INSULET CORP
Form 10-K
February 26, 2019
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-33462

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

Delaware	04-3523891
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
100 Nagog Park Acton, Massachusetts	01720
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

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

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

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

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

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, 2018 was approximately $5.0 billion.

The number of shares outstanding of each of the registrant's classes of common stock as of February 20, 2019:

Title of Class	Shares Outstanding
Common Stock, $0.001 Par Value Per Share	59,278,993

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, 2018. 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® System, an innovative, discreet and easy-to-use continuous insulin delivery system for people with insulin-dependent diabetes. The Omnipod System consists of two product lines: the Omnipod Insulin Management System (“Omnipod”), which we have been selling since 2005, and our next generation Omnipod DASH™ Insulin Management System ("Omnipod DASH" or "DASH"), which began a U.S. limited market release in 2018. Collectively, we refer to these products as the "Omnipod System".

There are two primary types of insulin therapy practiced today: multiple daily injection (“MDI”) therapy using syringes or insulin pens; and pump therapy using insulin pumps. Insulin pumps are used to perform continuous subcutaneous insulin infusion and typically use a programmable device and an infusion set to administer insulin into the person’s body. Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. We estimate that approximately one-third of the Type 1 diabetes population in the United States and less than one fifth of the Type 1 diabetes population outside the United States use insulin pump therapy. An even smaller portion of the insulin-dependent Type 2 diabetes population in the United States use insulin pump therapy. We believe these factors present a significant available market for the Omnipod System globally.

The Omnipod System features two discreet, easy-to-use devices: a small, lightweight, self-adhesive disposable tubeless Pod ("Pod"), which is worn on the body and provides up to three days of non-stop insulin delivery without the need to see or handle a needle; and a handheld Personal Diabetes Manager ("PDM"). The Pod can be worn in multiple locations, including the abdomen, hip, back of upper arm, upper thigh or lower back and, because it is waterproof, there is no need to remove it when showering, swimming or performing other activities. The Omnipod System communicates wirelessly, provides for virtually pain-free automated cannula insertion and eliminates the need for traditional MDI therapy or the use of traditional pump and tubing. We believe that the Omnipod System’s unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience, and ease.

We began commercial sales of the Omnipod in the United States in 2005 and we sell the Omnipod directly to end-users or through intermediaries. The Omnipod is also available in multiple countries in Europe, as well as in Canada and Israel. On July 1, 2018, we commenced direct commercial operations for the Omnipod in Europe immediately following the expiration of our distribution agreement with our former European distributor. In June 2018, the U.S. Food and Drug Administration ("FDA") cleared for commercial sale our Omnipod DASH, which is our next-generation digital mobile Omnipod platform within the Omnipod System family, featuring secured Bluetooth wireless technology for connectivity between the Pod and the color touchscreen smartphone PDM. The DASH PDM is optimized for use with the CONTOUR® NEXT ONE Blood Glucose (BG) Meter for the direct transfer of blood glucose readings to the PDM's bolus calculator. Bluetooth functionality will also provide connectivity to our smartphone apps. We commenced a limited commercial release of Omnipod DASH in 2018 prior to a planned full market launch in the U.S. in the first half of 2019.

For the year ended December 31, 2018, approximately 69% of our consolidated revenue was from sales in the United States and approximately 31% from international sales.

In January 2018, the Centers for Medicare & Medicaid Services (“CMS”) issued guidance clarifying that Medicare Part D Plan Sponsors may provide coverage for products such as the Omnipod System under the Medicare Part D (prescription drug) program. During 2018, we began securing coverage with Medicare Part D carriers to ensure beneficiaries living with diabetes have access to the Omnipod System. Securing Medicare Part D coverage also provides a direct pathway to increased Medicaid coverage at the state level, as many state-run Medicaid programs follow CMS prescription drug guidance to determine coverage. This increased Medicaid access allows access for lower-income individuals and families for whom Omnipod had previously not been a covered option. In April 2018, we also significantly increased our market access when we secured in-network coverage of Omnipod with

UnitedHealthcare, the largest commercial payer in the United States.

In addition to the diabetes market space, we have partnered with pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of subcutaneous drugs across other therapeutic areas. The majority of our drug delivery revenue currently consists of sales of Pods used in Amgen's Neulasta Onpro kit, an innovative delivery system for Amgen’s white blood cell booster to help reduce the risk of infection during intense chemotherapy.

