreement between Insulet Corporation and Flextronics Marketing (L) Ltd., dated July 15, 2014 (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 7, 2014) |
| 10.17 | Purchase and Sale Agreement by and between 100 Nagog Park Limited Partnership and Insulet Corporation, dated December 16, 2016 (Incorporated by reference to our Current Report on Form 8-K, filed December 20, 2016) |
| 10.18# | Supply Agreement, dated November 21, 2013, between Amgen and Insulet Corporation, as amended by Amendment No. 1 through Amendment No. 14 |
| 10.19 | Form of Employee Non-Competition and Non-Solicitation Agreement by and between Insulet Corporation and each of its executive officers (Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-140694) filed February 14, 2007) |
| 10.20 | Offer Letter by and between Insulet Corporation and Paul Lucidi, dated May 11, 2010 (Incorporated by reference to our Annual Report on Form 10-K, filed March 10, 2011) |
| 10.21 | Offer Letter by and between Insulet Corporation and Charles Liamos (Incorporated by reference to our Current Report on Form 8-K, filed January 10, 2011) |
| 10.22 | Employment Agreement by and between Insulet Corporation and Patrick J. Sullivan dated September 16, 2014 (Incorporated by reference to our Current Report on Form 8-K, filed September 16, 2014) |
| 10.23 | Amended and Restated Executive Severance Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.24 | Rules and Conditions for the Directors' Compensation Program (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.25 | Agreement by and between Insulet Corporation and Michael Levitz dated March 23, 2015 (Incorporated by reference to our Current Report on Form 8-K, filed April 1, 2015) |
| 10.26 | Amended and Restated Executive Severance Plan (Incorporated by reference to our Current Report on Form 8-K, filed December 20, 2016) |
| 10.27 | Insulet Corporation 2000 Stock Option and Incentive Plan (Incorporated by reference to Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-140694) filed April 25, 2007) |
| 10.28 | Insulet Corporation Second Amended and Restated 2007 Employee Stock Purchase Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 28, 2014) |
| 10.29 | Form of Non-Qualified Stock Option Agreement for Company Employees under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.30 | Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |

| <u>Number</u> | <u>Description</u> |
|---------------|---|
| 10.31 | Form of Time Vesting Restricted Stock Unit Agreement for Employees under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.32 | Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.33 | Form of Time Vesting Restricted Stock Unit Agreement for Singapore Employees under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.34 | Form of Time Vesting Restricted Stock Unit Agreement for Non-Employee Directors under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.35 | Form of Incentive Stock Option Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.36 | Form of Non-Qualified Stock Option Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.37 | Form of Time Vesting Restricted Stock Unit Agreement for Employees at the Vice President Level and Above under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.38 | Form of Time Vesting Restricted Stock Unit Agreement for Section 16 Officers under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.39 | Form of Non-Qualified Stock Option Agreement for Patrick J. Sullivan under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.40 | Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan - October 2014 New Hires (Incorporated by reference to our Quarterly Report on Form 10-Q, filed November 5, 2014) |
| 10.41 | Form of UK Time Vesting Restricted Stock Unit Agreement for Employees at the Vice President Level and Above under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.42 | Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan - 2015 Sales Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.43 | Form of Non-Qualified Stock Option Agreement for Brad Thomas under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.44 | Form of Non-Qualified Stock Option Agreement for Shacey Petrovic under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.45 | Form of Time Vesting Restricted Stock Unit Agreement for Brad Thomas under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.46 | Form of Time Vesting Restricted Stock Unit Agreement for Shacey Petrovic under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.47 | Form of UK Non-Qualified Stock Option Agreement for Employees at the Vice President Level and Above under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 26, 2015) |
| 10.48 | Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Definitive Proxy Statement on Form DEF14A, filed April 2, 2015) |
| 10.49 | Form of Canada Non-Qualified Stock Option Agreement for Company Employees under the Insulet Corporation Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 12, 2015) |

| <u>Number</u> | <u>Description</u> |
|---------------|--|
| 10.50 | Form of Canada Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 12, 2015) |
| 10.51 | Form of Performance Vesting Restricted Stock Unit Agreement under the Insulet Corporation Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 12, 2015) |
| 10.52 | Form of Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 12, 2015) |
| 10.53 | Form of Non-Qualified Stock Option Agreement for Michael Levitz, David Colleran and Michael Spears (Incorporated by reference to our Registration Statement on Form S-8 (No. 333-208387) filed December 8, 2015) |
| 10.54 | Form of Time Vesting Restricted Stock Unit Agreement for Michael Levitz, David Colleran and Michael Spears (Incorporated by reference to our Registration Statement on Form S-8 (No. 333-208387) filed December 8, 2015) |
| 10.55 | Form of Non-Executive Employee Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 29, 2016) |
| 10.56 | Form of Non-Executive Employee Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 29, 2016) |
| 10.57 | Form of Section 16 Officer Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 29, 2016) |
| 10.58 | Form of Section 16 Officer Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 29, 2016) |
| 10.59 | Form of Vice President Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 29, 2016) |
| 10.60 | Form of Vice President Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Annual Report on Form 10-K, filed February 29, 2016) |
| 10.61 | Form of International Non-Qualified Stock Option Agreement under the Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 4, 2016) |
| 10.62 | Form of Time Vesting Restricted Stock Unit Agreement for Non-Employee Directors under the Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 4, 2016) |
| 10.63 | Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 4, 2016) |
| 10.64 | Form of Vice President Incentive Stock Option Agreement (Three Year Vest) under the Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 4, 2016) |
| 10.65 | Insulet Corporation Fourth Amended and Restated 2007 Employee Stock Purchase Plan (Incorporated by reference to our Quarterly Report on Form 10-Q, filed August 4, 2016) |
| 12.1 | Insulet Corporation Statement Regarding Computation of Ratios of Earnings to Fixed Charges (Incorporated by reference to our Registration Statement on Form S-3, filed June 22, 2011) |
| 21.1 | Subsidiaries of the Registrant |
| 23.1 | Consent of Independent Registered Public Accounting Firm (Grant Thornton LLP) |
| 23.2 | Consent of Independent Registered Public Accounting Firm (Ernst & Young LLP) |
| 24.1 | Power of Attorney (included on signature page) |

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| <u>Number</u> | <u>Description</u> |
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| 31.1 | Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer. |
| 31.2 | Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer. |
| 32.1* | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Chief Executive Officer and Chief Financial Officer. |
| 101 | The following materials from Insulet Corporation's Annual Report on Form 10-K for the year ended December 31, 2016 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Loss; (iv) the Consolidated Statements of Stockholders' Equity; (v) the Consolidated Statements of Cash Flows |

* This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

+ Confidential treatment granted as to certain portions of this exhibit.

Confidential treatment requested as to certain portions of this exhibit.

Supply Agreement, dated November 21, 2013, between Amgen and Insulet Corporation, as amended by Amendment No. 1 through Amendment No. 14

Supply Agreement
By and Between
Amgen Inc.
and
Insulet Corporation

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

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* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

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* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

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SUPPLY AGREEMENT

This Supply Agreement (as defined further below, this “Agreement”) is entered into as of November 21, 2013 (the “Effective Date”), by and between Amgen Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at One Amgen Center Drive, Thousand Oaks, CA 91320-1799 (“Amgen”), and Insulet Corporation, a corporation organized and existing under the laws of the State of Delaware and having its principal office at 9 Oak Park Drive, Bedford, MA 01730 (“Insulet”).

INTRODUCTION

- A. WHEREAS, Amgen is engaged in the business of discovering, developing, manufacturing and marketing human therapeutics;
- B. WHEREAS, Insulet is engaged in the business of developing, manufacturing and marketing infusion devices and systems;
- C. WHEREAS, Amgen and Insulet are parties to that certain Development Agreement effective as of [*], pursuant to which, among other things, Insulet is to perform certain drug delivery system development activities in return for certain compensation all as set forth therein (as may be amended from time to time, the “Development Agreement”); and
- D. WHEREAS, Amgen desires to purchase from Insulet, and Insulet desires to sell to Amgen, drug delivery systems on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained in or referenced by this Agreement, the Parties hereto have reviewed and accepted all referenced material and any appendices, exhibits or other attachments and agree to be bound by the terms and conditions set forth in this Agreement as follows:

1. **Definitions.**

For purposes of this Agreement, the terms defined in this article shall have the respective meanings set forth below. Capitalized terms used in this Agreement but not defined herein shall have the meanings ascribed to such terms in the Development Agreement:

- 1.1 “Agreement” means this Supply Agreement together with all Appendices referenced herein and attached hereto as each may be amended from time to time pursuant to Section 12.5.
- 1.2 “Business Day” means any day other than a Saturday or Sunday on which banking institutions in New York, NY, are open for business.
- 1.3 “Commercialization” or “Commercialize” will mean any activities directed to marketing, promoting, distributing, importing, offering to sell, and/or selling the System.
- 1.4 “Commercial Year” means (i) the First Commercial Year, and (ii) the twelve month period beginning on the first anniversary of the First Commercial Year, and each subsequent twelve month period thereafter during the Term.
- 1.5 “Confidential Information” of a Party means (i) all Technology [Controlled] by such Party, and (ii) all ideas, information and data of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available by or on behalf of such Party (“Disclosing Party”) to the other Party or its representatives (“Receiving Party”), including any of the foregoing of Third Parties disclosed by or on behalf of such Party. Confidential Information of Party includes information regarding such Party’s products, financial information, business information or objectives and reports and audits, and all biological materials of a Party. Notwithstanding the foregoing, Confidential Information will not include Technology or other information that:
- (a) was known or used by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party as demonstrated by contemporaneous written records; or

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- (b) either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party or its Affiliates by sources other than the Disclosing Party rightfully in possession of such Technology or other information and not bound by confidentiality obligations to the Disclosing Party; or
- (c) either before or after the date of the disclosure to the Receiving Party or its Affiliates is or becomes published or otherwise is or becomes part of the public domain through no breach hereof on the part of the Receiving Party or its Affiliates; or
- (d) is independently developed by or for the Receiving Party or its Affiliates without reference to or reliance upon the Confidential Information of the Disclosing Party as demonstrated by contemporaneous written records.

Notwithstanding the foregoing, (1) any Confidential Information will not be deemed to be within the foregoing exceptions merely because such information is embraced by more general information in the public domain or in the possession of the Receiving Party or any of its Affiliates, and (2) any combination of features will not be deemed to be within the foregoing exceptions merely because individual features are in the public domain or in the possession of the Receiving Party or any of its Affiliates, but only if the combination itself and its principle of operation are in the public domain or in the possession of the Receiving Party or any of its Affiliates.

1.6 “Conforming Lot” has the meaning ascribed to it in the Quality Agreement.

1.7 “Customized Insulet Device” shall have the meaning set forth in the Insulet Product Definition Document INSPR020-PDD, Amgen Delivery Device ADD) attached hereto as Exhibit 1.7 as updated from time to time by mutual agreement of the Parties (“Product Definition Document”).

1.8 “Device” means any [*].

1.9 “Disposition” means to either reject or pass a batch, or part thereof, of Customized Insulet Devices by the quality unit of a Party pursuant to such Party’s quality systems and, with respect to Insulet, in compliance with the Quality Agreement.

1.10 “Executive Officers” means Insulet’s President and Chief Operating Officer (who, as of the Effective Date, is Charles Lianos) (or an officer or employee of Insulet then serving in a substantially equivalent capacity) and Amgen’s Executive Vice President, Operations (who, as of the Effective Date, is Madhu Balachandran) (or the officer or employee of Amgen then serving in a substantially equivalent capacity).

1.11 “Facility” means Insulet’s or its Affiliate’s or sub-contractor’s facility at which the Custom Insulet Device is Manufactured.

1.12 “First Commercial Year” means the first full calendar year beginning after the granting of Regulatory Approval by the FDA for the System.

1.13 “Governmental Authority” means a country, federal, state, provincial, commonwealth, supranational, cantonal or local regulatory agency, department, bureau or other governmental entity with authority over the testing, Manufacture, use, storage, import, promotion, marketing or sale of a Customized Insulet Device.

1.14 “Lot Release Procedures” means the testing procedures for the Customized Insulet Device set forth in the Quality Agreement, as may be amended by the mutual agreement of the Parties, in writing, from time to time, that are the basis for determining whether a lot of Customized Insulet Devices is appropriate for release by Insulet.

1.15 “Manufacturing Services” shall mean, with respect to each Customized Insulet Device to be supplied hereunder, the preparation, assembly, and production of each such item. “Manufacture,” “Manufacturing,” “Manufactured,” and other variants of manufacturing services shall have comparable meanings.

1.16 “Minimum Lot Quantity” means [*] ([*]) units of Customized Insulet Devices.

1.17 “Non-Conforming Lot” means, except if due to [*], a lot of Customized Insulet Device Manufactured by Insulet that, based the performance of and results from the Lot Release Procedures and comparison to release criteria set forth in the Lot Release Procedures, is inappropriate for release by Insulet.

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- 1.18 “Partial Commercial Year” means the remainder of the calendar year commencing on the first day of the month following the granting of Regulatory Approval by the FDA for the System.
- 1.19 “Party” means Insulet or Amgen and, when used in the plural, “Parties” shall mean Insulet and Amgen.
- 1.20 “Purchase Order” shall mean each written order for the purchase of Customized Insulet Device issued by Amgen or its Affiliates in accordance with Section 2.7.
- 1.21 “Quality System Regulation” shall mean the applicable quality system requirements, as amended from time to time, for the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use according to CFR Part 820, and any applicable guidance document or standard published or recognized by the FDA.
- 1.22 “Ship” shall mean the delivery, pursuant to Section 2.11, by Insulet of Customized Insulet Devices meeting the Release Criteria to Amgen or its designee. “Shipping,” “Shipped,” “Shipment”, and other variants shall have comparable meanings.
- 1.23 “Specifications” means the specifications and requirements of a Customized Insulet Device, including but not limited to performance requirements, materials, equipment, systems, standards and workmanship as set forth in the Product Definition Document.
- 1.24 “Supply Territory” means [*] and additional countries and regions as provided for pursuant to Section 12.2(b).
- 1.25 “Supply Territory Expansion Reimbursable Expenses” means, with respect to each Supply Territory Expansion Request, those [*] in support of [*].
- 1.26 “Unit Price” means the price set forth in Section 3.1 payable, pursuant to the terms of this Agreement, by Amgen for Customized Insulet Devices.

Terms defined elsewhere in this Agreement are set forth below:

| Term | Section Number |
|-----------------------------|---------------------------|
| Additional Supply Territory | 12.2(b) |
| Agreement | 1 st Paragraph |
| Amgen | 1 st Paragraph |
| Amgen Indemnified Party | 8.2 |
| Announcement | 5.1(a) |
| Applicable Securities Rules | 5.1(a) |
| Applications | 11.3(b) |
| Binding Portion | 2.6(a) |
| [*] | 4 |
| [*] | 4 |
| Change | 12.2(a) |
| Change Order | 12.2(a) |
| Development Agreement | 4 th Paragraph |
| Disclosing Party | 1.5 |
| Effective Date | 1 st Paragraph |
| [*] | 4 |
| [*] | 2.3 |
| Forecast | 2.6(a) |
| Forecast-Based [*] | 3.1 |
| Indemnified Party | 8.3(a) |
| Indemnifying Party | 8.3(a) |

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| | |
|------------------------------------|---------------------------|
| Infringement Claim | 8.2 |
| Initial Period | 9.1 |
| Insulet | 1 st Paragraph |
| Insulet Enforcement Actions | 11.3(e) |
| Insulet Indemnified Party | 8.1 |
| Licensed Marks | 11.3(b) |
| Loss | 8.1 |
| Mandatory Disclosure | 5.1(a) |
| [*] | 4 |
| Notice of Permitted Assignment | 12.4 |
| Order-Based [*] | 3.1 |
| Permitted User | 5.1(b) |
| [*] | 2.3 |
| POD Marks | 11.3(c) |
| Product Definition Document | 1.7 |
| Product Warranty | 6.9(c) |
| PTO | 11.3(b) |
| Publication | 5.4 |
| Purchase Order | 2.7(a) |
| Quality Agreement | 2.2 |
| Receiving Party | 1.5 |
| Renewal Period | 9.1 |
| Severed Clause | 12.11 |
| [*] | 12.17 |
| Supply Territory Expansion Request | 12.2(b) |
| Taxes | 3.6 |
| Term | 9.1 |
| Trademarks | 11.3(c) |

2. **Manufacture; Supply.**

2.1 Subcontractors. Subject to the terms of the Quality Agreement, Insulet has the right to use Affiliates and subcontractors for the performance of Insulet's obligations hereunder, provided that at all times that Insulet shall remain fully liable for any and all acts or omissions of such Affiliates and subcontractors.

2.2 Quality Agreement. Concurrent with the execution of this Agreement, the Parties are entering into the document attached hereto as Exhibit 2.2 specifying the quality and regulatory procedures and responsibilities of the Parties hereunder with respect to the Manufacture of Custom Insulet Devices (the "Quality Agreement").

2.3 [*]. Amgen shall [*], and Insulet shall [*] those responsibilities set forth in the [*] subject to the applicable terms [*]. Insulet shall [*].

2.4 Specification Changes. The Specifications or the specifications for the Insulet Device (as defined in the Development Agreement) may be amended or supplemented by the Parties in accordance with the terms and conditions of the Quality Agreement.

2.5 Audits. Amgen shall have the right, pursuant to the terms and conditions of the Quality Agreement, to cause an inspection and audit of any Facilities being used by Insulet, its Affiliates or any subcontractor for the Manufacture of Customized Insulet Devices.

2.6 Forecasts.

- a. As soon as practicable after the Effective Date and at least [*] days prior to the [*] of each calendar month thereafter, Amgen will provide Insulet with eighteen (18) month rolling

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forecasts of Amgen's anticipated monthly requirements for Custom Insulet Devices (each, a "Forecast"), which Forecasts shall commence on the month immediately following delivery of such forecast. The [*] of each such Forecast shall be binding on Amgen (the "Binding Portion") and Amgen shall issue Purchase Orders for all amounts included in the Binding Portion of such Forecasts.

- b. Except as mutually agreed in writing by the Parties, for each Forecast following the initial Forecast provided by Amgen, the quantity of Customized Insulet Device forecast (i) for the [*] months of such Forecast shall not vary from the amounts forecasted for such months in the most recent previously delivered Forecast, (ii) the amounts forecasted for the [*] of such Forecast shall not exceed [*] percent ([*]%) of the amounts forecasted for such month in the most recent previously delivered Forecast and (iii) the amounts forecasted for the [*] months of such Forecast shall not exceed [*] percent ([*]%) of the amounts forecasted for such months in the most recent previously delivered Forecast. Accompanying each Forecast, Amgen shall place a binding Purchase Order in accordance with Section 2.7 for Custom Insulet Devices for the first month contained in such Forecast.
- c. Each Party acknowledges and agrees that, except with respect to the Binding Portion of each Forecast, as may be adjusted pursuant to Section 2.6(b), (a) the Forecasts are for planning purposes only, (b) Amgen will prepare such Forecasts in good-faith, but does not guarantee the accuracy of any portions of such Forecasts, and (c) with the exception of the Binding Portion of the Forecasts, Insulet does not guarantee its ability to meet the requirements of such Forecasts.

2.7 Purchase Orders: Precedence.

- a. Amgen may use its standard purchase order form for any notice provided for hereunder; provided that all purchase orders must reference this Agreement and include and specify the proposed delivery date, quantities and destination (each, a "Purchase Order"). The Parties agree that the terms and conditions contained in this Agreement shall govern and prevail over any terms and conditions of any such Purchase Order, acknowledgment form or other instrument.
- b. Unless otherwise accepted pursuant to Section 2.8, Insulet shall not be obligated to supply quantities of Customized Insulet Devices set forth in Purchase Orders to the extent such quantities are in excess of the Binding Portion of a Forecast for the applicable month.
- c. Unless otherwise accepted by Insulet pursuant to Section 2.8, Insulet shall not be obligated to Ship Customized Insulet Devices [*] after the date each Purchase Order is received by Insulet.
- d. Each Purchase Order shall be for no less than the Minimum Lot Quantity.
- e. In addition to the quantities set forth in the Binding Portion of the Forecast and any Purchase Orders issued and accepted pursuant hereto, within [*] days after receipt of a Notice of Permitted Assignment (as defined in Section 12.4), Amgen may place one or more Purchase Orders for a quantity [*] of Customized Insulet Devices [*] of Customized Insulet Devices set forth in the Forecast current as of the date of receipt of such Notice of Permitted Assignment, for delivery no sooner than [*] after the date of such Purchase Order. Quantities of Customized Insulet Devices set forth in Purchase Orders pursuant to this Section 2.7(e) shall be deemed included in and part of the Binding Portion of the Forecast and the rights and obligations of each Party with respect to the Binding Portion of the Forecast shall apply thereto.