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We have substantially completed the construction of a highly-automated manufacturing facility in Acton, Massachusetts, with planned production out of the facility beginning in the first half of 2019. The facility also serves as our global headquarters. We expect that, following start-up related activities, the new facility will allow us to lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base and support our growth trajectory.

Market Opportunity: Management of Diabetes

Diabetes is a chronic, life-threatening disease for which there is no known cure. It is caused by the body's inability to produce or effectively utilize the hormone insulin, which 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 to survive. It is estimated that approximately one million to two million people in the United States have Type 1 diabetes.
- Type 2 diabetes, the more common form, 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 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 therapies, which often include insulin therapy. It is estimated that approximately two million to three million people in the United States have Type 2 diabetes that requires daily insulin administration.

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.

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 insulin pump 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. Additionally, the time spent managing fluctuations in blood glucose levels and the fear associated with hypoglycemia can be incredibly stressful 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.

As previously noted, there are two primary types of insulin therapy practiced today: MDI therapy and insulin pump therapy. Insulin pumps are used to perform continuous subcutaneous insulin infusion and typically use a programmable device and an infusion set to administer insulin into the person's body. MDI therapy involves the administration of fast-acting insulin before meals (bolus) to lower blood glucose levels to a healthy range. MDI therapy may also require a separate injection of a long-acting (basal) insulin, to control glucose levels between meals;

typically once or twice per day. By comparison, insulin pump therapy uses only fast-acting insulin to fulfill both mealtime (bolus) and background (basal) requirements. Insulin pump therapy allows individuals to customize their bolus and basal insulin doses to meet their insulin needs throughout the day, and is intended to more closely resemble the physiologic function of a healthy pancreas.

Insulin pump therapy has been shown to provide numerous advantages relative to MDI therapy. For example, insulin pump therapy eliminates individual insulin injections (approximately five per day), delivers insulin more accurately and precisely than injections, often improves HbA1c (a common measure of blood glucose levels) over time, provides greater flexibility with meals, exercise and daily schedules, and can reduce severe low blood glucose levels.

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We believe that these distinct advantages, including technological advancements and increased awareness of insulin pump therapy as compared to other available insulin therapies will continue to generate demand for insulin pump devices.

Our Solution: The Omnipod System

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

Pod Omnipod PDM Omnipod DASH PDM

The Omnipod System is a discreet two-part design, the 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 user 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 user's personalized insulin-delivery instructions and, wirelessly monitors the Pod's operation.

The Omnipod System provides continuous insulin delivery at preset rates, eliminating the need for individual insulin injections and the interruptions that come with them. In addition, 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 is delivered automatically at a programmed rate, all day and night.
- An extra dose of insulin can be delivered when a patient needs it to match the carbohydrates in a meal or snacks or to correct high blood glucose.

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 tubed insulin pumps. As a result, the Omnipod System is easy for patients to use, which also reduces the training burden on healthcare professionals and end-users. We believe that the Omnipod System’s overall ease of use, flexibility, and substantially lower training burden make it very attractive to people with insulin-dependent diabetes and help redefine for whom insulin pump therapy is appropriate, allowing healthcare professionals to prescribe pump therapy to a broader group of patients.

The Omnipod System’s unique patented design and proprietary manufacturing process allow us to provide pump therapy at a relatively low up-front investment compared to conventional tubed insulin pumps. We believe that our pricing model, which includes little or no initial investment, reduces the risk to third-party payors of significant up-front investments commonly associated with traditional tubed insulin pumps.

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Several publications over the past decade have found that compared to multiple daily injections therapy, the use of the Omnipod System by individuals with both Type 1 and Type 2 diabetes across all age groups is associated with good glycemic control, reduced total daily dose of insulin, and reduced frequency and severity of hypoglycemic episodes. These results are consistent with other published literature of other continuous subcutaneous insulin infusion devices similar to the Omnipod System. In addition, research in adults with Type 1 diabetes has found that compared to prior treatment modality, the use of the Omnipod System is associated with improved quality of life. We believe that this data is clinically meaningful to healthcare providers and provides support for the use of the Omnipod System in the treatment of both Type 1 and Type 2 diabetes.

We have partnered with Glooko Inc. ("Glooko") to connect our Omnipod System user data with Glooko's comprehensive diabetes data management system (including Glooko and Diasend in selected regions). Glooko provides a cloud-based application for clinicians and patients accessible through a kiosk, home computer or a mobile application on the user's smartphone that provides patients and their health care providers access to insulin delivery trends, blood glucose levels and other integrated data.