2.8 Delivery Date Confirmations, Shipping Schedule. Within [*] Business Days after Amgen submits to Insulet a Purchase Order, Insulet shall issue a notice to Amgen acknowledging or rejecting the delivery dates specified in the Purchase Order. Insulet may only reject quantities of Customized Insulet Devices set forth in Purchase Orders to the extent of the following: (a) any portion of a Purchase Order that does not conform to the requirements of Section 2.7(b), Section 2.7(c) or Section 2.7(d) or (b) if the fees set forth in the Purchase Order are inconsistent with the Unit Price Amounts applicable as set forth in Section 3. Failure by Insulet to issue such notice within such [*] Business Day period shall be deemed an acceptance of the applicable Purchase Order.

2.9 Adjustments in Purchase Order Quantities. Purchase Orders are not subject to cancellation by Insulet or Amgen once accepted by Insulet. Reduction in the quantity of Customized Insulet Devices ordered, suspension of deliveries and all other changes to a previously-accepted Purchase Order are permitted only pursuant to written agreement of the Parties (such agreement not to be unreasonably withheld, conditioned

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or delayed). Subject to Section 2.7(b) and the remainder of this Section 2.9 and subject to Manufacturing and other capacity constraints of Insulet, Insulet shall use commercially reasonable efforts to accommodate Amgen's requests for Customized Insulet Devices in excess of the quantities set forth in the Forecasts. If Amgen requests and Insulet agrees in writing to any change to the quantities set forth in a Purchase Order, then the Purchase Order shall be deemed to be revised according to Insulet's written agreement.

2.10 Carryover of Forecast. To the extent Amgen fails to provide any Forecast required under Section 2.6, the last applicable Forecast previously provided by Amgen shall be deemed to be the latest Forecast provided by Amgen as required by Section 2.6 and such failure will not be considered to be a breach of this Agreement by Amgen.

2.11 Shipment.

- a. With respect to each Purchase Order, Insulet will promptly notify Amgen in writing of any anticipated delay in Shipping Customized Insulet Devices by the delivery date(s) specified in each such Purchase Order.
- b. Insulet shall ship Customized Insulet Devices under suitable controls and pursuant to all reasonable instructions provided by Amgen. Amgen shall have the right to designate the freight forwarder to be used by Insulet by notifying Insulet of such no later than [*] days prior to the applicable delivery date; provided, in the absence of such instructions, Insulet shall use a freight forwarder previously designated by Amgen. [*]. [*]. In the event of conflict, the terms of this Agreement take precedence over the Incoterms.
- c. Insulet shall package all Customized Insulet Devices in accordance with standard commercial practices that meet or exceed Applicable Laws and meet the ship testing requirements defined in the Product Definition Document. Unless instructed otherwise by Amgen, Insulet shall (i) Ship Purchase Orders complete; (ii) ensure that all packages and documents conspicuously bear the applicable Purchase Order number; (iii) enclose a packing slip with each Shipment and, when more than one package is Shipped, identify the package containing the packing slip; (iv) ensure that all Customized Insulet Devices included in a Shipment have an expiration date no less than the approved shelf life [*]; and (v) ship Customized Insulet Devices on plastic pallets.

2.12 Lot Release Procedure. With respect to each lot of Customized Insulet Devices, Insulet shall perform the Lot Release Procedure in accordance with the requirements set forth in the Quality Agreement and determine whether each such lot is a Conforming Lot and Insulet shall only Ship to Amgen and its designees Conforming Lots.

3. **Compensation.**

3.1. Unit Price Amounts. Amgen shall pay Insulet the Unit Price for each Customized Insulet Device ordered by Amgen and Manufactured by Insulet in a given Commercial Year as follows:

| | | | |
|-----|---|--|-----|
| [*] | Aggregate Number of Customized Insulet Devices Ordered by Amgen | With respect to each [*], Unit Price for each Customized Insulet Device Shipped to Amgen | [*] |
|-----|---|--|-----|

[*]

For the avoidance of doubt, [*].

For the Partial Commercial Year and each Commercial Year, the Unit Price [*] (set forth in the table above) applicable thereto that Amgen will pay, and Insulet will invoice, during such period (the "Forecast-Based [*]") shall be determined based on the lesser of the following quantities of Customized Insulet Devices set forth in the Forecast submitted immediately prior to the commencement of the Partial Commercial Year or Commercial Year, as the case may be: (i) [*]% of the quantity of Customized Insulet Devices in the Binding Portion of such Forecast and (ii) the aggregate of the quantities of Customized Insulet Devices set forth in the [*]months of such Forecast. Promptly after the end of the Partial Commercial Year and each Commercial Year, but in no event later than [*], Insulet will notify Amgen of the aggregate quantity of Customized Insulet Devices actually ordered by Amgen for delivery during such period and whether the Unit Amount [*] applicable thereto (the "Order-Based [*]") is the same as the Forecast-Based [*] and, in the event that the Order-Based [*] is not the same as the Forecast-Based [*], then within [*] days after receipt of such

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notice either (a) if the Order-Based [*] is [*], then Amgen shall pay to Insulet the difference between the [*] and [*] Unit Prices applicable to each Customized Insulet Device or (b) if the Order-Based [*] is [*], then Insulet shall pay to Amgen the difference between the [*] and [*] Unit Prices applicable to each Customized Insulet Device.

3.2. Inclusive. Insulet acknowledges and agrees that the Unit Price is all inclusive including inclusive of technical support services, complaint investigation services, root cause analysis, corrective actions activities, equipment maintenance, and purchase and maintenance of toolsets.

3.3. [*]. As full and complete compensation for [*] will pay [*]. For the avoidance of doubt, Amgen will [*].

3.4. [*] Capital Expense. In return for Insulet making capital investments in support of Manufacturing a Customized Insulet Device that includes a [*], Amgen will reimburse, up to an amount not to exceed \$[*], Insulet the actual, reasonable costs incurred by Insulet and payable to Third Parties with respect to such capital investments. Promptly after incurring such costs, Insulet will invoice Amgen for such and include with each such invoice reasonably detailed documentation of the costs incurred.

3.5. Supply Territory Expansion Reimbursable Expenses. With respect to each Supply Territory Expansion Request, Amgen will compensate Insulet as full and complete compensation the Supply Territory Expansion Reimbursable Expenses. Promptly after incurring such Supply Territory Expansion Reimbursable Expenses, Insulet will invoice Amgen for such and include with each such invoice reasonably detailed documentation of such expenses.

3.6. Taxes. The pricing, fees and amounts payable by Amgen to Insulet hereunder do not include any taxes imposed by law on Amgen as the purchaser of Customized Insulet Devices for any national, state or local property, sales, service, use, excise, value added, gross receipts or other such taxes (“Taxes”). In addition to any amounts otherwise payable by Amgen pursuant to this Agreement, Amgen agrees to pay or reimburse Insulet for all Taxes which Insulet is required to pay or collect or which are required to be withheld in respect of the transactions contemplated by this Agreement except income and payroll taxes.

3.7. Invoices.

- a. Insulet shall submit invoices to Amgen on a [*] basis for amounts payable by Amgen hereunder (i) pursuant to Section 3.1, Section 3.3, Section 3.4, and Section 3.5 for [*] and (ii) testing as provided in Section 12.1. Insulet will endeavor to submit such invoices promptly following the [*]. Invoices will be submitted in electronic format to the following electronic address (which addresses may be changed, from time-to-time, by Amgen upon prior notice to Insulet): email address: AccountsPayableMailroom@Amgen.com.
- b. Each invoice shall contain:
 - i. Purchase Order number;
 - ii. number of Customized Insulet Devices Shipped to Amgen in [*];
 - iii. applicable Unit Price for each such Customized Insulet Device, and Unit Price Amounts;
 - iv. if any, amounts due on account of Section 3.3, Section 3.4, Section 3.5 and, with respect to Section 3.4, Section 3.5 and Section 12.1, reasonable documentation thereof; and
 - v. the total amount payable by Amgen.
- c. Amounts listed in each invoice shall be specified in United States dollars. To the extent Amgen reasonably requires additional information for any amounts stated on an invoice, Amgen shall promptly notify Insulet of same and Insulet shall respond promptly to such request.
- d. Amgen may request that Insulet submit at times other than those specified herein an invoice for portions of the Compensation that have not yet been invoiced but represent amounts payable for actual performance of Insulet’s obligations hereunder. When Amgen makes such a request, Insulet shall deliver to Amgen a complete invoice reflecting such portions of the Compensation, if any, believed by Insulet to be payable. Insulet shall endeavour to deliver such invoice by the deadline identified in Amgen’s request therefore and, if no deadline is specified in Amgen’s request, [*] days following Insulet’s receipt of Amgen’s request.

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- e. If Amgen disputes in good faith an amount stated in an invoice, Amgen will pay the undisputed amounts and notify Insulet in writing of the dispute concerning the remaining amounts within [*] days after Amgen's receipt of such invoice and provide a reasonably detailed basis therefore. Upon resolution of disputed amounts, Insulet shall submit an invoice pursuant to this Section 3.7 for the amounts that the Parties mutually agree are no longer in dispute. Payment by Amgen does not constitute acceptance of the Insulet's performance hereunder or an admission of liability.

3.8. Timing of Payments. Subject to Section 3.7(e), Amgen will pay each invoice in full within [*] days after receipt. With respect to each invoice, payment terms shall be [*] days after Amgen's receipt of each invoice. All amounts payable hereunder shall be paid in U.S. currency. Amgen will pay [*].

4. [*]. Notwithstanding the foregoing, for the purposes of this Section 4, if [*]. [*] shall extend to [*] provided that Amgen [*] or, in the alternative, Amgen [*]. [*] Insulet will notify Amgen [*]. In the event of a [*]. In the event Amgen [*] set forth in this Section 4 [*]

[*]

5. **Confidentiality.**

5.1 Confidential Information. With respect to any Confidential Information of a Party disclosed by or on behalf of it or its Affiliates to the other Party or its representatives during the Term, the Receiving Party agrees: (i) not to use any Confidential Information of the Disclosing Party in connection with activities other than those contemplated by this Agreement, (ii) except as provided in Section 5.1(b) and Section 5.4, not to disclose Confidential Information of the Disclosing Party to Third Parties without the prior written consent of the Disclosing Party, (iii) except as provided in Section 5.1(a) and Section 5.1(b), that the Confidential Information of the Disclosing Party will be maintained in confidence.

- a. Neither Party shall make any public announcement about the Agreement, or any part thereof, or its business relationship with the other Party or one or more of its Affiliates (collectively, "Announcement") unless prior written consent is obtained from such other Party, which consent may be withheld in such other Party's sole discretion. Notwithstanding the foregoing provisions of this Section 5.1, a Party may disclose Confidential Information of the Disclosing Party, the terms of this Agreement, or make an Announcement if such Party determines, based on advice from its outside counsel, that it is required to make such disclosure to comply with Applicable Law or the rules of a securities exchange on which such Party is listed ("Applicable Securities Rules"); and each such disclosure a "Mandatory Disclosure". With respect to each Mandatory Disclosure, as much in advance of each such Mandatory Disclosure as practicable, such Party shall (i) notify the other Party of the proposed content of the Mandatory Disclosure, (ii) give the other Party reasonable opportunity to review and comment on the proposed content of the Mandatory Disclosure, and (iii) in good faith, consider and revise the content of the Mandatory Disclosure based on comments received from the other Party and submit the revised Mandatory Disclosure to the other Party for review and consent, such consent not to be unreasonably withheld, delayed or conditioned. A Party shall include in each Mandatory Disclosure only the information required to be disclosed by Applicable Law or Applicable Securities Rules, and, to the extent possible, shall seek confidential treatment of each Mandatory Disclosure.
- b. Disclosures to Employees and Subcontractors. A Receiving Party is permitted to disclose Confidential Information of the Disclosing Party to its employees and Subcontractors and to Receiving Party's Affiliates and employees of Affiliates who have a need to know such Confidential Information to assist the Receiving Party in fulfilling its obligations under this Agreement (each a "Permitted User"), provided that each Permitted User is bound by obligations at least as stringent as those set forth in Section 5 and that the Receiving Party is responsible for and liable to the Disclosing Party for each and every failure by a Permitted User to comply with the terms of this Section 5.

5.2 Survival. The terms of this Section 5 shall survive termination or expiration of this Agreement until the tenth anniversary of such expiration or termination of this Agreement.

5.3 Disclosure of Terms of Agreement. The Parties agree that the contents of this Agreement shall be considered Confidential Information of the Parties. Notwithstanding the foregoing and Section 5.2, each Party shall have the right to disclose in confidence the material terms of this Agreement to Third Parties retained by such Party to perform legal, accounting or similar advisory services who have a need to know such terms in order to provide such advisory services provided that such Third Parties are subject to written obligations of confidentiality at least as stringent as those

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contained in Section 5 and that such Party is responsible for and liable to the other Party for each and every failure by such Third Parties to comply with the terms of this Section 5. Additionally, notwithstanding the foregoing and Section 5.2, each Party shall have the right to disclose in confidence the material terms of this Agreement to Third Parties that are (i) potential acquirers or assignees of substantially all of Insulet's assets or business as set forth in a term sheet that includes the material terms of an acquisition or assignment or (ii) investment bankers, investors, or lenders, provided in each case that such Third Parties are subject to written obligations of confidentiality at least as stringent as those contained in Section 5 (other than investment bankers, investors and lenders, who must be bound prior to disclosure by commercially reasonable obligations of confidentiality) and that such Party is responsible for and liable to the other Party for each and every failure by such Third Parties to comply with the terms of this Section 5.

5.4 Publications. Except to the extent provided otherwise in this Section 5, whether to be presented orally or in written form, no Announcement, news release, public statement, publication, or presentation relating to the existence of this Agreement, the subject matter herein, or a Party's performance hereunder (collectively, a "Publication") shall be made without the other Party's prior written approval. Each Party agrees to submit, at least [*] days prior to submission for publication, such Publication it proposes to make to the other Party for purposes of such other Party's review and comment. Each Party agrees to respond as promptly as reasonably practicable to a proposed Publication in accordance with timelines agreed upon by the Parties, and likewise agrees that it shall not unreasonably withhold, condition, or delay approval of such Publication. In addition, if at any time during such [*] day period, the other Party informs such Party that its proposed publication discloses inventions made by either Party in carrying out the Development Program that have not yet been protected through the filing of a patent application, or the public disclosure of such proposed publication could be expected to have a material adverse effect on any Patent Rights or Technology of such other Party, then such Party will either (a) delay such proposed publication, for up to [*] days from the date the other Party informed such Party of its objection to the proposed publication, to permit the timely preparation and first filing of patent application(s) on the information involved or (b) remove the identified disclosures prior to publication. Insulet shall not make use of Amgen or any of its Affiliates' name in any advertising or promotional material, or otherwise, without the prior written consent of Amgen.

6. **Representations and Warranties.**

6.1 Representations of Authority. Each Party represents and warrants to the other Party that it has full corporate right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement.

6.2 Consents. Each Party represents and warrants to the other Party that (i) as of the Effective Date, all necessary consents, approvals and authorizations of all government authorities and other Persons required to be obtained by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained by it as of the Effective Date and (ii) its performance hereunder shall be in material compliance with Applicable Laws.

6.3 No Conflict. Each Party represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Applicable Laws and (ii) do not and will not conflict with, violate, breach or constitute a default under any written agreement to which it is a party.

6.4 Applicable Laws. Each Party represents and warrants to the other Party that it will perform its obligations under this Agreement and will cause those of its Affiliates and Subcontractors and their respective employees, directors, officers, and agents contributing to or in connection with performance hereunder to perform, in compliance with Applicable Laws.

6.5 Enforceability. Each Party represents and warrants to the other Party that this Agreement is a legal and valid obligation binding upon it and is enforceable in accordance with its terms.

6.6 Employee Obligations. Each Party represents and warrants to the other Party that all of its employees, officers, and subcontractors who have been, are or will be involved in the Manufacturing or Shipping have executed or will have executed agreements or have existing obligations under law requiring assignment to such Party of all intellectual property made during the course of and as the result of their association with such Party, and obligating the individual to maintain as confidential such Party's Confidential Information, to the extent required to support such Party's obligations under this Agreement.

6.7 Intellectual Property. Each Party represents and warrants to the other Party as follows:

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- a. To such Party's knowledge, the performance of its obligations under the Agreement will not result in the infringement of any intellectual property rights or the use of misappropriated trade secrets of any Third Party.
- b. Such Party has the right to grant the rights and licenses granted to the other Party under this Agreement.
- c. To such Party's knowledge, no Third Party with which such Party has entered into any written agreement under which Intellectual Property Rights material to this Agreement are licensed from such Third Party intends to cancel or terminate such written agreement and no Third Party has the right to cancel or terminate such written agreement.

6.8 Debarment. Each Party, and its Affiliates and their respective employees, directors, officers, consultants, and contractors contributing to or in connection with performance hereunder is not presently nor has ever been: (i) the subject of a debarment action or is debarred pursuant to Section 306 of the U.S. Federal Food, Drug, and Cosmetic Act of 1938, as amended, or other applicable local law; (ii) the subject of a disqualification proceeding or is disqualified as a clinical investigator pursuant to 21 C.F.R. § 312.70; or (iii) the subject of an exclusion proceeding or excluded from participation in any federal health care program under 42 C.F.R. Part 1001 et seq. Furthermore, each Party agrees and represents and warrants to the other Party that it will not employ or otherwise engage any individual or entity in connection with its performance hereunder who has been debarred, disqualified, or excluded, as described above, and shall immediately notify the other Party upon it becoming aware of any inquiry concerning, or the commencement of any proceeding or disqualification that is the subject of this Section that involves it or any such representative(s). Notice of or failure to provide such notice shall constitute a material breach hereunder.

6.9 Representations and Warranties of Insulet. Insulet represents and warrants to Amgen (and not to Third Parties) the following:

- a. Subject to Section 6.9(c), with respect to Customized Insulet Devices Manufactured at times other than during the [*], such Customized Insulet Devices Shipped hereunder will (i) meet the Specifications and Product Definition Document requirements; (ii) have been Manufactured and Shipped in compliance with, in all material respects, Applicable Laws and the Quality Agreement; and (iii) to the extent required hereunder, meet and be manufactured in compliance with current Good Manufacturing Practices pursuant to 21 C.F.R. Part 820, any other Quality System Regulations, and ISO 13485 standards.
- b. Subject to Section 6.9(c), with respect to Customized Insulet Devices Manufactured during the [*], such Customized Insulet Devices Shipped hereunder will (i) meet the requirements set forth in the Specifications, Product Definition Document and Quality Agreement with respect to sterilization; (ii) have been Manufactured and Shipped in compliance with, in all material respects, Applicable Laws and the Quality Agreement; and (iii) to the extent required hereunder, meet and be manufactured in compliance with current Good Manufacturing Practices pursuant to 21 C.F.R. Part 820, any other Quality System Regulations, and ISO 13485 standards.
- c. The warranties set forth in Sections 6.9(a) and 6.9(b) (the "Product Warranty") shall be in effect with respect to any Customized Insulet Device for the period beginning on the [*]. Amgen's [*], and Insulet's [*], for any breach of the Product Warranty shall be for Insulet to: (i) replace non-conforming Customized Insulet Devices returned to Insulet, and such remedy shall be available only for defects reported during the applicable warranty period; and (ii) in the event that such a breach necessitates a recall of the System, Insulet shall reimburse Amgen's reasonable, necessary, direct, external costs associated with such recall, provided that such costs do not exceed [*] during the Term. The Product Warranty does not apply with respect to Customized Insulet Devices that are, following Shipment by Insulet, subject to abuse, alteration, misuse, or improper operation.
- d. The Manufacture of each Customized Insulet Device and, generically in combination with a human therapeutic, with respect to the Territory, the use of each Customized Insulet Device does not, to the knowledge of Insulet, infringe any patent, copyright, trade secret or other proprietary right of any Third Party, provided that Amgen's sole and exclusive remedy for the breach of this representation shall be indemnification, defense and hold harmless pursuant to Section 8.2(iii) and the rights and remedies set forth in Section 8.3(b).
- e. That Insulet and its Affiliates and subcontractors and their respective employees, directors, officers and agents contributing to or in connection with performance hereunder, (i) have not and will not offer or give to Amgen or any of Amgen's representatives gifts, entertainment, payments, loans or other gratuities in order to or that may influence the award of a contract or obtain favorable treatment under any agreement with Amgen or its representatives and (ii) have not and will not use federal funds to influence or attempt to influence any employee of the United States Federal government or a member of congress in connection with this Agreement.