Third-Party Reimbursement

In the United States, our products are generally reimbursed by third-party payors when sold directly to end-users, and we bill those payors for products provided to end-users. Prior to 2018, coverage was more limited in the United States due to the lack of an established mechanism for Medicare or broad Medicaid coverage for the majority of the Omnipod System. In January 2018, CMS issued guidance clarifying that Medicare Part D Plan Sponsors may provide coverage for products such as the Omnipod System under the Medicare Part D (prescription drug) program. We have been successful in securing coverage with Medicare Part D plans, which allows many additional people with diabetes to access our product. The ability of Medicare Part D plans to cover the Omnipod System also provides us with a direct pathway to gain Medicaid coverage at the state level, as many state-run Medicaid look to Medicare to determine coverage. This allows access for lower-income individuals and families on Medicaid for whom Omnipod is currently not an option. In addition, in April 2018, we also significantly increased our third-party reimbursement when we secured in-network coverage of Omnipod with UnitedHealthcare, the largest commercial payer in the United States. We continue to work with third-party payors in the United States to establish coverage and payment for the Omnipod System. 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.

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. Common medical criteria for third-party payors approving reimbursement for pump therapy may 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. Third-party payors may decline to reimburse for procedures, supplies or services determined not to be “medically necessary” or “reasonable.” Reimbursement may also be declined by insurers based upon the contract between the insurer and the insured group.

In Europe, in connection with of our recent assumption of direct operations in mid-2018, we have worked with local healthcare systems to establish coverage and payment processes for the Omnipod System. In certain non-U.S. locations in which we sell through a distributor, our distribution partners establish appropriate reimbursement contracts with healthcare systems in those countries and provinces.

Markets and Distribution Methods

We sell the Omnipod directly to patients or indirectly through intermediaries, such as independent distributors and the pharmacy channel, in the United States, Canada, Europe, and Israel. In 2018, following FDA clearance, we also commenced a limited commercial release of Omnipod DASH directly to customers in the U.S. For the year ended December 31, 2018, approximately 46% of our Omnipod System sales in the United States were through intermediaries. Consistent with CMS’s decision in 2018 that products such as the Omnipod System are coverable under the Medicare Part D prescription drug benefit, we have been expanding access to our Omnipod System through the

pharmacy channel, which we believe provides several competitive advantages over the durable medical equipment ("DME") distribution method used by traditional pump companies. Internationally, the majority of our sales are through intermediaries.

Our sales and marketing efforts are 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:

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- First, build patient awareness about the features and benefits that the Omnipod System provides.
- Second, build physician support by increasing the clinical evidence that demonstrates the benefits that the Omnipod System provides and improving the patient-monitoring data available to physicians providing diabetes care.
- Third, provide payors with the clinical and economic justification for why the Omnipod System is a unique value to the patients whom they insure.

Training. We believe that training patients how to use the Omnipod System is an important factor to promote successful outcomes and patient retention. We have streamlined and standardized our patient training by developing improved online resources and increased our field clinician team to directly train new Omnipod System customers.

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 support.

Competition

The diabetes medical device market is highly competitive, subject to rapid change and significantly affected by new product introductions. The Omnipod System competes for patients in the insulin delivery market. Because the majority of new Omnipod System end-users come from MDI therapy, which currently is the most prevalent method of insulin delivery, we believe that we primarily compete with companies that provide MDI therapy. To a smaller extent, we also compete with companies in the insulin pump market, which today consists of conventional tubed pump companies, including Medtronic MiniMed, a division of Medtronic Public Limited Company ("Medtronic"), and Tandem Inc. Medtronic historically has held the majority share of the conventional tubed insulin pump market in the United States. The competitive landscape in our industry continues to undergo significant change. For example, Animas Corporation, a division of Johnson & Johnson, exited the insulin pump market in the United States and other countries in late 2017. In addition to the established insulin pump competitors, several companies are working to develop and market new insulin patch pumps and smart pens. These companies are at various stages of development and the number of such companies often changes as they enter or exit the market. Our non-insulin drug delivery product line also competes with drug delivery device companies such as West Pharmaceutical Services, Inc.