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6.10 Exclusive Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES TO THE OTHER PARTY, OR TO ANY OTHER PERSON OR ENTITY, WITH RESPECT TO PERFORMANCE HEREUNDER OR ANY DELIVERABLE, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING THOSE OF NONINFRINGEMENT, TITLE, MERCHANTABILITY, COURSE OF DEALING, USAGE OF TRADE, AND FITNESS FOR A PARTICULAR PURPOSE.

7. Risk Allocation.

7.1. Insurance. Each Party shall maintain levels and types of insurance coverage as are reasonable and consistent with sound business practice or as required by Applicable Laws, to include at a minimum Workers' Compensation or any similar statutory equivalent, employers' liability, and commercial general liability. Any combination of self-insurance, primary and/or excess liability insurance policies shall be deemed compliant with this requirement. At a Party's request, the other Party shall submit a certificate of insurance evidencing any applicable Workers' Compensation, Employers' Liability and Commercial General Liability policies that may be in effect as of the Effective Date and, thereafter, not more frequently than annually thereafter.

8. Indemnification and Limitation of Liability.

8.1 Indemnification by Amgen. Amgen will indemnify, defend and hold harmless Insulet and its Affiliates, and their respective officers, directors, employees, agents, successors and assigns (" Insulet Indemnified Party ") against all Third Party actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' and professionals' fees) (collectively, " Loss ") to the extent arising from Amgen's or its Affiliates' or subcontractors', or their respective employees', contractors' or agents' (i) [*], (ii) [*], (iii) [*] except to the extent of Insulet's obligations to indemnify, defend and hold harmless under Section 8.2, (iv) [*], except to the extent of Insulet's obligations to indemnify, defend and hold harmless under Section 8.2. Additionally, except to the extent of Insulet's obligations to indemnify, defend and hold harmless under Section 8.2, Amgen will indemnify, defend and hold harmless Insulet Indemnified Party against all Third Party claims (a) to the extent arising from [*] and (b) any and all Third Party [*].

8.2 Indemnification by Insulet. Insulet will indemnify, defend and hold harmless Amgen and its Affiliates, and their respective officers, directors, employees, agents, successors and assigns (" Amgen Indemnified Party ") against any and all Loss to the extent arising from Insulet's or its Affiliates' or subcontractors', or their respective employees', contractors' or agents' (i) [*] in performance or lack of performance of Insulet's obligations hereunder, (ii) breach of any of [*], (iii) infringement of the intellectual property of a Third Party, including patent claim, to the extent relating [*] (" Infringement Claim ").

8.3 Indemnification Procedure.

- a. In the event of a Loss for which a Party (the " Indemnified Party ") seeks from the other Party (the " Indemnifying Party ") indemnification and defense pursuant to Section 8.1 or Section 8.2, the Indemnified Party will promptly notify the Indemnifying Party of each such Loss, and the Indemnifying Party will assume the defense thereof with, counsel reasonably satisfactory to the Indemnified Party; provided that the Indemnified Party will have the right to retain its own counsel at its own cost except if representation of the Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential conflicting interests between the Parties in which case the cost shall be borne by the Indemnifying Party. The indemnifications provided for by Section 8.1 and Section 8.2 will not apply to amounts paid in settlement of any Loss if such settlement is effected without the consent of the Indemnifying Party, which consent will not be unreasonably withheld. The failure to promptly deliver notice of a Loss to the Indemnifying Party after service of the complaint, if materially prejudicial to the Indemnifying Party's ability to defend such complaint, will relieve the Indemnifying Party of any liability to the Indemnified Party under this Section 8.3 only to the extent so prejudiced. The Indemnified Party will reasonably cooperate with the Indemnifying Party in the investigation and defense of each Loss.
- b. With respect to each Infringement Claim, without limiting Amgen's other rights or remedies under this Agreement, Insulet shall use commercially reasonable efforts to obtain the intellectual property rights that are the subject of the claim or design around the alleged/actual infringement such that there is no infringement (while still being able to satisfy the Specifications for the Customized Insulet Device in accordance with this Agreement).

8.4 Limitation of Liability.

- a. EXCEPT WITH REGARD TO [*], ANY LIABILITY THAT ARISES FROM A PARTY'S [*], IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, CONSEQUENTIAL,

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SPECIAL OR PUNITIVE DAMAGES OF ANY KIND OR NATURE ARISING OUT OF THIS AGREEMENT OR THE SALE OF PRODUCTS, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING THE POSSIBILITY OF NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE PARTY HAS BEEN WARNED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE, AND EVEN IF ANY OF THE LIMITED REMEDIES IN THIS AGREEMENT FAIL OF THEIR ESSENTIAL PURPOSE. ANY "LOSS" FOR WHICH A PARTY IS OBLIGATED TO DEFEND, INDEMNIFY, HOLD HARMLESS THE OTHER PARTY SHALL BE CONSIDERED DIRECT DAMAGES OF SUCH OTHER PARTY.

- b. EXCEPT WITH RESPECT TO ANY LIABILITY OR LOSS THAT ARISES FROM (A) [*], IN NO EVENT SHALL INSULET'S AGGREGATE LIABILITY FOR DIRECT DAMAGES TO AMGEN UNDER THIS AGREEMENT AND THE DEVELOPMENT AGREEMENT, IN THE AGGREGATE, EXCEED [*].

9. Term and Termination.

9.1 Term. This Agreement shall become effective on the date first written above and unless terminated earlier in accordance with the terms of this Agreement, shall remain in full force and effect until the expiration of the fifth Commercial Year (the "Initial Period"). Prior to the expiration of the [*] and each Commercial Year thereafter, the Parties shall negotiate in good faith an extension of the term for an additional twelve (12) month period (each a "Renewal Period", and together with the Initial Period, the "Term"); provided that either Party may elect not to renew this Agreement by providing the other Party with notice of same at least twenty four (24) months prior to the Initial Period or expiration of the then current-Renewal Period, as applicable.

9.2 Termination Without Cause. Following the [*], Amgen may notify Insulet in writing of its intent to terminate this Agreement without cause, such termination to become effective twelve (12) months following the date of such notice.

9.3 Termination For Cause. Except as otherwise provided in Section 12.13 regarding Force Majeure, either Party may terminate the Agreement if (a) except with respect to obligations regarding Confidential Information set forth in Section 5, the other Party materially breaches any material provision of this Agreement and has not cured such breach within [*] days (or for such reasonable amount of time thereafter, but in no event longer than [*] days, if the default is not susceptible of cure within [*] days) after written notice thereof (specifying in reasonable detail the nature of the material breach) by the non-breaching Party; or (b) the other Party voluntarily commences any action or seeks any relief regarding its liquidation, reorganisation other than for corporate reorganisation, dissolution or similar act or under any bankruptcy, insolvency or similar law; or (c) if a proceeding is commenced or an order, judgement or decree is entered seeking the liquidation, reorganization, dissolution or similar act or any other relief under any bankruptcy, insolvency or similar law against the other Party, without its consent, which continues undismissed or unstayed for a period of [*] days.

9.4 Effect of Expiration or Termination. Expiration or termination of the Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 1, 3.6, 5, 6.9, 6.10, 7 (but only with respect to insurance applicable to indemnification obligations), 8, 9.4, 9.5, 10, 11, and 12 shall survive the expiration or termination of the Agreement.

9.5 Remaining Stock. In the event of termination other than as a result of breach by Amgen, Amgen shall have the right but not the obligation to purchase all usable stock of the Custom Insulet Devices which was Manufactured for Amgen.

10. Disputes.

10.1 Resolution of Disputes. The Parties recognize that a bona fide dispute as to certain matters related to a Party's rights or remedies under this Agreement may arise from time to time. In the event of the occurrence of such a dispute, the Parties shall undertake good faith efforts to resolve any such dispute in good faith. In the event the Parties shall be unable to resolve any such dispute, by written notice to the other Party, a Party may, but shall not be obligated to, have such dispute referred to the Executive Officers for attempted resolution by good faith negotiations within [*] days, or such other period as may be agreed to by the Parties, after such written notice is received.

10.2 Performance During Dispute. Each Party shall continue to diligently perform its obligations under this Agreement pending resolution of any dispute hereunder; provided, however, during the pendency of a dispute regarding payments to Insulet, Amgen shall not be obligated to pay amounts to Insulet that are the subject of a good faith dispute.

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11. INTELLECTUAL PROPERTY OWNERSHIP, PATENTS, LICENSES, AND [*].

11.1 Intellectual Property Ownership, Patents and Licenses. The Parties' intention is that if and to the extent that Development occurs during the Term of this Agreement, grants of rights, intellectual property ownership, protection, and related matters shall be consistent with the Parties' agreement with respect to such as set forth in Article 5 and Article 6 of the Development Agreement. Accordingly, the [*]. The aforementioned [*] as follows:

[*]

- 11.2 Retained Rights. Nothing contained in this Agreement confers or will be construed to confer any rights by implication, estoppel or otherwise, under any Intellectual Property Rights, other than the rights expressly granted in this Agreement and the Development Agreement. All rights not expressly granted by a Party under this Agreement or the Development Agreement are hereby reserved.
- 11.3 Trademarks.
- a. Limitations on Use. Except as set forth in this Section 11.3, Amgen shall not use, register, or seek to register any trademark for use with wearable infusion device for delivery of human therapeutics that is confusingly similar to, or contains the words, "POD", "OMNI", "OMNIPOD" or "INSULET".
 - b. Licensed Marks Assignment. Amgen has pending applications Serial No. [*], and [*] for the marks [*] and [*], respectively (collectively, "Applications") filed in the United States Patent and Trademark Office ("PTO") on the basis of Amgen's intent to use such trademarks (the "Licensed Marks"). Amgen agrees that Insulet shall become the owner of the [*] and [*] trademarks pursuant to this Section 11.3. With respect to each of the Licensed Marks, upon a statement of use or amendment to allege use is filed in the PTO and accepted by the PTO, Amgen will promptly assign the Application relevant to the Licensed Mark to Insulet. Amgen hereby agrees to use the Licensed Marks only in connection with the Customized Insulet Device and the System meeting reasonable standards of quality that equal or exceed the quality of similar products heretofore marketed or provided by Amgen, the quality of which is known and acceptable to Insulet.
 - c. Trademark License. Insulet hereby grants to Amgen an exclusive, worldwide, fully paid up, royalty-free, and sub-licensable (on terms and conditions substantially consistent herewith) right and license to use the Licensed Marks and related registrations (collectively, the "Trademarks") upon or in connection with the Customized Insulet Device and System. The license to the Trademarks granted to Amgen is exclusive, even as to Insulet, and Insulet will not use the Trademarks on any Device, products or other materials except those made for Amgen. Other than the Licensed Marks, this Section 11.3(c) does not preclude Insulet from using any marks that contain the word "POD" ("POD Marks"), on Devices, products or other materials not supplied to Amgen, and Amgen understands and agrees that Insulet may use or license such POD Marks [*]. All use of the Trademarks under this Agreement in connection with the Customized Insulet Device shall inure to the benefit of Insulet. Upon termination of this Agreement by Amgen pursuant to Section 9.3 (Termination for Cause), Insulet shall immediately do all that is necessary or required to assign the Trademarks to Amgen and Amgen shall have the unrestricted right to use and license the Trademarks.
 - d. New Trademark Filings and Maintenance. Insulet will have the obligation, at its own expense, to use best efforts to file and prosecute trademark applications and maintain registrations for the Trademarks covering the Customized Insulet Device and System in the Supply Territory. This Section 11.3 is a material provision of this Agreement and Insulet's failure to comply with this Section 11.3 shall be considered a material breach of this Agreement. Insulet shall promptly notify Amgen of the status of all trademark applications and registrations regarding the Trademarks. If Insulet does not timely take action before any deadline with respect to Trademarks, then Insulet hereby grants to Amgen a power of attorney to act on its behalf to take the necessary action during the grace period or otherwise, all at Amgen's expense, and without waiver of any other rights of Amgen under this Agreement.
 - e. Enforcement. If either Party shall become aware of any infringement by third parties of the Licensed Marks or any other use of the Licensed Marks or any term or trademark application confusingly similar to the Licensed Marks, such Party shall promptly notify the other Party of that infringement, use or application. Insulet agrees, at Insulet's expense, to defend and protect the Trademarks against infringement by third parties in the Supply Territory, including, without limitation, instituting suit to seek injunctions and monetary damages and filing opposition proceedings and cancellation actions against conflicting trademarks of third parties (collectively "Insulet Enforcement Actions"). Insulet shall consult with Amgen but will have control over the selection of counsel, the conduct of the matter, and the settlement of Insulet Enforcement Actions. Amgen shall have the right to participate in all such Insulet Enforcement Actions at Amgen's expense. Insulet shall be entitled to [*] of any recovery of monetary damages from Insulet Enforcement Actions. If Insulet fails to prosecute actions against any third party

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that Amgen reasonably believes is infringing or likely to cause confusion with the Trademarks, Amgen shall have the right, but not the obligation, to prosecute such action independently and, if it exercises such right, it shall fund [*] of the costs and expenses thereof and be entitled to [*] of any recovery of monetary damages. Amgen shall consult with Insulet but will have complete control over the selection of counsel, the conduct of the matter, and the settlement of all enforcement actions that are brought by Amgen. To the extent that Insulet fails to fulfill its obligations to defend and protect the Trademarks, and/or as necessary for Amgen to prosecute actions against infringers as permitted in this paragraph, Insulet irrevocably constitutes and appoints Amgen as its true and lawful representative and attorney-in-fact, with full power and authority in its name, place and stead, to fulfill such Insulet obligations and prosecute such actions. The foregoing grant of authority is a special power of attorney coupled with an interest, shall be irrevocable and shall continue in full force and effect notwithstanding the subsequent merger, dissolution or other termination of the existence of Insulet. The Parties shall cooperate and promptly do such acts and execute, acknowledge, and deliver such documentation as is necessary for the parties to fulfill their respective obligations pursuant to this Section 11.3.

12. Miscellaneous.

12.1 Regulatory Support and Submissions.

- a. Insulet will perform [*] of the Customized Insulet Device required or necessary to support submissions to or meetings with Regulatory Authorities, and Amgen will reimburse Insulet [*].
- b. Confidential Information of Insulet regarding the Customized Insulet Device that is required to be submitted to a Regulatory Authority will be managed through a Master File, where applicable, or an equivalent regionally appropriate mechanism for filing (referred to in this Agreement as a Master File). Information that is not Confidential Information of Insulet regarding the Customized Insulet Device may also be managed through a Master File, at the request of Amgen.
- c. With the exception of the Confidential Information of Insulet in a Master File, which Insulet shall file with the Regulatory Authorities upon Amgen's request as set forth in this Section 12.1, Amgen shall have the right, but not the obligation, to compile and file any and all submissions with the Regulatory Authorities required for the approval of Customized Insulet Devices and/or Systems for commercial or clinical use (such submissions include without limitation briefing documents in support of meetings, clinical trial applications, marketing applications, and responses to questions or requests for additional information from Regulatory Authorities). Insulet shall submit to Amgen, in electronic form compatible with Amgen's system requirements with Confidential Information of Insulet redacted, all documents necessary to be submitted to a Regulatory Authority. With the exception of Confidential Information of Insulet contained in a Master File: (i) Amgen shall own all right, title and interest in and to filings and submissions to Regulatory Authorities and Regulatory Approvals related to the Customized Insulet Devices and Systems; and (ii) with respect to the Customized Insulet Device, Insulet shall only submit to Regulatory Authorities those documents approved in writing and in advance by Amgen. With respect to Confidential Information of Insulet contained in a Master File, Amgen shall approve the index of content in writing prior to submission. Insulet will provide Amgen with a Letter of Authorization for the Master File that allows FDA to incorporate by reference the information into Amgen's submission.
- d. Unless otherwise agreed by the Parties or required by Regulatory Authorities, for each document necessary to be submitted to a Regulatory Authority that does not contain Confidential Information of Insulet, Insulet shall submit to Amgen for its review and comment a draft of each such document no later than sixty (60) days prior to the anticipated date for submittal to the Regulatory Authority. Insulet will consider in good faith any comments and suggestions that Amgen may have based on its review of the documentation, address such comments and suggestions, and make reasonable changes to the documentation given such comments and suggestions.
- e. Except for Confidential Information of Insulet's contained in a Master File, Insulet shall provide a copy of the Master File contents to Amgen at the time of submission and provide updated contents to Amgen when changes are made. With respect to Confidential Information of Insulet contained in a Master File, at the time of submission and when changes are made, Insulet shall submit to Amgen an index of the contents of the Master File and a brief description of contents. After submission to a Regulatory Authority, Insulet shall maintain a Master File throughout the life of the Customized Insulet Device and notify Amgen within [*] business days of each change to the content of a Master File. Insulet shall immediately notify Amgen of any communication from a Regulatory Authority regarding the Customized Insulet Device, to include but not limited to, information contained within a Master File. Amgen will reimburse Insulet its actual and reasonable costs incurred for compilation, submission, communication with a Regulatory Authority, and maintenance of a Master File to the extent the Master File is only

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required or necessary for the Customized Insulet Device and not required, necessary or conducted with respect to the Insulet Device.

- f. Insulet and Amgen will document medical device reporting roles and responsibilities in an amendment to this Agreement. Insulet will, in good faith, with the engagement of staff adequate in number and expertise, and prior to the filing date as specified by Amgen and Insulet, negotiate the foregoing amendment.

12.2 Changes.

- a. Each Party recognizes and acknowledges that changes to this Agreement arising from requirements of Regulatory Authorities applicable to Customized Insulet Devices (each a “Change”) may be necessary from time to time. In the event that either Party determines that a Change is desirable or necessary, such Party will notify the other Party of such Change in writing. Within [*] days after notice by either Party of a request for a Change, the Parties will negotiate in good faith with respect to such Change, in each case. Upon the mutual agreement of the Parties to approve a requested Change, the Parties will execute a written change order setting forth the agreed upon Change (each a “Change Order”). The Parties will perform their obligations under this Agreement as modified by each Change Order. If the Parties are unable to agree on any Change within the above-referenced [*] day period, the Parties will continue to perform their respective obligations hereunder as agreed to by the Parties.
- b. Notwithstanding anything to the contrary set forth in Section 12.1(a), upon Amgen’s request, from time-to-time, that Insulet Manufacture and supply the Customized Insulet Device for Commercialization in countries or regions specified by Amgen that are outside of the then-current Supply Territory pursuant to the Amgen-approved schedule (each such request a “Supply Territory Expansion Request”), Insulet will (a) submit to Amgen a proposed schedule and estimate of Supply Territory Expansion Reimbursable Expenses with respect to the Supply Territory Expansion Request, (b) subject to the Change process set forth in Section 12.1(a), do all that is necessary or required for it to Manufacture and supply the Customized Insulet Device for Commercialization in the countries or regions specified in the Supply Territory Expansion Request; and (c) be compensated by Amgen pursuant to Section 3.5. With respect to each Supply Territory Expansion Request, upon Regulatory Approval with respect to the territory(ies) that is(are) the subject of such request (each, an “Additional Supply Territory”), the definition of Supply Territory shall be automatically amended to include in each Additional Supply Territory. At Amgen’s request, Insulet shall file submissions, notifications, applications, documentation and related materials as Amgen may request in relation to obtaining approval of Regulatory Authorities for the Customized Insulet Devices and/or Systems anywhere in the world and any Change due to such requests shall be addressed pursuant to Section 12.1 and Section 12.1(a).
- c. In the event of a conflict between or among Change Orders, a Change Order dated later in time will control over a Change Order dated earlier in time. If a Change is mandated by a change in Applicable Laws, and failure to comply would render either Party’s performance under this Agreement or the use of the Customized Insulet Device illegal, each Party’s performance shall be temporarily suspended only to the extent such performance is illegal until such time as the Parties confer and the Parties shall mutually agree to a course of action and delegate responsibility for implementing such Change in order to comply with such amended Applicable Laws.

12.3 Governing Law and [*]. This Agreement will be construed and the respective rights of the Parties determined according to the substantive laws of the Commonwealth of Massachusetts notwithstanding the provisions governing conflict of laws under such Massachusetts law to the contrary. The Parties [*].

12.4 Assignment. Neither Amgen nor Insulet may assign this Agreement in whole or in part without the consent of the other Party, except if such assignment occurs in connection with the sale or transfer of all or substantially all of the business or assets of the assigning Party, in which case, the assigning Party shall provide the other Party notice of such assignment within [*] days thereof (“Notice of Permitted Assignment”).

12.5 Entire Agreement; Amendments. This Agreement (including all attachments hereto and documents or portions of documents incorporated herein by reference) constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all other previous arrangements with respect to the subject matter hereof, whether written or oral. For the avoidance of doubt, this Agreement does not modify or supersede the Development Agreement. Any amendment or modification to this Agreement will be made in writing signed by both Parties.

12.6 Notices.

- a. Notices to Amgen will be addressed to:

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Amgen Inc.
 One Amgen Center Drive
 Thousand Oaks, CA 91320
 Attention: Vice President Global Strategic Sourcing
 Mailstop: 10-2-D

With a copy to:

Amgen Inc.
 One Amgen Center Drive
 Thousand Oaks, CA 91320
 Attention: Law Department, Contracting and Operations Group; Mailstop: 35-2-A

- b. Notices to Insulet will be addressed to:
 Insulet Corporation
 9 Oak Park Drive
 Bedford, MA 01730
 Attention: General Counsel
- c. Each Party may change its notice recipients under this Section 12.6 by giving notice to the other Party in the manner herein provided. Any notice required or provided for by the terms of this Agreement will be in writing and will be (a) sent by registered or certified mail, return receipt requested, postage prepaid, (b) sent via a reputable overnight courier service, or (c) sent by facsimile transmission with an original to be followed the same day via a reputable overnight courier service, in each case properly addressed in accordance with this Section 12.6. The effective date of each notice will be the actual date of receipt by the Party receiving the same.

12.7 Independent Contractors. It is understood and agreed that the relationship between the Parties hereunder is that of independent contractors and that nothing in this Agreement will be construed as authorization for either Amgen or Insulet to act as agent for the other. For any performance required under this Agreement (i) between two business entities based in the United States of America and (ii) being performed in the United States of America and/or its territories, Insulet agrees that this Agreement shall be performed in full compliance with, if and to extent applicable to Insulet, the Equal Opportunity Clauses set forth in 41 C.F.R. §§ 60-1.4(a), 60-250.5(a) and 60-741.5(a) and the employee notice and related obligations found at 29 C.F.R. Part 471, Appendix A to Subpart A, Title VII of the Civil Rights Act of 1964; Sections (1) and (3) of Executive Order No. 11625 relating to the promotion of Minority Business Enterprises; Americans with Disabilities Act; Age Discrimination in Employment Act; Fair Labor Standards Act; Family Medical Leave Act; and all corresponding implementing rules and regulations, all of which, including the contract clauses required and regulations promulgated thereunder, are incorporated herein by reference.

12.8 No Strict Construction. This Agreement has been prepared jointly and will not be strictly construed against any Party.

12.9 Headings. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and will have no effect on the meaning of the provisions hereof.

12.10 No Implied Waivers; Rights Cumulative. No failure on the part of Amgen or Insulet to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of

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any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

12.11 Severability. If, under applicable law or regulation, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid or unenforceable provision, a " Severed Clause"), the Parties will consult one another and use reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement. In the event such a valid and enforceable provision cannot be agreed upon, the invalidity of one or more Severed Clauses will not affect the validity of this Agreement as a whole, unless the Severed Clauses are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the Severed Clauses.

12.12 Execution in Counterparts: Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission will be deemed to be original signatures.

12.13 Force Majeure. A Party shall not be deemed to have breached this Agreement to the extent its failure to perform directly results from a Force Majeure Event and such Party uses its good faith efforts to resume, and does resume, performance as soon as reasonably practicable after the occurrence of the Force Majeure Event.

12.14 Interpretation: Precedence. Whenever the context may require, any pronoun will include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation." Unless the context requires otherwise, (A) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (B) any reference to any laws herein will be construed as referring to such laws as from time to time enacted, repealed or amended, (C) any reference herein to any Person will be construed to include the Person's successors and assigns, (D) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (E) any reference herein to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion; (F) all references herein to Articles, Sections, Appendices, Exhibits or Schedules will be construed to refer to Articles, Sections, Appendices, Exhibits and Schedules of this Agreement; and (G) all references to the "knowledge" of a Party will refer to the actual knowledge of any of such Party's officer or director level employees or members of its Board of Directors, or the knowledge which any such person would reasonably be expected to have assuming reasonable inquiry in light of such person's position with such Party. In the event of any conflict between this Agreement and any Appendix attached hereto, the terms of this Agreement shall control.

12.15 [*]. Nothing contained herein shall [*].

12.16 Construction. The Parties acknowledge that each Party is of equal bargaining strength and has actively participated in the preparation and negotiation of this Agreement. Each Party is entering into this Agreement on its own free will and is not acting under duress or coercion of any kind or nature whatsoever. Each Party has had the right and opportunity to consult with legal counsel of its choice in connection with this Agreement; and each Party has either done so, or has voluntarily declined to do so free from duress or coercion. Any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not apply in the interpretation of this Agreement, any portion hereof, or any Modifications hereto.

12.17 [*]. Prior to the [*], each Party agrees that it will [*].

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IN WITNESS WHEREOF, the Parties have caused this Supply Agreement to be executed by their respective duly authorized officers effective as of the Effective Date.

INSULET CORPORATION

By: /s/ Charles T Lamos

Name: Charles T Lamos

Title: COO

AMGEN INC.

By: /s/ William Reis

Name: William Reis

Title: Vice President, Global Strategic Sourcing

By: /s/ William Rich

Name: William Rich

Title: Vice President, Supply Chain

*

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 1.7

[*]

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Exhibit 2.2

Quality Agreement

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 001
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 001 (“Amendment”), entered into effective as of April 15, 2014 (“Amendment 1 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled “Supply Agreement” effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (“Agreement”).

B. Amgen and Insulet desire, and are willing, to amend the Agreement to provide for the purchase by Insulet of certain components for use in the Manufacture of Customized Insulet Devices with the intent to reduce Manufacturing lead times.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Agreement Article 3. Article 3 of the Agreement is hereby amended by adding the following text as a new Section 3.9:

“3.9 Amgen-Specific Components

- a. If, prior to Amgen’s first submittal of the Forecast, Amgen requests in writing that Insulet purchase some or all of the Amgen-Specific Components (defined below) and Amgen submits to Insulet a purchase order for such, Insulet shall promptly purchase and maintain in its inventory the Amgen-Specific Components specified in, such request (the “Requested Amgen-Specific Components”); provided, however, that Amgen shall only have the right to request, and Insulet shall only be obligated to purchase and maintain in its inventory, up to [*] of each Amgen-Specific Component. Insulet shall take delivery of each Requested Amgen-Specific Component no later than the lead time (set forth in Section 3.9(b), below) applicable to each such Requested Amgen-Specific component. Insulet shall only use the Requested Amgen-Specific Components for the Manufacture of Customized Insulet Devices. The Manufacture of one Customized Insulet Device requires one of each of the Amgen-Specific Components (referred to as the “Customized Insulet Device Amgen-Specific Components Set”). Until the number of Customized Insulet Devices equal to the number of Customized Insulet Device Amgen-Specific Component Sets represented by the Requested Amgen-Specific Components (the “Expedited Delivery Customized Insulet Devices”) has been ordered by Amgen by Purchase Order, Insulet shall deliver Customized Insulet Devices within three months after Amgen’s submission of the Purchase Order (regardless of the timing of Amgen’s submission of Forecasts or the quantities of Customized Insulet Devices set forth in the Binding Portion of a Forecast). For illustrative purposes, if before submitting its first Forecast Amgen orders [*] of each Amgen-Specific Component and thereafter submits Purchase Orders on [*] and [*] for [*] and [*] Customized Insulet Devices, respectively, then Insulet will deliver [*] Customized Insulet Devices on or before [*] and [*] Customized Insulet Devices on or before [*].

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b. The Amgen-Specific Components are the following:

| Item | Description of Amgen-Specific Component | Lead Times (weeks) |
|--------|---|--------------------|
| [*] | [REDACTED] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] or | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |

c. Amgen will pay Insulet [*] (US\$[*]) for each Customized Insulet Device Amgen-Specific Components Set that Amgen requests and Insulet purchases and maintains in its inventory pursuant to this Agreement. Insulet will credit to Amgen [*] (US\$[*]) for each Expedited Delivery Customized Insulet Device ordered by and delivered to Amgen.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the parties have executed this Amendment to the Agreement effective as of the Amendment 1 Effective Date.

Insulet Corporation

By: /s/ W. P. Ryan

Name: W. P. Ryan

Title: COO

Amgen Inc.

By: /s/ Ed Vrable

Name: Ed Vrable

Title: Director Strategic Sourcing

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 002
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 002 (“Amendment”), entered into effective as of June 25, 2014 (“Amendment 2 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled “Supply Agreement” effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the “Agreement”).

B. As of the Amendment 2 Effective Date, Amgen requires [*] for the Customized Insulet Device [*]. with the intent to [*] Amgen and Insulet desire, and are willing, to amend the Agreement to provide for the payment by Amgen of certain amounts for Customized Insulet Devices that [*], all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Invoices, Section 3.7. Section 3.7(a) of the Agreement is amended by deleting it in its entirety and replacing it with the following:

“(a) Insulet shall submit invoices to Amgen on a [*] basis for amounts payable by Amgen hereunder (i) pursuant to Section 3.1, Section 3.3, Section 3.4, and Section 3.5 for [*], (ii) pursuant to Section 3.10, and (ii) testing as provided in Section 12.1. Insulet will endeavor to submit such invoices promptly following the [*]. Invoices will be submitted in electronic format to the following electronic address (which addresses may be changed, from time-to-time, by Amgen upon prior notice to Insulet): email address: AccountsPayableMailroom@Amgen.com.”

2.2 Agreement Article 3. Article 3 of the Agreement is hereby amended by adding the following text as a new Section 3.10:

“3.10 PQ Validation [*].

“Insulet Acceptance Criteria” shall mean the lot acceptance criteria for the Insulet Eros lots as defined in Insulet’s “SOP-051 QA Final Acceptance of Product Rev R” in effect as of June 17, 2014.

“PQ Validation [*]” means each [*] that, [*]. For the avoidance of doubt, a PQ Validation [*].

In the event of changes to the [*] or in the event of changes to the [*], whether it be due to [*] changes or [*], that require a [*] and, pursuant to [*], Amgen has approved a [*], Amgen will pay Insulet [*] (US\$[*]) for [*]. Except for the payment of the [*] obligated to make any payments, or reimburse any amounts, to [*].”

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the parties have executed this Amendment to the Agreement effective as of the Amendment 2 Effective Date.

Insulet Corporation

By: /s/ Brian K. Roberts

Name: Brian K. Roberts

Title: CFO

Amgen Inc.

By: /s/ Sev Sislian

Name: Sev Sislian

Title: Category Manager

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 003
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 003 (“Amendment”), entered into effective as of June 26, 2014 (“Amendment 3 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled “Supply Agreement” effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the “Agreement”).

B. Amgen and Insulet desire, and are willing, to amend the Agreement to set forth medical device reporting roles and responsibilities, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 New Section 2.13. The Agreement is hereby amended by adding to it a new Section 2.13 that reads as follows:

“2.13 Safety Agreement. Medical device reporting roles and responsibilities are set forth in the Safety Agreement, attached hereto as Exhibit 2.13, which is incorporated herein by reference and applies hereto.”

2.2 Agreement Section 12.2(f). The Agreement is hereby amended by deleting Section 12.2(f) in its entirety.

2.3 Exhibit 2.13 (Safety Agreement). The Agreement is hereby amended by adding to the Agreement a new Exhibit 2.13 with content as set forth in Exhibit 2.13 attached hereto.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the parties have executed this Amendment to the Agreement effective as of the Amendment 3 Effective Date.

Insulet Corporation

By: /s/ Brian K. Roberts

Name: BRIAN K. ROBERTS

Title: CFO

Amgen Inc.

By: /s/ Sev Sislian

Name: SEV SISLIAN

Title: CATEGORY MANAGER

Amgen Inc.

By: N.A.

Name: N.A.

Title: N.A.

Exhibit 2.13

Safety Agreement

(Attached)

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.13

SAFETY AGREEMENT

THIS SAFETY AGREEMENT (“**Safety Agreement**”) is entered into as of June 27, 2014 (the “**Safety Agreement Effective Date**”) by and between Amgen Inc., a Delaware corporation (“**Amgen**”), and Insulet Corporation, a Delaware corporation (“**Insulet**”).

AGREEMENT

1. **SUPPLY AGREEMENT.** This Safety Agreement is incorporated by reference in and governed by that certain Supply Agreement by and between the Parties, dated as of November 21, 2013 (as might be amended from time to time, the “**Agreement**”).
2. **DEFINITIONS.** All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Safety Agreement and the defined terms of the Agreement, the definitions set forth in this Safety Agreement shall control with respect to this Safety Agreement. The following definitions are used herein:
 - 2.1 **Drug Adverse Event.** Drug Adverse Event (or “Drug AE”) shall mean any untoward medical occurrence in a patient who has been administered an Amgen Product and which does not necessarily have a causal relationship with the treatment.) Drug AEs include without limitation any unfavorable and unintended sign, symptom or disease temporally associated with the use of an Amgen Product, whether or not considered related to Amgen Product, including any clinically significant worsening of a pre-existing condition. For purposes of this Safety Agreement, any doubt as to whether information constitutes a Drug AE shall be resolved by treating it as a Drug AE. The following events also shall be deemed Drug Adverse Events for purposes of this Agreement, even if the patient has not suffered an adverse outcome:
 - Incidents of pregnancy when either the mother or father is a patient or clinical trial subject to whom .Amgen Product has been administered;
 - Incidents when a lactating woman is actively taking an Amgen Product while breastfeeding;
 - Lack of therapeutic effect;
 - Suspected transmission of an infectious agent via an Amgen Product;
 - Incidents of overdose, abuse, or misuse of an Amgen Product, including off-label use or attempted suicide;
 - Medication errors involving an Amgen Product; and
 - Incidents of occupational exposure . to an Amgen Product.
 - 2.2 **Device Adverse Event.** Device Adverse Event (or “Device AE”) shall mean an event that reasonable suggests that the Customized Insulet Device or a similar device marketed by Insulet:
 - May have caused or contributed to death or serious injury.
 - Has malfunctioned and that the Customized Insulet Device or a similar device marketed by Insulet would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, or
 - Resulted in an event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.
 - 2.3 **Privacy Laws and Regulations.** Privacy Laws and Regulations shall mean, as are in effect from time to time, applicable data privacy laws, including without limitation the national and sub-national laws based on the European Union Data Protection Directive to the extent applicable to data processors, and U.S. state data breach notification and information security laws and regulations specific to the handling of Personal Information to the extent applicable to a Party or its representatives or third-party service

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providers, including, but not limited to the requirements set forth at 45 Massachusetts M.G.L. c. 93H and 201 CMR §§ 17.00-17.05.

2.4 Personal Information. Personal Information shall mean any information from which an individual may be identified, including without limitation an individual's name, address, telephone number, social security number, account numbers, account balances, account histories, and "personal information," "nonpublic personal information," "protected health information" (and other similar information, however described) as defined in applicable Privacy Laws and Regulations and that is obtained as a result of, or in connection with, the development, marketing, or commercialization of an Amgen Product.

3. DRUG ADVERSE EVENT AND DEVICE ADVERSE EVENT HANDLING AND EXCHANGE.

3.1 Collection of Events Generally .

- (i) Each Party will record in writing all available information of which it becomes aware regarding each Drug AE or Device AE that it is required to exchange under this Safety Agreement and shall use reasonable efforts to obtain the following information from the person providing the Drug AE or Device Adverse Event information (the "reporter"):
 - (a) confirmation that the patient was exposed to an Amgen Product and/or used the Customized Insulet Device;
 - (b) the details of the Drug AE or Device AE;
 - (c) the details that identify the affected Amgen Product and/or Customized Insulet Device (Product name, Part number, Lot number, Serial number, Use by date, etc.);
 - (d) the contact information for the patient's healthcare provider; and
 - (e) a description of the source of the report (for example, consumer, healthcare provider, etc.).
- (ii) If the reporter is the patient's healthcare provider, the notifying Party shall obtain the reporter's contact information.
- (iii) Each Party will provide the other Party with such assistance as may be reasonably requested in investigating and obtaining follow-up information with respect to Drug AEs or Device AEs.

3.2 Insulet's Obligations Regarding Reporting, Investigation, and Follow Up of Drug AEs and Device AEs

- (i) Within [*] of Insulet's awareness of information relating to a Drug AE or Device AE, Insulet will transmit to the designated Amgen phone number on Attachment A all available information of which it is then aware regarding such event.
- (ii) If Insulet receives any other information or documents relating to a Drug AE or Device AE, within [*] after receipt of such, Insulet shall provide such information and/or the originals of such documents to Amgen's designated contact.
- (iii) No later than the [*] of each calendar month during the Term of the Agreement, Insulet shall submit to Amgen a written report including the following: (1) a line listing of Drug AEs and Device Adverse Events of which Insulet is aware that occurred or of which it became aware during the previous calendar month or (2) a statement certifying that Insulet is not aware of the occurrence of any Drug AEs or Device Adverse Events during the previous calendar month. If a line listing is provided, Amgen will inform Insulet if Amgen did not receive an AE or Device Adverse Event reflected on the line listing and within [*] after receipt of such notice, Insulet shall transmit such missing reports to Amgen.

3.3 Amgen's Obligations Regarding Device Adverse Events

No later than the [*] of each calendar month during the Term of the Agreement, Amgen shall submit to Insulet a written report including the following: (1) a line listing of Device Adverse Events of which Amgen is aware that occurred or of which it became aware during the previous calendar month or (2) a statement certifying that Amgen is not aware of the occurrence of any Device Adverse Events during the previous calendar month. If a line listing is provided, Insulet will inform Amgen if Insulet did not receive a Device Adverse Event reflected on the line listing and within [*] after receipt of such notice, Amgen shall transmit such missing reports to Insulet (unless such event was originally received from Insulet under Section 3.2 above).

4. PHARMACOVIGILANCE

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

As between the Parties, Amgen is responsible for pharmacovigilance matters and maintaining the global safety database for the Amgen Products. All Drug Adverse Events, Device Adverse Events, recalls or pharmacovigilance events will be communicated according to this Safety Agreement and Section 6.9(c) of the Agreement.

5. SAFETY AND REGULATORY COMMUNICATIONS

- (i) Amgen shall control all regulatory matters relating to the Amgen Products or Customized Insulet Device, including without limitation regulatory communications and filings, regulatory/safety reporting to Governmental Authorities, packaging and labeling, recalls, reimbursements and returns, and any other corrective actions related to an Amgen Product or Customized Insulet Device.
- (ii) Notwithstanding the above, if Insulet, acting in good faith, determines that a Device AE or malfunction of the Customized Insulet Device is applicable to or is reasonably likely to occur with its other drug delivery systems as designed, manufactured and marketed, then to the extent Insulet is obligated under the Medical Device Reporting (MDR) regulations, Insulet is permitted to meet its separate reporting responsibilities regarding for its other drug delivery systems, as the case may be. However, under these circumstances, the other drug delivery system would be the product listed in the MDR Report, not the Customized Insulet Device.
- (iii) Insulet shall notify Amgen within **one (1) business day** after Insulet's receipt of any safety or regulatory communication regarding Drug AEs or Device Adverse Events from a Governmental Authority concerning an Amgen Product, Customized Insulet Device, or similar device marketed by Insulet.
- (iv) If Insulet receives notification of an impending regulatory inspection related to an Amgen Product or Customized Insulet Device. Insulet shall notify Amgen within **one (1) business day** after such notification.

Insulet shall not disclose any Confidential Information of, or make any commitments regarding Drug Adverse Events or Device Adverse Events on behalf of Amgen or its Affiliates to a Governmental Authority except to the extent Amgen has given prior written authorization to Insulet to do so.

6. RISK MANAGEMENT ACTIVITIES

Insulet shall cooperate with Amgen in implementing any and all Amgen Product-related risk management activities relating to the Customized Insulet Device and Section 12.2(a) of the Agreement, to the extent Amgen reasonably requests Insulet to do so.

7. TRAINING

Insulet represents and warrants that its Quality Management System training includes training relating to the identification and reporting of complaints, including Drug Adverse Events.

8. QUALITY MANAGEMENT SYSTEM

Insulet shall implement, maintain, and adhere to a set of policies, plans, practices, and supporting infrastructure as defined in the Quality Agreement.

9. MISCELLANEOUS

9.1 Audits

Amgen's audit rights under Article 3 of the Quality Agreement shall be deemed to include the right to audit Insulet's compliance with this Safety Agreement.

9.2 Personal Information

Each Party hereby represents and warrants that while this Safety Agreement is effective, and continuing as long as a Party controls, possesses, stores, transmits or processes Personal Information (including after expiration or termination of this Safety Agreement): (a) it will adhere to and comply with the requirements of all applicable Privacy Laws and Regulations; and (b) except as expressly permitted in this Safety Agreement, it will, and will cause those acting on its behalf to, protect against the loss, destruction, processing, transmission, disclosure, and use of Personal Information. Except as expressly set forth in this Safety Agreement or otherwise authorized in advance and in writing by the other Party, each Party shall not provide anything to the other Party that contains any of the following information about an individual (each, a "**Restricted Data Element**"): social security or taxpayer identification number; driver's license or other

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state-issued identification number; credit card or other financial account number; health insurance information, including identification number; medical information (other than that expressly required to be provided under the terms of this Safety Agreement), including irrelevant medical information, passport number or other identification number issued by a Governmental Authority; alien registration number; mother's maiden name, when labeled as such; employee identification number; DNA or other biometric data, such as fingerprints and retinal scans. Unless, and then only to the extent, this Safety Agreement expressly requires or the Parties otherwise agree in advance and in writing to exchange Personal Information, the Party providing such Personal Information to the other Party will, and will cause those acting on its behalf to, redact all Restricted Data Elements from any documents or other materials that are provided to the receiving Party. To the extent this Safety Agreement expressly requires or the Parties otherwise agree in advance and in writing to exchange Personal Information, this exchange will be conducted with appropriate attention to privacy concerns.

9.3 Language

English will be used as the common language for all information exchanged between the Parties pursuant to this Safety Agreement.

IN WITNESS WHEREOF, the Parties have executed this Safety Agreement through their duly authorized representatives.

Amgen Inc.

By: /s/ Deborah J. Arrindell, MD JD MPH

Name: Deborah J. Arrindell, MD JD MPH

Title: Executive Director, Safety

Insulet Corporation

By: /s/ Tracey Haas Wielinski

Name: Tracey Haas Wielinski

Title: VP, Global Regulatory, Clinical Affairs
and QA

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

ATTACHMENT A

Reporting Addresses

From Insulet to Amgen

Telephone: 1-800-77-AMGEN

Safety-related regulatory queries:

| | | |
|-----|-----|-----|
| [*] | [*] | [*] |
| [*] | [*] | [*] |

Parties are responsible for confirming successful transmission of the information (such as a facsimile transmission report, return receipt, express mail tracking documentation or electronic confirmation).

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 004
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 004 ("Amendment"), entered into effective as of August 6, 2014 ("Amendment 4 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled "Supply Agreement" effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the "Agreement").

B. Amgen and Insulet desire, and are willing, to amend the Agreement to set forth additional or changed roles and responsibilities with respect to quality, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Exhibit 2.2 (Quality Agreement). Exhibit 2.2 (Quality Agreement) to the Agreement is hereby amended by adding to Exhibit 2.2 new Sections 24, 25, and 26 with content as set forth in Exhibit 1 to this Amendment.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

[Signature Page Follows]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 4 Effective Date.

Insulet Corporation

By: /s/ Kevin Schmid

Date: August 6, 2014

Name: Kevin Schmid

Title: Vice President, Business Development

Insulet Corporation

By: /s/ Tracey Wielinski

Date: 6 August 2014

Name: Tracey Wielinski

Title: Vice President of Global Regulatory/Clinical Affairs and Quality Assurance

Amgen Inc.

By: /s/ Sev Sislian

Date: August 6, 2014

Name: Sev Sislian

Title: GSS, Category Manager

Amgen Inc.

By: /s/ Anthony Mire-Sluis

Date: August 6, 2014

Name: Anthony Mire-Sluis

Title: Vice President Quality

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 1

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 005
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 005 (“Amendment”), entered into effective as of August 11, 2014 (“Amendment 5 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled “Supply Agreement” effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (“Agreement”).

B. Amgen provided to Insulet a Forecast (and associated Purchase Orders numbered [*] for a total of [*] Customized Insulet Devices to be delivered between [*] and [*] (“[*] Forecasted Customized Insulet Devices”). In order to adjust Insulet’s manufacturing capacity availability, Insulet has requested that Amgen accept delivery of the [*] Forecasted Customized Insulet Devices during the month of [*]. Section 2.9 of the Agreement provides that, among other things, changes to previously-accepted Purchase Orders are permitted pursuant to a written agreement of the Parties.

C. Amgen and Insulet desire, and are willing, to enter into this written agreement, pursuant to Section 2.9 of the Agreement, to change the aforementioned Purchase Orders to provide that Insulet will deliver the [*] Forecasted Customized Insulet Devices during [*], on the terms set forth in the Agreement as modified below.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Agreement Article 3. Article 3 of the Agreement is hereby amended by adding the following text as a new Section 3.11:

“3.11 [*] Forecasted Customized Insulet Devices. Amgen provided to Insulet a Forecast (and associated Purchase Orders numbered [*] (the “[*]Purchase Orders”) for a total of [*] Customized Insulet Devices to be delivered between [*] and [*] (“[*] Forecasted Customized Insulet Devices”). Amgen and Insulet hereby agree that, notwithstanding anything to the contrary set forth in this Agreement, the Forecast that includes the [*] Forecasted Customized Insulet Devices, or the [*] Purchase Orders, Insulet will deliver to Amgen the [*] Forecasted Customized Insulet Devices during the month of [*]. In return for Amgen agreeing to [*] Forecasted Customized Insulet Devices, the following sections of the Agreement will not apply to the [*] Forecasted Customized Insulet Devices delivered in the month of [*]: [*]. For the avoidance of doubt, Amgen will [*]. Additionally, in the event [*].”

| Amendment 5 Table 1 | |
|---------------------|-----|
| [*] | [*] |
| [*] | [*] |
| [*] | [*] |
| [*] | [*] |

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

[Remainder of this page left blank intentionally]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the parties have executed this Amendment to the Agreement effective as of the Amendment 5 Effective Date.

Insulet Corporation

By: /s/ Brian Roberts

Name: Brian Roberts

Title: Chief Financial Officer

Amgen Inc.

By: /s/ Sev Sislian

Name: Sev Sislian

Title: GSS Category Manager

Amgen Inc.

By: /s/ Bill Rich

Name: Bill Rich

Title: Vice President External Supply

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 006
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 006 ("Amendment"), entered into effective as of August 14, 2014 ("Amendment 6 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled "Supply Agreement" effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the "Agreement").

B. Amgen and Insulet desire, and are willing, to amend the Agreement to set forth an amended and restated Quality Agreement, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Exhibit 2.2 (Quality Agreement). Exhibit 2.2 (Quality Agreement) to the Agreement is hereby replaced in its entirety with the Exhibit 2.2 (Quality Agreement) attached hereto.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

[Signature Page Follows]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 6 Effective Date.

Insulet Corporation

By: /s/ Kevin Schmid

Date: August 18, 2014

Name: Kevin Schmid

Title: Vice President, Business Development

Insulet Corporation

Amgen Inc.

By: /s/ Sev Sislian

Date: August 18, 2014

Name: Sev Sislian

Title: GSS, Category Manager

Amgen Inc.

By: /s/ Tracey Wielinski

Date: 18 August 2014

Name: Tracey Wielinski

Title: Vice President of RA/QA

By: /s/ Anthony Mire-Sluis

Date: August 18, 2014

Name: Anthony Mire-Sluis

Title: Vice President Quality

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.2 (Quality Agreement) (amended and restated on August 14, 2014)

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 007
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 007 ("Amendment"), entered into effective as of February 10, 2015 ("Amendment 7 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

- A. Amgen and Insulet entered into that certain agreement titled "Supply Agreement" effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the "Agreement").
- B. Concurrently with entering into the Agreement, the Parties entered into the Quality Agreement (set forth as Exhibit 2.2) and, effective as of August 14, 2014, amended and restated the Quality Agreement as set forth in Amendment 6 to the Agreement.
- C. Amgen and Insulet desire, and are willing, to amend the Quality Agreement to set forth an amended and restated Quality Agreement, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Exhibit 2.2 (Quality Agreement). Effective as of the Amendment 7 Effective Date, Exhibit 2.2 (Quality Agreement) to the Agreement is hereby replaced in its entirety with the Exhibit 2.2 (Quality Agreement) attached hereto.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

[Signature Page Follows]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 7 Effective Date.

Insulet Corporation

By: /s/ Kevin Schmid

Date: February 11, 2015

Name: Kevin Schmid

Title: Vice President, Business Development

Insulet Corporation

Amgen Inc.

By: /s/ Sev Sislian

Date: February 12, 2015

Name: Sev Sislian

Title: GSS, Sr. Category Manager

Amgen Inc.

By: /s/ Tracey Wielinski

Date: 10 February 2015

Name: Tracey Wielinski

Title: Vice President Regulatory,

Clinical Affairs, and Quality Assurance

By: /s/ Troy Wright

Date: 12 February 2015

Name: Troy Wright

Title: Director, Quality Assurance,

Contract Manufacturing Quality

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.2 (Quality Agreement) (amended and restated on February 10, 2015)

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 008
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 008 ("Amendment"), entered into effective as of June 22, 2015 ("Amendment 8 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

- A. Amgen and Insulet entered into that certain agreement titled "Supply Agreement" effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the "Agreement").
- B. Concurrently with entering into the Agreement, the Parties entered into the Quality Agreement (set forth as Exhibit 2.2) and, thereafter, have amended and restated the Quality Agreement.
- C. Amgen and Insulet desire, and are willing, to amend the Quality Agreement to set forth an amended and restated Quality Agreement, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Exhibit 2.2 (Quality Agreement). Effective as of the Amendment 8 Effective Date, Exhibit 2.2 (Quality Agreement) to the Agreement is hereby replaced in its entirety with the Exhibit 2.2 (Quality Agreement) attached hereto.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

[Signature Page Follows]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 8 Effective Date.

Insulet Corporation

By: /s/ Daniel Levangie

Date: June 23, 2015

Name: Daniel Levangie

Title: President, Drug Delivery

Insulet Corporation

Amgen Inc.

By: /s/ Sev Sislian

Date: June 24, 2015

Name: Sev Sislian

Title: GSS, Sr. Category Manager

Amgen Inc.

By: /s/ Brian Keogh

Date: 23 June 2015

Name: Brian Keogh

Title: Director, Quality Assurance

By: /s/ Troy Wright

Date: 23 June 2015

Name: Troy Wright

Title: Director, Quality Assurance

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.2 (Quality Agreement) (amended and restated on June 22, 2015)

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 009
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 009 (“Amendment”), entered into effective as of June 26, 2015 (“Amendment 9 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled “Supply Agreement” effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the “Agreement”).

B. Amgen and Insulet desire, and are willing, to amend the Agreement to (i) eliminate Amgen’s obligation to compensate Insulet for Insulet’s [*] during each [*], (ii) eliminate Amgen’s obligation to pay [*], (iii) permit Insulet to, at no cost to Amgen, hold a certain quantity of Customized Insulet Devices in inventory at [*], and (iv) provide that Amgen is permitted to have [*] persons perform PIP duties and any additional employees present for the purpose of training, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Section 1.6 (Conforming Lot). Section 1.6 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“1.6 “Conforming Lot” has the meaning ascribed to it in the Quality Agreement and, in addition, with respect to Insulet Held Customized Insulet Devices, is a lot (or a portion thereof) that has been stored and managed in compliance with the requirements set forth in Section 2.11(b).”

2.2 Section 1.17 (Non-Conforming Lot). Section 1.17 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“1.17 “Non-Conforming Lot” means (i) a lot of Customized Insulet Device Manufactured by Insulet that, based the performance of and results from the Lot Release Procedures and comparison to release criteria set forth in the Lot Release Procedures, is inappropriate for release by Insulet or (ii) Insulet Held Customized Insulet Devices for which Insulet has failed to meet one or more of the requirements set forth in Section 2.11(b).”

2.3 Section 2.3 ([*]). Section 2.3 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“2.3 [*]. Amgen shall [*]. Insulet shall [*]. Additionally, Amgen shall [*].”

2.4 Section 2.11 (Shipment). Section 2.11(b) of the Agreement is hereby amended by adding to the end of Section 2.11(b) the following:

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

“At no cost or expense to Amgen and as an accommodation to support Insulet’s management of its manufacturing network, Insulet is permitted to store at [*], Customized Insulet Devices in a quantity up to that equal to the [*] of the then-current Forecast (“ Insulet Held Customized Insulet Devices ”). With respect to Insulet Held Customized Insulet Devices, (i) Insulet will maintain (and provide to Amgen upon Amgen’s reasonable request made from time-to-time) an up-to-date list identifying with specificity the inventory of the Insulet Held Customized Insulet Devices, (ii) Insulet will store and manage such consistent and in compliance with the terms of this Agreement (including the Quality Agreement), (iii) Insulet will bear the risk of loss with respect to Insulet Held Customized Insulet Devices prior to receipt of the same by Amgen, and (iv) without modifying or limiting the requirements set forth in Section 2.11(c)(iv), they must be Shipped to Amgen, if ever, no later than [*] after the date of Manufacture with a remaining shelf life of no less than [*].”

2.5 Section 3.1 (Unit Price Amount). Section 3.1 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“3.1 Unit Price Amounts. Amgen shall pay Insulet the Unit Price for each Customized Insulet Device ordered by Amgen and Manufactured by Insulet in a given Commercial Year as follows:

| | | |
|-----|---|--|
| [*] | Aggregate Number of Customized Insulet Devices Ordered by Amgen | With respect to each [*], Unit Price for each Customized Insulet Device Shipped to Amgen |
|-----|---|--|

[*]

For the Partial Commercial Year and each Commercial Year, the Unit Price [*] (set forth in the table above) applicable thereto that Amgen will pay, and Insulet will invoice, during such period (the “Forecast-Based [*]”) shall be determined based on the lesser of the following quantities of Customized Insulet Devices set forth in the Forecast submitted immediately prior to the commencement of the Partial Commercial Year or Commercial Year, as the case may be: (i) [*] of the quantity of Customized Insulet Devices in the Binding Portion of such Forecast and (ii) the aggregate of the quantities of Customized Insulet Devices set forth in the [*] of such Forecast. Promptly after the end of the Partial Commercial Year and each Commercial Year, but in no event later than [*], Insulet will notify Amgen of the aggregate quantity of Customized Insulet Devices actually ordered by Amgen for delivery during such period and whether the Unit Amount [*] applicable thereto (the “Order-Based [*]”) is the same as the Forecast-Based [*] and, in the event that the Order-Based [*] is not the same as the Forecast-Based [*], then within [*] days after receipt of such notice either (a) if the Order-Based [*] is [*], then Amgen shall pay to Insulet the difference between the [*] and [*] Unit Prices applicable to each Customized Insulet Device or (b) if the Order-Based [*] is [*], then Insulet shall pay to Amgen the difference between the [*] and [*] Unit Prices applicable to each Customized Insulet Device.”

2.6 Section 3.3 ([*] Production Run Compensation). Section 3.3 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“3.3 [*]. Amgen shall [*].”

2.7 Section 3.7 (Invoices). Section 3.7(a) of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“(a) Insulet shall submit invoices to Amgen on a [*] basis for amounts payable by Amgen hereunder (i) pursuant to Section 3.1, Section 3.4, and Section 3.5 for [*] and (ii) testing as provided in Section 12.1. Insulet will endeavor to submit such invoices promptly following the [*]. Invoices will be submitted in electronic format to the following electronic address (which addresses may be changed, from time-to-time, by Amgen upon prior notice to Insulet): email address: AccountsPayableMailroom@Amgen.com.”

2.8 Section 3.10 ([*]). Section 3.10 of the Agreement is hereby amended by deleting it in its entirety.

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 9 Effective Date.

Insulet Corporation

By: /s/ Dan Levangie

Date: June 29, 2015

Name: Dan Levangie

Title: President, Drug Delivery

Insulet Corporation

By: /s/ Brian Keogh

Date: 29 June 2015

Name: Brian Keogh

Title: Director, Quality Assurance

Amgen Inc.

By: /s/ Sev Sislian

Date: July 6, 2015

Name: Sev Sislian

Title: GSS, Sr. Category Manager

Amgen Inc.

By: /s/ Chris Kozlik

Date: July 6, 2015

Name: Chris Kozlik

Title: Director, External Supply Chain

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.2 (Quality Agreement) (amended and restated on May [xx], 2015)

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 010
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 010 (" Amendment "), entered into effective as of September 29, 2015 (" Amendment 10 Effective Date "), by and between Amgen Inc. (" Amgen ") and Insulet Corporation (" Insulet ") amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled "Supply Agreement" effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the " Agreement ").

B. Amgen and Insulet desire, and are willing, to amend the Agreement to (i) update the shipping terms to replace [*], with [*], (ii) provide for [*], (iii) provide that Insulet will [*] and provide that Amgen will [*], and (iv) if the [*], then provide for certain [*].

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Section 2.11(b) (Shipment). Section 2.11(b) of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

"(b) Insulet shall ship Customized Insulet Devices under suitable controls and pursuant to all reasonable instructions provided by Amgen. Amgen shall have the right to designate the freight forwarder to be used by Insulet by notifying Insulet of such no later than [*] days prior to the applicable delivery date; provided, in the absence of such instructions, Insulet shall use a freight forwarder previously designated by Amgen. All Customized Insulet Devices shall be delivered [*]. In the event of conflict, the terms of this Agreement take precedence over the Incoterms.

At no cost or expense to Amgen and as an accommodation to support Insulet's management of its manufacturing network, Insulet is permitted to store at Insulet's Facility located in Billerica, Massachusetts, Customized Insulet Devices in a quantity up to that equal to the [*] of the then-current Forecast (" Insulet Held Customized Insulet Devices "). With respect to Insulet Held Customized Insulet Devices, (i) Insulet will maintain (and provide to Amgen upon Amgen's reasonable request made from time-to-time) an up-to-date list identifying with specificity the inventory of the Insulet Held Customized Insulet Devices, (ii) Insulet will store and manage such consistent and in compliance with the terms of this Agreement (including the Quality Agreement), (iii) Insulet will bear the risk of loss with respect to Insulet Held Customized Insulet Devices prior to receipt of the same by Amgen, and (iv) without modifying or limiting the requirements set forth in Section 2.11(c)(iv), they must be Shipped to Amgen, if ever, no later than [*] after the date of Manufacture with a remaining shelf life of no less than [*]."

2.2 Section 2 (Manufacture; Supply). Section 2 of the Agreement is hereby amended by adding at the end of Section 2 new Sections 2.14 and 2.15 that read as follows:

"2.14 [*]. Insulet will [*]."

"

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

2.3 Section 3.1 (Unit Price Amounts). Section 3.1 of the Agreement is hereby amended by adding at the end of Section 3.1 the following:

[*]

Amgen will [*]. With respect to [*]."

3. CONCLUSION

This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the Parties notwithstanding that each of the Parties may have signed different counterparts. A facsimile transmission or PDF of this Amendment bearing a signature on behalf of a Party shall be legal and binding on such Party. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 10 Effective Date.

Insulet Corporation

By: /s/ Dan Levangie

Date: 10/1/15

Name: Dan Levangie

Title: President, Drug Delivery

Amgen Inc.

By: /s/ Sev Sislian

Date: 10/1/15

Name: Sev Sislian

Title: GSS, Sr. Category Manager

Amgen Inc.

By: /s/ Patricia Turney

Date: 10/1/15

Name: Patricia Turney

Title: Executive Director, Supply Chain

Amgen Inc.

By: /s/ Bill Rich

Date: 1 October 2015

Name: Bill Rich

Title: VP, Device Technologies

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 011
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 011 ("Amendment"), entered into effective as of May 03, 2016 ("Amendment 11 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled "Supply Agreement" effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the "Agreement").

B. Concurrently with entering into the Agreement, the Parties entered into the Quality Agreement (set forth as Exhibit 2.2) and, thereafter, have amended and restated the Quality Agreement.

C. Amgen and Insulet desire, and are willing, to amend the Quality Agreement to set forth an amended and restated Quality Agreement, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Exhibit 2.2 (Quality Agreement). Effective as of the Amendment 11 Effective Date, Exhibit 2.2 (Quality Agreement) to the Agreement is hereby replaced in its entirety with the Exhibit 2.2 (Quality Agreement) attached hereto.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

[Signature Page Follows]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 11 Effective Date.

Insulet Corporation

By: /s/ Daniel Levangie

Date: May 3, 2016

Name: Daniel Levangie

Title: President, Drug Delivery

Insulet Corporation

Amgen Inc.

By: /s/ Sev Sislian

Date: May 3, 2016

Name: Sev Sislian

Title: GSS, Sr. Manager - Devices

Amgen Inc.

By: /s/ Michael Spears

Date: May 3, 2016

Name: Michael Spears

Title: Vice President, Quality, Regulatory
and Clinical affairs

By: /s/ Troy Wright

Date: 3 May 2016

Name: Troy Wright

Title: Site Head, Contract Manufacturing Quality

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.2 (Quality Agreement) (amended and restated on May 03, 2016)

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 012
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 012 ("Amendment"), entered into effective as of August 24, 2016 ("Amendment 12 Effective Date"), by and between Amgen Inc. ("Amgen") and Insulet Corporation ("Insulet") amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled "Supply Agreement" effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the "Agreement").

B. Concurrently with entering into the Agreement, the Parties entered into the Quality Agreement (set forth as Exhibit 2.2) and, thereafter, have amended and restated the Quality Agreement.

C. Amgen and Insulet desire, and are willing, to amend the Quality Agreement to set forth an amended and restated Quality Agreement, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1 Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1 Exhibit 2.2 (Quality Agreement). Effective as of the Amendment 12 Effective Date, Exhibit 2.2 (Quality Agreement) to the Agreement is hereby replaced in its entirety with the Exhibit 2.2 (Quality Agreement) attached hereto.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

[Signature Page Follows]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 12 Effective Date.

Insulet Corporation

By: /s/ Michael Graffeo

Date: 9/1/16

Michael Graffeo Vice President Business Development Drug Delivery

for

Daniel Levangie

Title: President, Drug Delivery

Insulet Corporation

Amgen Inc.

By:

Date:

Name: Sev Sislian

Title: GSS, Sr. Manager - Devices

Amgen Inc.

By: /s/ Michael Spears

Date: 9/1/16

Name: Michael Spears

Title: Vice President, Quality, Regulatory and Clinical Affairs

By:

Date:

Name: David Blake

Title: Sr. Manager, Contract Manufacturing Quality

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.2 (Quality Agreement) (amended and restated on August 24, 2016)

[Superseded by Amendment Number 014 to the Supply Agreement
by and between Amgen Inc. and Insulet Corporation]

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**AMENDMENT NUMBER 13
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 13 (“Amendment”), entered into effective as of December 20, 2016 (“Amendment 13 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled “Supply Agreement” effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the “Agreement”).

B. Amgen and Insulet desire, and are willing, to amend the Agreement to include additional terms, rights, and remedies intended to strengthen and enhance business continuity and manufacturing resiliency related to the manufacture and supply of the Customized Insulet Device, all as set forth herein.

NOW, THEREFORE, in consideration of the Parties respective promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1. Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1. Section 2.1. Section 2.1 of the Agreement is hereby amended by adding a new Section 2.1.1 that reads as follows:

“2.1.1 Key Subcontractor and Other Suppliers and Subcontractors.

(i) As of December 20, 2016, Flextronics Medical Sales and Marketing Ltd. is instrumental to the Manufacturing of Customized Insulet Devices (“Key Subcontractor”). Insulet represents and warrants that the Key Subcontractor has the right (and such right is not and shall not be limited or interfered with in anyway by Insulet during the Term) to manufacture the Customized Insulet Device and purchase from other subcontractors (including without limitation [*]) goods and services that are necessary or required for the manufacture and supply of the Customized Insulet Device.

(ii) Insulet shall, on or before [*], enter into a written agreement (“Key Subcontractor/Insulet/Amgen Agreement”) by and among Insulet, Amgen and the Key Subcontractor providing for each of the following:

(a) upon the occurrence of any Supply Trigger Event, Quality Trigger Event or Contract Non-Assumption Trigger Event (as evidenced by Trigger Notification delivered in accordance with the terms of this Section 2.1.1) and, if subject to cure, until such time as such Trigger Event has been cured pursuant to Section 2.18.1, the following apply:

(I) Amgen has with respect to the Customized Insulet Device the right, at its option, to direct and purchase directly from, or make payments directly to, on behalf of Insulet, Key Subcontractor to support the continued commercialization of the Customized Insulet Device;

(II) the Key Subcontractor has, and Insulet shall cooperate and not interfere with, the right and obligation [*];

(III) the Key Subcontractor will cooperate with (including without limitation providing transparency regarding and collaboration on resolution of supply issues, production planning and staffing,

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

components and toolset inventory and use, production planning, staff scheduling) and take direction from (including without limitation Amgen's technical decisions) Amgen with respect to manufacture and supply of Customized Insulet Devices;

(IV) the Key Subcontractor has the permission and right to purchase from others (including without limitation [*]) goods and services that are necessary or required for the manufacture and supply of the Customized Insulet Device and use or have used by its suppliers or subcontractors any equipment owned or controlled by Insulet that is located at facilities owned, controlled or operated by such Key Subcontractor or its suppliers or subcontractors to support supply to Amgen of the Customized Insulet Device; and

(V) the Key Subcontractor agrees to manufacture and supply Amgen the Customized Insulet Device (A) in quantities that Insulet would have been obligated to supply to Amgen and (B) meeting the terms and conditions that the Key Subcontractor would have been obligated to meet in supplying to Insulet, in each case pursuant to, at Amgen's election, (X) a separate agreement by and between Amgen and Key Subcontractor which such agreement shall be on substantially the same terms as set forth in that certain Materials Supplier Agreement by and between Insulet and Key Subcontractor dated as September 1, 2016 ("Insulet/Flex Materials Supplier Agreement") (that separate agreement is attached to the Key Subcontractor/Insulet/Amgen Agreement noting that certain proprietary commercial and financial terms have been redacted), (Y) the Insulet/Flex Materials Supplier Agreement, or (Z) a replacement agreement mutually agreed by Amgen and Key Subcontractor which is appropriate for the manufacture and supply of Customized Insulet Devices for Amgen.

(b) A license grant providing that: [*]

(c) In addition to the license grant, Insulet will promptly [*].

Amgen agrees to cooperate in good faith with Insulet and Key Subcontractor in the negotiation of the Key Subcontractor/Insulet/Amgen Agreement.

(iii) Insulet shall do all that is reasonably necessary or required to facilitate, and not interfere with or impede, Amgen's ability to direct and purchase directly from, or make payments directly to on behalf of Insulet, Key Subcontractor as provided in this Section 2.1.1.

(iv) If Insulet proposes, or Amgen and Insulet mutually agree in writing, to substitute or replace Key Subcontractor with one or more third parties (each a "Subsequently Identified Key Subcontractor"), prior to any substitution or replacement, Insulet shall have secured an agreement with each Subsequently Identified Key Subcontractor, substantially similar to the Key Subcontractor/Insulet/Amgen Agreement by and among Insulet, Amgen and the Subsequently Identified Key Subcontractor that includes the terms, permissions, and rights specified in this Section 2.1.1.

(v) Insulet represents and warrants to Amgen that, with the exception of the activities undertaken as of December 20, 2016 by the Key Subcontractor, no Intellectual Property Rights owned or controlled by Insulet or its Affiliates are necessary or required to undertake activities supporting manufacturing, supply and commercialization of the Customized Insulet Device (including without limitation sterilization and testing). Additionally, Insulet represents and warrants to Amgen that Insulet has submitted to Amgen any and all documents, information, data, processes and procedures of or used by Insulet that are necessary or required for third parties that undertake activities supporting manufacturing and supply of the Customized Insulet Device (including without limitation sterilization and testing) other than those activities done by the Key Subcontractor or the Key Subcontractor's subcontractors and suppliers (such third parties, the "Other Subcontractors") to undertake activities supporting manufacturing and supply of the Customized Insulet Device. With respect to any such documents, information, data, processes and procedures created or revised after December 20, 2016, Insulet will promptly submit the same to Amgen. Insulet shall, on or before [*], send written notices (the content of which has been approved by Amgen (such approval not to be unreasonably withheld)) to Other Subcontractors providing that, although Amgen is free at any time to enter into agreements with Other Subcontractors that include additional, different or better terms than those with Insulet, upon the occurrence of any [*] and, if subject to cure, until such time as such Trigger Event has been cured pursuant to Section 2.18.1, the Other Subcontractor has, and Insulet shall cooperate and not interfere with, the right to prioritize the use of materials, equipment and resources for the manufacturing and supplying of the Customized Insulet Device over use with respect to other devices of Insulet.

(vi) Amgen hereby agrees and covenants not to notify the Key Subcontractor(s) of the occurrence of a [*] (defined below).

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

(vii) Within [*] after Amgen notifies Insulet of its good faith assertion that there has been a [*] including the basis (in reasonable detail) for such assertion (the “Insulet Response Period”), Insulet shall notify Amgen of its agreement with or good faith objection to Amgen’s assertion that a [*] or [*] has occurred and, if an objection, include the basis (in reasonable detail) for such objection. If within the [*], Insulet notifies Amgen of its objection to Amgen’s assertion that there has been a [*] or [*] (each a “Trigger Event Assertion Dispute”), then the Parties shall follow the dispute resolution process set forth in Exhibit 2.1.1(vii).

(viii) For purpose of this Agreement, “Trigger Notification” shall mean (i) notice mutually agreed to by Amgen and Insulet that there has been a [*] or [*]; (ii) notice from Amgen accompanied by an affidavit or certification by an officer of Amgen that Insulet has not responded within [*] of Amgen’s notice to Insulet of a [*] or [*]; (iii) notice from an arbitrator appointed in accordance with the terms of this Agreement that there has been either a [*] or [*]; or (iv) notice from outside counsel for Amgen that there has been a [*].

2.2. Section 2.4. Section 2.4 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“2.4 Specification and Design Changes. The Specifications or the specifications for the Insulet Device (as defined in the Development Agreement) may be amended or supplemented by mutual agreement of the Parties in accordance with the terms and conditions of the Quality Agreement. In each event that Amgen submits to Insulet a proposal to change, or Insulet proposes to Amgen changes to, the Specifications, Insulet will promptly submit to Amgen an assessment of the impact on the quality, regulatory, and design changes to the Specifications, and Unit Price and, thereafter, (i) the Parties will negotiate in good faith any changes to the quality, regulatory, and design changes to the Specifications and Unit Price and (ii) the proposed changes will not be implemented unless and until the Parties mutually agree to such changes, if any, to the quality, regulatory, and design changes to the Specifications and/or Unit Price.”

2.3. Section 2.7. Section 2.7 of the Agreement is hereby amended by adding a new Section 2.7(f) that reads as follows:

“(f) Notwithstanding anything to the contrary contained herein, the Parties agree that, as of December 20, 2016 Insulet has, and shall have available throughout the Term, capacity for Manufacturing the Customized Insulet Device up to (i) [*] units annually (“Annual Capacity”) and (ii) [*] units monthly for shipments delivered March through April and [*] units monthly for shipments delivered May through February (respectively, the “Monthly Capacity”). Furthermore, the Parties agree that notwithstanding Section 2.6(b) of the Agreement, the Forecast shall not exceed either the Annual Capacity or the Monthly Capacity. Unless agreed otherwise, Insulet shall not be obligated to supply quantities of Customized Insulet Device set forth in Purchase Orders to the extent such quantities are in excess of the either the Annual Capacity or Monthly Capacity.”

2.4. Section 2.11(b). Section 2.11(b) of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

“(b) Insulet shall Ship Customized Insulet Devices under suitable controls and pursuant to all reasonable instructions provided by Amgen. Amgen shall have the right to designate the freight forwarder to be used by Insulet by notifying Insulet of such no later than [*] prior to the applicable delivery date; provided, in the absence of such instructions, Insulet shall use a freight forwarder previously designated by Amgen. [*] In the event of conflict, the terms of this Agreement take precedence over the Incoterms.

At no cost or expense to Amgen and as an accommodation to support Insulet’s management of its manufacturing network and enhance supply assurance, Insulet is permitted to store at [*], Customized Insulet Devices in a quantity up to that equal to the [*] of the then-current Forecast (“Insulet Held Customized Insulet Devices”). With respect to Insulet Held Customized Insulet Devices, (i) Insulet will maintain (and provide to Amgen upon Amgen’s reasonable request made from time-to-time) an up-to-date list identifying with specificity the inventory of the Insulet Held Customized Insulet Devices, (ii) Insulet will store and manage such inventory consistent with, and in compliance with, the terms of this Agreement (including the Quality Agreement), (iii) Insulet will bear the risk of loss with respect to Insulet Held Customized Insulet Devices prior to receipt of the same by Amgen, and (iv) without modifying or limiting the requirements set forth in Section 2.11(c)(iv), they must be Shipped to Amgen, if ever, with a remaining shelf life of no less than [*].”

2.5. Article 2. Article 2 of the Agreement is hereby amended by adding new Section 2.16, Section 2.17, and Section 2.18 that read as follows:

“2.16 Redundancy.

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

2.16.1 Specified Supply Chain Redundancy. Insulet shall use commercially reasonable efforts to achieve the specified redundancy listed in Exhibit 2.16 and Exhibit 2.17a, by the dates indicated therein.

2.16.2 [*]. [*], Insulet shall submit to Amgen [*].

2.16.3 Maintaining Specified and Other Supply Chain Redundancy. Insulet shall, and as applicable shall cause its suppliers and subcontractors to, store and maintain tools in compliance with applicable laws, applicable standard operating procedures, practices or policies of Insulet and, as applicable, any third party that will store tools, and manufacturers' recommended storage conditions.

2.16.4 Component Safety Stock. Insulet shall, by the dates indicated in Exhibit 2.16, maintain in inventory, or, as applicable, cause its suppliers or subcontractors to maintain in inventory, so that they are promptly available and in condition useful for use in the Manufacturing or shipment of Customized Insulet Devices, the component inventories set forth in Exhibit 2.16.

2.17 Manufacturing Redundancy and Resiliency. Upon Amgen's request made from time-to-time during the Term, but not more often than [*], Insulet will submit to Amgen information in a reasonable level of detail regarding the facilities and subcontractors necessary or required to Manufacture the Customized Insulet Device to enable Amgen to perform a risk assessment of the Manufacturing supply chain and identify to and discuss with Insulet specific mitigation activities that Amgen may be interested in pursuing with Insulet and the funding for and other terms related thereto.

Representatives from each Party with expertise in supply chain and device engineering and manufacturing will meet (either telephonically or in person) quarterly at each Quarterly Business Review and the purpose of the meeting will be to review the resiliency and redundancy of manufacturing the Customized Insulet Device. During each review, Insulet shall provide an update on the status of its progress against the commitments made in Sections 2.16.1, 2.16.2, and 2.16.4.

To the extent that Insulet fails to maintain any previously achieved commitment set forth in Exhibit 2.16, Exhibit 2.17a, or Exhibit 2.17b, Insulet shall either cure this by the next Quarterly Business Review or shall promptly submit to Amgen a written plan setting forth the actions to be taken to cure the same using at least commercially reasonable efforts. Insulet shall include in each such plan an explanation of the root cause of the failure, [*]. If upon review Amgen concludes, acting reasonably, that such commitment is no longer met as a result of a circumstance [*], Amgen will notify Insulet that the Unit Price will be reduced as set forth in Section 3.1.2.

2.18 Trigger Event. The following definitions are used in this Agreement:

" Contract Non-Assumption Trigger Event " means:

- (i) Insulet becomes the subject of a [*] bankruptcy proceeding under [*] of the United States Bankruptcy Code (the "Bankruptcy Code") and any of the following events occur: [*]; or
- (ii) Insulet becomes the subject of a [*] bankruptcy proceeding under [*].

" [*] " means [*].

" Perform Key Supply Activities " means, with respect to Key Subcontractor, to [*].

" Performance of Other Activities " means, other than the activities to Perform Key Supply Activities, those activities (including without limitation sterilization and testing) necessary or required to manufacture and supply the Customized Insulet Device including without limitation sterilization, testing and use of any and all documents, processes, and procedures of Insulet and equipment owned or controlled by Insulet that are located at facilities owned, controlled or operated by those performing such activities.

" Quality Trigger Event " means any [*].

" Supply Trigger Event " means a [*].

2.18.1 [*]. Without limiting Amgen's rights and remedies with respect to, or prior to [*].

2.18.2 [*]. Until the Occurrence of Cure with respect to each [*] or [*], as the case may be, or upon the occurrence of a [*], to enable manufacturing, supply and commercialization of Customized Insulet Devices,

- (i) Amgen shall have the right, at its election, to (A) direct Key Subcontractor, and Key Subcontractor is permitted to, Perform Key Supply Activities and (B) undertake, or have third parties (including Other Subcontractors) undertake, Performance of Other Activities; and

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

(ii) Insulet shall permit and cooperate and not interfere with, the prioritization of the use of [*], components, toolsets, and other equipment and resources for the manufacturing and supplying of the Customized Insulet Device (including without limitation prioritization over manufacturing other devices for Insulet).

Upon each [*] or [*], until the Occurrence of Cure and Amgen's election, if ever, to direct Key Subcontractor to Perform Key Supply Activities and undertake, or have third parties undertake, Performance of Other Activities, Insulet shall (y) permit Amgen to participate, engage and collaborate with Insulet and its suppliers and subcontractors to gain information regarding and identify remedial actions with respect to the origin and mitigation of the [*] or [*] (including without limitation providing transparency regarding and collaboration on resolution of supply issues, production planning and staffing, components and toolset inventory and use, production planning, and staff scheduling) and (z) cooperate with and do all that is necessary or required to conduct and prioritize lot qualification testing.

Insulet shall cooperate with Amgen and promptly take such further actions and execute and deliver to Amgen all information, instruments and documents as may be reasonably necessary to carry out this Section 2.18.2 in order to provide and secure to Amgen the full and complete enjoyment of its rights and privileges hereunder.

2.18.3 [*]. On or before [*], Insulet will [*]. Amgen agrees to [*].

2.6. Section 3.1. Section 3.1 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

"3.1 Unit Price Amounts. On and after [*], Amgen shall pay Insulet the Unit Price for each Customized Insulet Device ordered by Amgen and Manufactured by Insulet in a given Commercial Year as follows: With respect to each Conforming Lot, Unit Price for each Customized Insulet Device Shipped to Amgen, [*] subject to adjustments as specified in Section 3.1.2, below.

3.1.1 Intentionally Omitted.

3.1.2 Additional Compensation; Unit Price Adjustments.

(i) In consideration for certain agreed to modifications made to the Customized Insulet Device and as full and final compensation for lots numbered [*] through [*], inclusive, Insulet shall be entitled to invoice Amgen for an additional [*] for each Customized Insulet Device that Insulet Manufactured and Shipped to Amgen for lots numbered [*] through [*], inclusive.

(ii) On and after [*], the [*]:

(a) [*]

(b) [*]

(c) [*]

(iii) After the occurrence of a [*], Amgen shall pay Insulet, its successors and assigns, and Insulet shall be entitled to only, an amount equal to [*] of the Unit Price as of the day of the [*] occurrence, for each Customized Insulet Device manufactured by the Key Subcontractor, pursuant to those certain rights set forth in Section 2.18.2, that is ordered, received and not rejected by Amgen."

2.7. Section 9.1. Section 9.1 of the Agreement is hereby amended by deleting it in its entirety and replacing it with the following:

"9.1 Term. This Agreement shall become effective on the date first written above and unless terminated earlier in accordance with the terms of this Agreement, shall remain in full force and effect until December 31, 2023 (the "Initial Period"). Prior to January 1, 2022 and each Commercial Year thereafter, the Parties shall negotiate in good faith an extension of the term for an additional two year period (each a "Renewal Period", and together with the Initial Period, the "Term"); provided that either Party may elect not to extend the Initial Period or Term, as the case may be, by providing the other Party with notice of same at least twenty four (24) months prior to the end of the Initial Period or expiration of the then current-Renewal Period, as applicable."

2.8. Exhibits. The Exhibits to the Agreement are amended by appending to the Agreement new Exhibit 2.1.1(vii), Exhibit 2.16, Exhibit 2.17a, and Exhibit 2.17b with content as set forth in the Exhibit 2.1.1(vii), Exhibit 2.16, Exhibit 2.17a and Exhibit 2.17b attached hereto.

3. CONCLUSION

This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the Parties notwithstanding that each of the Parties

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may have signed different counterparts. A facsimile transmission or PDF of this Amendment bearing a signature on behalf of a Party shall be legal and binding on such Party. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 13 Effective Date.

Insulet Corporation

By: /s/ Shacey Petrovic

Date: 12/21/16

Name: Shacey Petrovic

Title: President and Chief Operating
Officer

Amgen Inc.

By: /s/ Venkata P. Yepuri

Date: 12/20/16

Name: Venkata P. Yepuri

Title: Executive Director/
Head of Global Strategic Sourcing

Amgen Inc.

By: /s/ Patricia Turney

Date: 12/20/16

Name: Patricia Turney

Title: Vice President, External Supply

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.1.1(vii)
Dispute Resolution Process

With respect to each Trigger Event Assertion Dispute, during the [*] after notice to Insulet from Amgen that Amgen desires to attempt to resolve through negotiation the Trigger Event Assertion Dispute (such period (which may be extended by mutual agreement of the Parties), the “Executive Negotiations Period”; and such negotiations, the “Executive Negotiations”), the Parties shall promptly meet (either telephonically or in person) and attempt in good faith to resolve the Trigger Event Assertion Dispute by negotiation between executives (vice president level or higher) who have authority to settle the controversy. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

Any Trigger Event Assertion Dispute which is not resolved by the Executive Negotiations during the Executive Negotiations Period shall be finally resolved by the independent arbitration panel (the “Arbitrator Panel”) in accordance with the 2013 Administered Arbitration Rules of the International Institute for Conflict Prevention & Resolution Rules, as the same may be amended from time to time. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq., and judgment upon the award rendered by the arbitrator may be entered by any court having jurisdiction thereof. The place of arbitration shall be Boston, Massachusetts.

With respect to any Trigger Event Assertion Dispute which is not resolved by Executive Negotiations, within [*] after the end of the Executive Negotiations Period, the Parties shall meet (either in person or telephonically) and attempt to agree on the appointment of an independent arbitrator panel (the “Arbitrator Panel”). For purposes of an arbitrator or the Arbitrator Panel, “independent” shall mean having no past or present family, business or other relationship with either of the Parties or any of their respective Affiliates, directors, or officers, unless following full disclosure of all such relationships, the Parties agree in writing to waive such requirement with respect to an individual. If within [*] after the Executive Negotiations Period, the Parties are unable to agree on a single independent arbitrator for the Arbitrator Panel, then, within [*] thereafter, each Party will designate an independent arbitrator, and the two independent arbitrators together will select a third independent arbitrator within [*] after having been designated themselves by the Parties (in which case, the Arbitrator Panel will consist of three independent arbitrators). Within [*] after the designation of the Arbitrator Panel, each Party shall submit a written statement of its positions on the [*] or [*], as the case may be, to the Arbitrator Panel and the other Party. Each Party shall have [*] to submit a written response thereto including supporting information. The Arbitrator Panel shall have the right to meet with the Parties, either alone or together. There will be no discovery allowed. For the sake of clarity, the term “discovery” as used herein includes without limitation document requests and production, depositions, interrogatories, and requests for admission. No later than [*] after the designation of the Arbitrator Panel or such later date as agreed to in writing by the Parties, the Arbitrator Panel shall make a written decision (including the reasons for such) on whether a [*] or [*], as the case may be, has occurred. The decision of the Arbitrator Panel shall be final, binding and enforceable and shall be appealable only (a) following denial by the Arbitration Panel of a request for reconsideration submitted to the Arbitration Panel by a Party no later than [*] after the Arbitration Panel issued its written decision, and, thereafter, (b) pursuant to Section 10 of the Federal Arbitration Act.

The Party against whom a final decision is rendered shall pay the fees and costs of the Arbitrator Panel and the CPR Institute for Dispute Resolution. Otherwise, each Party shall bear all of its other costs and expenses of the dispute resolution process set forth in this Section.

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Exhibit 2.16
[*]

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Exhibit 2.17a
[*]

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Exhibit 2.17b
[*]

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**AMENDMENT NUMBER 014
TO THE SUPPLY AGREEMENT
BY AND BETWEEN AMGEN INC. AND INSULET CORPORATION**

This Amendment Number 014 (“Amendment”), entered into effective as of January 23, 2017 (“Amendment 14 Effective Date”), by and between Amgen Inc. (“Amgen”) and Insulet Corporation (“Insulet”) amends the Agreement (defined below).

RECITALS

A. Amgen and Insulet entered into that certain agreement titled “Supply Agreement” effective as of November 21, 2013 and identified by contract number CW2146852 pursuant to which Insulet is to, among other things, Manufacture and sell to Amgen the Customized Insulet Devices (as amended, the “Agreement”).

B. Concurrently with entering into the Agreement, the Parties entered into the Quality Agreement (set forth as Exhibit 2.2) and, thereafter, have amended and restated the Quality Agreement.

C. Amgen and Insulet desire, and are willing, to amend the Quality Agreement to set forth an amended and restated Quality Agreement, all as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained or referenced herein, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments hereto and agree to be bound by the terms and conditions set forth in the Agreement as modified herein as follows:

1. DEFINITIONS

1.1. Capitalized Terms. All capitalized terms not defined herein shall have the meaning ascribed to them in the Agreement. In the event of a conflict between the capitalized terms defined and set forth in this Amendment and the defined terms of the Agreement, the definitions set forth in this Amendment shall control.

2. AMENDMENTS TO THE AGREEMENT

2.1. Exhibit 2.2 (Quality Agreement). Effective as of the Amendment 14 Effective Date, Exhibit 2.2 (Quality Agreement) to the Agreement is hereby replaced in its entirety with the Exhibit 2.2 (Quality Agreement) attached hereto.

3. CONCLUSION

Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

[Signature Page Follows]

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IN WITNESS THEREOF, the authorized representatives of the Parties have executed this Amendment to the Agreement effective as of the Amendment 14 Effective Date.

Insulet Corporation

By: /s/ Michael Graffeo

Date: 3 February 2017

Name: Michael Graffeo

Title: VP Business Development

Amgen Inc.

By: /s/ Sev Sislian

Date: 1/30/17

Name: Sev Sislian

Title: GSS, Sr. Manager - Devices

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

**Exhibit 2.2 (Quality Agreement) (amended and restated on January 23, 2017)
(Attached)**

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

Exhibit 2.2 Quality Agreement (Insulet/Amgen)
Amended & Restated January 20, 2016

QUALITY AGREEMENT

This Quality Agreement (including its attachments which are incorporated herein by reference) sets forth roles and responsibilities of each Party, outlines minimum quality system requirements for Customized Insulet Devices ordered by Amgen and Manufactured and supplied by Insulet to Amgen, and specifies preventative or proactive measures that will provide for continuous supply of materials. This Quality Agreement is entered by and between Insulet Corporation (“Insulet”) and Amgen Inc. (“Amgen”).

Approval Signatures

This Quality Agreement, developed jointly by Insulet and Amgen, is hereby approved by the Parties as an acceptable description of the activities in support of the quality of the Manufacturing and supplying of Customized Insulet Devices.

Signatures below indicate understanding of, and agreement with the content. Any changes to this document must be approved in writing by Insulet and Amgen. Changes can only be approved by the same functional roles and levels as the original approvers. This Quality Agreement is immediately effective upon the last date of signature set forth below.

Insulet Corporation

By: /s/ Michael Supczak

Date: 1/20/17

Name: Michael Supczak

Title: Sr. Director, Quality Assurance

Amgen Inc.

By: /s/ David Blake

Date: 1/23/17

Name: David Blake

Title: Sr. Manager Quality Systems,

Contract Manufacturing Quality

* Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

1. PURPOSE

Pursuant to that certain Supply Agreement entered into November 14, 2013, by and between Amgen and Insulet (as amended from time to time, the "Supply Agreement"), Insulet will Manufacture and supply to Amgen, and Amgen will order and purchase from Insulet, the Customized Insulet Device. Capitalized terms used but not defined herein shall have the meanings ascribed to the same as set forth in the Supply Agreement.

This Quality Agreement outlines the responsibilities for the major elements of the quality assurance program applicable to the Customized Insulet Device Manufacture by Insulet. This Quality Agreement does not limit or supersede any other contractual agreement between the Parties and is applicable to all Customized Insulet Devices Manufactured by Insulet as required by the Supply Agreement.

2. SCOPE AND DELIVERABLES

- 2.1. This Quality Agreement defines the high level Quality System requirements and related deliverables applicable to the Manufacture of Customized Insulet Devices ordered by Amgen pursuant to the Supply Agreement.
- 2.2. On or before [*] after the effective date of this Quality Agreement, Insulet will submit to Amgen for Amgen's review (and Insulet will consider in good faith and revise the draft plan based on Amgen's review) and approval (such approval not to be unreasonably withheld) a Quality Plan that will be a controlled document defining the Quality System Requirements set-forth in this Quality Agreement and the details of how Insulet will fulfill these requirements. This will be done in the form of references to the procedures, documents and other controls in place to ensure the requirements are consistently met. Insulet will comply with the Quality Plan approved of by Amgen.

3. REGULATORY

- 3.1. Compliance: Insulet will Manufacture for Amgen Customized Insulet Devices under requirements of, and in compliance with, the following applicable to the Manufacture and supply of Customized Insulet Device (collectively, "Quality System"):
 - 3.1.1. FDA, Quality System Regulation, Title 21 Code of Federal Regulations Part 820 (21 CFR §820),
 - 3.1.2. ISO 13485: 2003, Medical Devices - Quality Management System, and
 - 3.1.3. ISO 14971: 2012, Medical Devices - Application of risk management to medical devices.
- 3.2. Compliance Audits : Insulet shall allow Amgen's Regulatory Authorities and/or Notified Body to perform an announced/unannounced Quality Systems audit periodically (annually or as necessary). A Regulatory Authority or Notified Body shall be permitted to audit Insulet's suppliers on behalf of Amgen (accompanied by Insulet), and Insulet shall endeavor to secure such right from Insulet's suppliers, as related to the Customized Insulet Device, and Amgen's Regulatory Authority and Notified Body will follow the requirements set forth in this section with respect to the conduct of audits. With respect to an announced audit, Amgen's Regulatory Authority and Notified Body shall notify Insulet a minimum of [*] calendar days prior written notice of routine audits. In addition, Amgen may, after notifying Insulet, perform audits of Insulet's compliance with the Quality System Requirements, and to assess the effectiveness of its quality system. Insulet will have an internal audit program to monitor compliance with the Quality System.
- 3.3. Amgen observation right during Insulet's audit of its suppliers:
 - 3.3.1. Amgen has the right to be present as an observer during Insulet's audits of the [*] and Insulet's sterilization supplier and testing Laboratory as outlined in section 11.1.
 - 3.3.2. Insulet has sole audit authorship rights of the [*] and Insulet's sterilization suppliers and testing laboratory (section 11.1).
 - 3.3.3. Insulet will submit Audit Summary Report to Amgen within [*] after the last day of each audit.
 - 3.3.4. Insulet determines audit frequency as defined in the quality agreement between Insulet and their suppliers (section 11.1)
- 3.4. Audit Notices : Any compliance audit by Amgen of Insulet will be conducted during normal business hours after reasonable notice (typically [*] for planned audits) to Insulet and no more frequently than [*].

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- 3.5. Event (For-Cause) Audit. In addition to other audits set forth in this Quality Agreement or the Supply Agreement, during the Supply Term, Insulet shall permit Amgen to conduct audits of Insulet upon the occurrence of an Event Audit Circumstance (as defined below) upon reasonable (given the nature of the Event Audit Circumstance) prior notice to Insulet and during the Insulet's normal business hours. Each of the following is an Event Audit Circumstance that may trigger a For-Cause audit:
- 3.5.1. Receipt of a Warning Letter or any other regulatory agency action from the FDA or other Governmental Authority;
 - 3.5.2. Recall or market withdrawal of Customized Insulet Device;
 - 3.5.3. Receipt of an unmitigated, unacceptable trending of complaints (i.e. Severity A and B) as reviewed in the Quarterly Business Review meeting;
 - 3.5.4. Existence of unmitigated, unacceptable data trends with respect to the manufacturing lot qualification testing, packaging, labeling, sterilization, or rejection of finished goods of Customized Insulet Device.
- 3.6. For-Cause Audit Notices: Any For-Cause audit by Amgen of Insulet will be conducted during normal business hours after [*].
- 3.7. Audit Follow-up: Any out of compliance observations noted during compliance and for-cause audits will be addressed per Insulet's Corrective and Preventive Action system. Insulet will provide Amgen with a corrective action plan that addresses the compliance observation and a schedule for implementation of the corrective action(s) (which schedule shall reflect implementation of corrective actions within [*] time period, but in no event longer than required by applicable law).
- 3.8. Facility Registration: Insulet is responsible to maintain the U.S. FDA Establishment Registration for its facility(ies) such that it is up to date and readily available for FDA inspection. Additionally, Insulet will maintain ISO 13485:2003 certification.
- 3.9. Agency Inspections: Insulet will notify Amgen of inspection notifications and inspection results that may involve or impact Customized Insulet Devices. Insulet will provide Amgen copies of inspection reports that it receives from any regulatory agency or any notice of any claim or action by any agency relating to non-compliance with any applicable laws, rules or regulations that may affect Customized Insulet Devices or the Manufacture thereof. Except to the extent as it may be required by law, Insulet will not communicate directly with any regulatory agency (including FDA) regarding the Customized Insulet Device, except through or with the explicit review and approval of Amgen. To the extent relevant to the Manufacture or supply of Customized Insulet Devices, Insulet may require Amgen representatives to be present during any Third Party audit of Insulet products or processes. Amgen has the right to have representatives' present during an inspection by Regulatory Authorities or a Notified Body that relates to the Customized Insulet Device.
- 3.10. Support during audits by Regulatory Authorities or a Notified Body at Amgen: In the event that Amgen is involved in such inspection, e.g. a Pre-Approval Inspection (PAI), Insulet shall make reasonable effort to support Amgen questioning by providing a team to respond to questions pertaining to Customized Insulet Device or common platform technology, services or QMS. Amgen shall request the information electronically or by phone. Insulet will make documents, including those considered Confidential Information of Insulet and information from its suppliers, available to review to representatives of Regulatory Authorities or a Notified Body within twenty four (24) hours after request, or as expeditiously as possible, during inspection/registration audits of Amgen.

4. QUALITY SYSTEM

- 4.1. Insulet will establish and maintain a documented quality system in compliance with 21 CFR §820 and ISO 13485:2003. Insulet will have written procedures for the control of changes to the materials, packaging

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components, suppliers, equipment, processing steps, Customized Insulet Device requirements, sampling, test methods, and releasing requirements.

4.2. Change Notification and Approval

4.2.1. Insulet to:

- i. Notify Amgen of all changes related to the Manufacture, testing, packaging, labeling and shipping of Customized Insulet Devices including without limitation changes to components, suppliers, specifications, risk management documents, procedures, and CoC (collectively, "Controlled Change") prior to implementation of each such change

4.2.2. Amgen to:

- i. Review and approve, such approval not to be unreasonably withheld, each Controlled Change with respect to the Manufacture of the Customized Insulet Device.
- ii. Prior to each Customized Insulet Device production run, ensure all Controlled Changes have been approved in Amgen system.

- 4.3. Insulet shall ensure the execution of the [*] sterilization validation of the device in accordance with applicable international regulatory requirements and internal procedures. In addition, Insulet shall perform an annual requalification, reassessment and verification of the same.
- 4.4. Lot Release Procedures are attached hereto as Appendix B.
- 4.5. Insulet will notify Amgen within [*] when a non-conformance or deviation beyond the established Quality Control Plan has been identified that may affect Manufacturing or supply of Customized Insulet Devices.
- 4.6. Insulet will be responsible for supplying Amgen with quality reports. The content and frequency will be defined in the Quality Plan applicable to the Customized Insulet Device.
- 4.6 Insulet will have procedures in place to ensure data with respect to Customized Insulet Devices is complete and accurate; that it can be traced to its source and that it is readily available during regulatory inspections.
- 4.7 Insulet will notify Amgen of any incompleteness or inaccuracies related to data with respect to Customized Insulet Devices which may impact the quality or the safety of any of the Amgen product, as soon as possible, but not to exceed [*] after becoming aware such information.

5. MANAGEMENT RESPONSIBILITY

- 5.1. Executive Management at Insulet is responsible for quality planning and assures that resources are dedicated to achieve quality objectives, and manufacture and provide Customized Insulet Devices that meet Specifications approved by Amgen.
- 5.2. Insulet and Amgen will conduct Quality and Compliance Reviews regarding the Manufacture of Customized Insulet Devices. The reviews will include: CAPA, product complaints, critical manufacturing data and yield trending, nonconformance reports (NCRs) and deviations, EO test trends, external audit reports as they pertain to Manufacture of Customized Insulet Devices, and status of previous open actions and other quality and compliance related topics. Unless otherwise agreed by Amgen, the Parties will complete one review per calendar quarter during the Term after the commencement of 1st commercial build of Customized Insulet Device.

6. QUALITY AUDIT

- 6.1. Insulet will establish and maintain procedures for internal quality audits and audit of their CMOs and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the Quality System.

7. DESIGN CONTROLS

- 7.1. Design Controls are the responsibility of Insulet and will follow and be consistent with established Insulet procedures. Insulet has the responsibility for the control, approval and issuance including but not limited to the following:
 - 7.1.1. Material Specifications
 - 7.1.2. Process Requirements
 - 7.1.3. Parts Specifications
 - 7.1.4. Finished Goods Specifications
 - 7.1.5. Packaging Component Specifications
 - 7.1.6. Label Specifications

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- 7.2. Amgen is responsible for design control for the combination product (that is, the System) including combination product design verification, design validation, human factors and drug-device interaction testing.
- 7.3. Insulet shall ensure that all design control requirements have been met prior to the first shipment of Customized Insulet Device for human use. The interface between the groups and roles and responsibilities of each Party with respect to each phase of design controls is set forth in Appendix C.
- 7.4. Control of changes to the Customized Insulet Device and components thereof will follow requirements set forth in Section 4.2.
8. DOCUMENT CONTROL
- 8.1. Insulet shall maintain document control procedures as defined in the Supply Agreement and in compliance with 21 CFR 820.40 and ISO 13485. Insulet shall make this documentation available for review by Amgen during quality systems audits and upon request. Insulet shall make the Design History File (DHF), Device Master Record (DMR), Device History Record (DHR) and Insulet's other related quality systems records that are relevant to the Customized Insulet Device accessible to Amgen upon reasonable request and in support of all Regulatory Authority inspections. Insulet will work with Amgen to make these documents available through agreed upon measures, such as electronic systems or through review. The provisions of the Supply Agreement regarding Confidential Information apply to this Quality Agreement and interactions between the Parties with respect hereto.
- 8.2. Insulet will maintain documents in compliance with 21 CFR 820.180 and MDD 93/42/EEC for the time equivalent to design and expected life of the Customized Insulet Device but no less than five (5) years from the date of release for commercial distribution by Insulet. Insulet will notify Amgen prior to the end of the document retention period and the scheduled destruction of any contents of the DHF, DMR or DHR.
9. RISK MANAGEMENT
- 9.1. With respect to the Services, Insulet shall develop and comply with a risk management system that is compliant with ISO 14971 and all other product applicable standards to risk management. Insulet and Amgen shall fulfill the deliverables listed in the Risk Management Deliverables Table below.
- 9.2. Insulet shall have provisions for Amgen to audit Insulet's risk management procedures and documents. Insulet shall have risk deliverables listed in the table below reviewed and approved by Amgen.

Risk Management Deliverables Table

| DELIVERABLE | PRIMARY RESPONSIBILITY | COMMENTS OR RATIONALE |
|------------------------|------------------------|--|
| Risk Management File | Amgen | Amgen will establish and maintain a Risk Management File per its internal procedures and ISO 14971. Insulet shall provide required information for Amgen risk management file (e.g. risk document titles and identifiers). |
| Risk Management Plan | Insulet and Amgen | Amgen will create and maintain Risk Management Plan per internal procedures and ISO 14971. Insulet will create a risk management plan to describe risk activities, and how overall risk will be evaluated. |
| Risk Assessments | Insulet and Amgen | Insulet will perform risk assessments per internal procedures. Amgen will conduct use and system risk assessments per internal SOP and ISO 14971. |
| Risk Management Report | Insulet and Amgen | The results of Insulet assessments will be documented in a Risk Management Report per internal procedures and ISO 14971. Amgen will generate and maintain a Risk Management Report per internal procedures and ISO 14971 which includes a summary of risks identified by Insulet and Amgen. |

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An Amgen/Insulet Risk Management flowchart is in Exhibit 1.

10. INSPECTION, MEASURING, TESTING

- 10.1. Insulet shall assure that that measuring and test equipment is appropriate for its intended use and periodically serviced and/or calibrated in compliance with written procedures for such. Insulet shall be responsible for test method and equipment validation(s) as required by Insulet's approved procedures.

11. PURCHASING CONTROL

- 11.1. Insulet is responsible for the qualification of materials and the approval of new or alternate sub-tier suppliers for the Manufacture of Customized Insulet Device. The following suppliers will not be changed without prior written approval from Amgen:

| Subcontractor Name | Location | Product/Service |
|--------------------|----------|-----------------|
|--------------------|----------|-----------------|

[*]

Insulet shall establish, maintain the requirements, including quality requirements, for the selection of suppliers, subcontractors and consultants. Evaluation of the suppliers, subcontractors and consultants shall be performed in compliance with Insulet's procedures. These procedures as well as the schedule for performing the evaluations shall be documented and made available for review by Amgen during routine Quality Systems audits.

- 11.2. All fluid path components coming into contact with the Amgen Product will be manufactured [*]. Assembly of the fluid path components, sub-assemblies, and the entire Customized Insulet Device, including all packaging, will be performed [*]. Fluid path components are defined in the following table:

| Part Number | Part Description | Approved Supplier | Mfg. Country | Material Description |
|-------------|------------------|-------------------|--------------|----------------------|
|-------------|------------------|-------------------|--------------|----------------------|

[*]

12. IDENTIFICATION AND TRACEABILITY

- 12.1. Insulet will maintain a system to assure proper identification and acceptance status of material, components and Customized Insulet Devices throughout the manufacturing cycle and records to allow for traceability of materials and components used in each lot of Customized Insult Devices.

13. PRODUCTION AND PROCESS CONTROLS

- 13.1. Insulet will maintain written procedures for production and process control of the Customized Insulet Device. Insulet will sterilize the Customized Insulet Device in accordance with the Insulet Product Definition Document INSPR020-PDD, Amgen Delivery Device ADD specifications. Sterilization results will be provided on the Certificate of Conformance.

- 13.2. Amgen will notify Insulet of any requested changes to the Specifications or Manufacturing of the Customized Insulet Device including without limitation changes required by Applicable Law or Government Authority and changes to the following:

- Item #1 - Design Requirement Document;
- Item #2 - Subsystem components (e.g., hardware, electrical, mechanical and software);
- Item #3 - Manufacturing improvement (e.g., procedures, in line testing and equipment);
- Item #4 - Lot qualification procedures;
- Item #5 - Risk documents;
- Item #6 - Shipping process and condition; and
- Item #7 - Materials (e.g., packaging component and label artwork).

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Within [*] calendar days for Items [*] and [*] calendar days for Items [*] after each such notification from Amgen, Insulet will submit to Amgen an assessment of cost and schedule for implementation of the changes. Insulet will implement the changes as agreed upon by the Parties, such agreement not to be unreasonably withheld, including those required by Governmental Authorities or Applicable Law. [*]

14. ACCEPTANCE ACTIVITIES

14.1. For each lot of Customized Insulet Devices, Insulet shall require [*] to conduct identification, sampling and testing in accordance with the Lot Release Procedures in Appendix B. A lot of Customized Insulet Devices Manufactured by [*] that, based on the performance of and results from the Lot Release Procedures and comparison to release criteria set forth in the Lot Release Procedures in Appendix B, is appropriate for release by [*] (each an "In-Process Conforming Lot"). In-Process Conforming Lots will proceed to sterilization in accordance with the Sterilization/[*] Procedures. For each In-Process Conforming Lot that completes the Sterilization/[*] Procedures, and is shipped to Insulet, Insulet will perform lot qualification testing per Lot release procedure in Appendix B. The lot passes acceptance criteria and Insulet release requirement will become Conforming Lot, and prior to ship to Amgen, Insulet will provide to Amgen electronic versions of the DHRs (Device History Record) and a Certificate of Conformance that will contain the following information:

14.1.1 [*];

14.1.2. [*];

14.1.3 [*];

14.1.4 [*];

14.1.5 [*];

14.1.6 [*].

14.1.7 [*];

14.1.8 [*];

14.1.9 [*];

14.1.10[*]; and

14.1.11 [*].

14.2. Amgen maintains final acceptance responsibility for all Customized Insulet Devices Shipped to Amgen. Amgen may reject any lot of Customized Insulet Devices (a) that is not associated with a valid Certificate of Conformance, (b) that, upon examination, is not in a condition consistent with the Certificate of Conformance, provided that any such deviation from the Certificate of Conformance does not arise after Shipping, or (c) that does not meet the warranties set forth in the Supply Agreement. Amgen shall notify Insulet by giving written notice of rejection to Insulet within [*] after the receipt of final documentation from Insulet as outlined in section 13.2. If Amgen determines in good faith that it is reasonably likely that Amgen will reject Customized Insulet Devices, Amgen will provide verbal notification of such to Insulet within [*] after each such determination. Any disputes concerning Amgen's rejection of a lot of Customized Insulet Devices will be resolved in accordance with Section 10 of the Supply Agreement.

15. SHIPPING REQUIREMENTS

15.1. Shipping environmental condition from [*] facility to Insulet shall be:
[*]

16. NON-CONFORMING CUSTOMIZED INSULET DEVICES

16.1. During the [*] Production Run Period, Amgen quality will disposition lots that are not Conforming Lots, or portions thereof, by directing Insulet in writing that such lots, or portions thereof, be disposed of or that such Lots, or portions thereof, be delivered to Amgen without further processing.

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17. CORRECTIVE AND PREVENTIVE ACTION

- 17.1. Insulet will establish and maintain a corrective and preventive action (CAPA) program in accordance and compliance with applicable requirements of Regulatory Authorities.
- 17.2. Trending and analysis of all non-conformances will be performed by Insulet to verify the effectiveness of corrective and/or preventive actions and such trending and analyses will be reviewed with Amgen during the quarterly Quality and Compliance Review.
- 17.3. After each Non-Conforming Lot and after completing the obligations set forth in Section 16.1 and 16.2 of the Quality Agreement, Insulet and Amgen (through its [*]) shall mutually agree on corrective action to resolve the cause of Non-Conformance, prior to conducting another production run.

18. [*]

- 18.1. [*]
- 18.2. [*]
- 18.3. [*]
- 18.4. [*]

19. QUALITY SYSTEM RECORD

- 19.1. Insulet will prepare and maintain Quality System Records. Quality System Records include or refer to the location of non-Customized Insulet Devices specific quality system procedures.

20. RETAIN SAMPLE

- 20.1. Insulet shall receive and store certain amount of Customized Insulet device as "Retention Sample" per Insulet procedure. Insulet and Amgen shall agree on the required number of retains to support the Customized Insulet Device. If additional samples are required, above and beyond what has been agreed upon, Amgen should be notified and have the opportunity to authorize. Any additional samples taken as retains, above and beyond, should be destroyed at the time the batch is released by Amgen.

21. RECALL/WITHDRAWALS/FIELD SAFETY CORRECTIVE ACTION

- 21.1. Insulet shall notify Amgen within one (1) business day after there is an actual recall or correction/removal or Field Safety Corrective Action (FSCA) related to the Insulet Device that could affect the Customized Insulet Device. Insulet will follow its established procedures for determining the scope of the potential problem and actions necessary.
- 21.2. Insulet will notify Amgen within one (1) business day after it determines that an issue with the Customized Insulet Device could require a recall or correction/removal or Field Safety Corrective Action (FSCA) from the market. Amgen will then determine whether the Customized Insulet Device should be the subject of a recall, correction or removal from the market.
- 21.3. In the event Amgen determines that any problem identified as reasonably likely to require a recall or correction/removal or Field Safety Corrective Action (FSCA) from the market related to the released Customized Insulet Devices, Amgen will notify Insulet of such within one (1) business day after such determination and follow its established procedures for determining the scope of the potential problem and any actions necessary.
- 21.4. When potential recall/withdrawal/Field Safety Corrective Action (FSCA) issue is identified by Amgen and communicated to Insulet by Amgen, Insulet shall immediately perform investigations regarding and related to the issue. Insulet shall submit to Amgen investigation reports regarding the defect, issue or cause for such regulatory reporting within an appropriate timeframe dependent on regulatory reporting requirements. Amgen shall have the final decision for a voluntary product recall or correction/removal as it relates to the Customized Insulet Device.

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22. ANNUAL PRODUCT QUALITY REVIEW

In support of an Annual Product Review, Insulet will provide one each calendar quarter to Amgen a quarterly status written report on scrap, yield, NCMR's, CAPA's and other quality related data on related components and products that may impact the Customized Insulet Device. Insulet will review information pertaining to the Customized Insulet device that will appear in Amgen Annual Product Review, prior to FDA submission.

23. CONFIDENTIALITY

Without limiting Article 5 of the Supply Agreement, information contained in Specifications, batch records, procedures, and test methods relating exclusively to the Customized Insulet Device will be treated as confidential pursuant to the Supply Agreement.

24. JOINT QUALITY COMMITTEE

- a) Formation. The Joint Quality Committee ("JQC") shall be comprised of two (2) members from each Party, which members shall initially be the persons set forth in the following. Amgen and Insulet shall designate one of its members to act as chairperson of the JQC. As of the Effective Date, the members of the JQC are the following or the designee:

Amgen:

[*]

Insulet:

[*]

Each Party may change its members on the JQC by giving prior notice to the other Party in the manner provided in the Supply Agreement.

- b) Responsibilities. The JQC shall have overall responsibility for managing, directing and overseeing the Quality Agreement and compliance with such including, but not limited to, the following: (1) establishing specific requirements for, and implementing the general concepts of, the Quality Agreement; and (2) monitoring and coordinating communication regarding the Parties' efforts under the Quality Agreement. The JQC shall not have any power to amend, modify or waive compliance with the terms of the Quality Agreement or Supply Agreement.

- c) Meetings. During the Term, the JQC will meet (telephonically or in person) at times as reasonably requested by a Party.

25. DECISION MAKING. The Parties recognize that a bona fide dispute as to certain matters related to a Party's rights or remedies under this Quality Agreement may arise from time to time. In the event of the occurrence of such a dispute, the JQC shall undertake good faith efforts to resolve any such dispute in good faith. In the event the JQC shall be unable to resolve any such dispute, by written notice to the other Party, a Party may, but shall not be obligated to, escalate such dispute pursuant to Section 10 of the Supply Agreement.

26. PRODUCT COMPLAINTS

26.1 DEFINITIONS

Amgen Product. For purposes of this Section 26, the defined term "Amgen Product" shall include suspected counterfeit product.

"**Privacy Laws and Regulations**" shall have the meaning ascribed to it in the Safety Agreement.

"**Product Complaint**" shall mean any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a drug or device after it is released for distribution to market or clinic by either Amgen or by distributors or other third parties for whom

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Amgen (or its designee) manufactures the drug or device; provided, however, with respect to Amgen, Product Complaint shall not include deficiencies solely related to or arising from an Amgen Product.

“**Product Complaint Sample**” shall mean, with respect to each Product Complaint, the actual unit of the Customized Insulet Device associated with such Product Complaint. When required by the mutually agreed-upon Product Complaint investigation process, and if available, Amgen will send to Insulet for investigation, the Product Complaint Sample.

26.2 PRODUCT COMPLAINT EVENT HANDLING

26.2.1 Collection of Product Complaints (the Customized Insulet device)

- a) Amgen shall notify Insulet of each Product Complaint of which Amgen becomes Aware, even if the information known to Amgen is incomplete. With respect to a Product Complaint, “**Aware**” means if: (1) any employee of Amgen has acquired information that reasonably suggests a Product Complaint has occurred; or (2) any of Amgen’s employees (A) who have management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities or (B) whose responsibilities include the collection and reporting of Product Complaints, becomes aware from any information that a Product Complaint may have occurred.
- b) Amgen shall provide to Insulet all information relating to Product Complaints received by Amgen from any source, including patients and healthcare providers.
- c) Amgen will, within [*], report to Insulet all information available to Amgen regarding each Product Complaint and shall use reasonable efforts to obtain the following information from the person providing the Product Complaint information (the “reporter”):
 - confirmation that the patient was exposed to an Amgen Product and/or used the Customized Insulet Device;
 - the details of the Product Complaint; and
 - the contact information for the reporter.
- d) On or before the [*] day of each calendar month, Insulet shall notify Amgen whether there were Product Complaints related to common platform technology (Insulet Device) that could impact, or are applicable to, the Customized Insulet Device. With respect to such Product Complaints, Insulet shall provide tracking and trending data, the content of which shall be mutually agreed upon between the Parties.

26.2.2 Reporting, Investigation, and Follow Up of Product Complaints

- a) Within **One (1) Business Day** after Amgen becoming Aware of a Product Complaint and information relating thereto, Amgen will transmit all available information of which it is then aware regarding such Product Complaint to Insulet via established communication process. Receipt of information will be confirmed by Insulet within **two (2) Business Days**. Insulet will conduct investigations per Insulet standard process timelines. The Complaint Handling Process Flow is attached as Exhibit 2 and applies hereto.
- b) If a Party receives additional information or documents relating to a previously reported Product Complaint, such Party shall provide such information and/or the originals of such documents to the other Party’s designated contact within **two (2) business days** after receipt. Examples of such additional information include without limitation the following:
 - Confirmed device failure; and
 - Identification of potential product security issues.
- c) Within two (2) Business Days of receipt of a Product Complaint from Amgen; Insulet will notify Amgen to conduct a regulatory reportability assessment for the following symptom code:

[*]

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- d) Insulet is responsible for conducting thorough investigations of Product Complaints, in alignment with agreed upon processes including those related to the authenticity, operation, functionality and performance of the Customized Insulet Device. The investigation shall be performed and documented in a written report which identifies the underlying cause if possible based on available information, and Corrective Actions, if required, necessary to correct the identified cause, including justification for such conclusions. The report shall include a visual inspection of the Product Complaint Sample, if there is a Product Complaint Sample or where applicable, to confirm the authenticity of the device that is the subject of the Product Complaint as a Customized Insulet Device.
- e) Upon Amgen's request, an investigational report shall be provided by Insulet to Amgen with respect to a Product Complaint.
- f) All Product Complaint samples will be returned to Insulet for investigation or destruction as outlined in the Insulet complaint handling procedure as applicable to Customized Insulet Device
- a. Amgen will provide Return Material kits to complainants for return of the Product Complaint Sample directly to Insulet.
 - b. Amgen will initiate return sample follow up activities if receipt of the return sample exceeds **seven (7) Business Days**.
- g) Each Party will provide the other Party with such assistance as may be reasonably requested in investigating and obtaining follow-up information with respect to Product Complaints.
- h) No later than the **fifteenth (15th) day** of each calendar month during the term of the Agreement, Amgen shall submit to Insulet a written report including the following: (1) a line listing of Product Complaints of which Amgen is Aware that occurred or of which it became Aware during the previous calendar month or (2) a statement certifying that Amgen is not Aware of the occurrence of any Product Complaints during the previous calendar month. If a line listing of Product Complaints is provided, Insulet will inform Amgen to the extent that Insulet did not receive any Product Complaint reflected on the line listing and within **two (2) Business Days** after receipt of such notice, Amgen shall transmit such missing reports to Insulet.
- i) No later than the **fifteenth (15th) day** of each calendar month during the Term of the Supply Agreement, Insulet shall submit to Amgen the following for the previous calendar month:
- Rolling 24 months complaint rate per symptom code
 - All trend investigations (Including similar devices)
 - All device failures, including applicable failures with similar devices
 - Open CAPAs and CAPA effectiveness verification for identified complaint codes
 - Adherence to cycle time (on-time closure)
- j) Contact information may be updated by each Party as necessary by prior written notice to the other Party all without the need to formally amend this Quality Agreement.

26.3. TRAINING

Insulet represents and warrants that its Quality Management System training includes training relating to the identification, communication, investigation and reporting of Product Complaints.

26.4 QUALITY MANAGEMENT SYSTEM

Insulet shall implement, maintain, and adhere to a set of policies, plans, practices, and supporting infrastructure as defined in the Quality Agreement to include a designated unit to receive, review, and investigate Product Complaints.

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Appendix A

[*]

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Appendix B

[*]

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Appendix C

[*]

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SUBSIDIARIES OF THE REGISTRANT

| <u>Name of Entity</u> | <u>State/Country of Organization</u> |
|---|--------------------------------------|
| Sub-Q Solutions, Inc. | Delaware |
| Insulet MA Securities Corporation | Massachusetts |
| Insulet Singapore Private Limited | Singapore |
| Insulet Canada Corporation | Canada |
| Insulet Consulting (Shenzhen) Co., Ltd. | China |

Consent of Independent Registered Public Accounting Firm

We have issued our reports dated February 27, 2017 , with respect to the consolidated financial statements, schedule, and internal control over financial reporting included in the Annual Report of Insulet Corporation on Form 10-K for the year ended December 31, 2016 . We consent to the incorporation by reference of said reports in the Registration Statements of Insulet Corporation on Forms S-3 (No. 333-158354, 333-174746, 333-172782, and 333-196486) and on Forms S-8 (No. 333-144636, 333-153176, 333-183166, 333-202689, 333-208193 and 333-208387).

/s/ GRANT THORNTON LLP

Boston, Massachusetts

February 27, 2017

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-3 No. 333-158354, 333-174746, 333-172782, and 333-196486, Forms S-8 No. 333-144636, 333-153176, 333-183166, 333-202689, 333-208193 and 333-208387) of Insulet Corporation and in the related Prospectus of our report dated February 29, 2016 (except for effects of discontinued operations, as discussed in Notes 2 and 3, as to which the date is September 6, 2016), with respect to the consolidated financial statements and schedules of Insulet Corporation, included in this Annual Report on Form 10-K for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 27, 2017

CERTIFICATION

I, Patrick J. Sullivan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Insulet Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Patrick J. Sullivan

Patrick J. Sullivan
Chief Executive Officer

Date: February 27, 2017

CERTIFICATION

I, Michael L. Levitz, certify that:

1. I have reviewed this Annual Report on Form 10-K of Insulet Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Michael L. Levitz

Michael L. Levitz
Chief Financial Officer

Date: February 27, 2017

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Insulet Corporation, a Delaware corporation (the "Company"), does hereby certify with respect to the Annual Report of the Company on Form 10-K for the fiscal year ended December 31, 2016, as filed with the Securities and Exchange Commission (the "Report") that, to their knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Patrick J. Sullivan

Patrick J. Sullivan

Chief Executive Officer

Date: February 27, 2017

/s/ Michael L. Levitz

Michael L. Levitz

Chief Financial Officer

Date: February 27, 2017