Research and Development

Our current research and development efforts are primarily focused on making improvements to the Omnipod System, including adding features and functionality that will deliver economic value, convenience and simplicity to our customers, and improving our supply chain operations. These efforts include:

Omnipod DASH. We have developed Omnipod DASH, our next generation of the Omnipod System, which features a secure Bluetooth-enabled Pod and PDM with a touch screen color user interface supported by smartphone connectivity incorporating state-of-the-art security features. Bluetooth functionality also provides connectivity to our smartphone apps, allowing users and those they approve (e.g. caregivers) to view their Omnipod DASH data on their personal smartphones. In June 2018, the FDA provided clearance for the commercial distribution of DASH in the U.S. We commenced a limited commercial release of DASH in 2018 and expect to commence a full market launch in the U.S. in the first half of 2019.

Omnipod Horizon™ Automated Insulin Delivery System ("Omnipod Horizon System"). We also are developing a hybrid closed loop control system that utilizes the DASH mobile platform to allow the Pod to communicate with Dexcom Inc.'s ("Dexcom") continuous glucose monitor and help control insulin delivery utilizing an algorithm located on the Pod. The Omnipod Horizon System is intended to be controllable through a secure mobile app on the user's smartphone (i.e. "phone control"). In July 2018, we announced positive results from a clinical trial finding that the Omnipod Horizon System performed well and was safe for over five days of use in adults, adolescents, and children with Type 1 diabetes. The Omnipod Horizon System recently was granted designation in the FDA's breakthrough device program, which is a program intended to help patients have more timely access to certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by expediting the development and review process. We believe that recent and ongoing developments in the use of Continuous Glucose Monitoring ("CGM") technology and Automated Insulin Delivery ("AID") algorithms in conjunction with insulin pump therapy will continue to provide people with

insulin-dependent diabetes benefits that will make insulin pump therapy an even more attractive treatment alternative to the existing MDI therapy market.

Paramount to our ability to deliver phone control is our commitment to cyber and information security. Just recently, Omnipod DASH became the first FDA-cleared insulin pump to be certified under the Diabetes Technology Society's "Standard for

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Wireless Diabetes Device Security" cybersecurity assurance standard and program, known as DTSec. This certification is a cybersecurity standard with the goal of raising confidence in the security of network connected medical devices through independent expert evaluation. In addition, Omnipod DASH recently received International Standards Organization ("ISO") 27001 certification, which is the international standard for best practice in an information security management system globally. With the DTSec and ISO 27001 certifications, Omnipod DASH is now globally recognized for incorporating the highest standards for cyber and information security and safety, including secure data transfer between the Pod and PDM, as well as secure cloud storage.

Concentrated Insulin Delivery. In collaboration with Eli Lilly, we are developing new products that leverage the DASH mobile platform 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. These new products are being specifically designed to deliver Humalog -® 200 units/mL and Humulin® R U-500 insulin, which are concentrated forms of insulin used by people with highly insulin resistant Type 2 diabetes. Together with our Omnipod DASH System, we believe these innovations significantly expand our access to more of the Type 2 diabetes market.

Supply Chain Operation Improvements. We continue to invest in improvements and efficiencies to our entire supply chain, including improvements in automation at our suppliers and contract manufacturer as well as our U.S. manufacturing facility in Acton, Massachusetts, set to commence manufacturing in the first half of 2019.

Manufacturing and Quality Assurance

We believe a key contributing factor to the overall attractiveness and success of the Omnipod System is the disposable nature of the Pod. In order to manufacture sufficient volumes and achieve a cost-effective per unit production price for the Omnipod, we have designed the Omnipod System to be manufactured through automation.

We produce our devices on varying degrees of semi-automated manufacturing lines at a facility in China, operated by a subsidiary of Flex Ltd. ("Flex") pursuant to a multi-year materials supply agreement. The agreement expires in December 2022 and is subject to an automatic renewal thereafter, unless otherwise canceled by the parties under the contract terms.

We have substantially completed the construction of a highly automated manufacturing facility that we own and will operate in Acton, Massachusetts. This facility now serves as our global headquarters and we plan to produce devices there beginning in the first half of 2019. We expect that, following start up related activities, the new facility will allow us to lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base, and support our strong growth trajectory. To date, we have invested approximately $193 million in property, equipment and infrastructure related to the new facility. We expect to continue to expand our investment in this facility in 2019 to support the growth of our business.

We utilize outside vendors for the supply of components, sub-assemblies, and various services used in the manufacture of the Omnipod System. Our outside vendors produce the components to our specifications and they are audited periodically by our Quality Assurance Department to confirm 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 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. Processes utilized in the manufacture, test and release of the Omnipod System have been verified and validated as required by the 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 and certain corresponding state agencies.

Intellectual Property

To maintain a competitive advantage, we believe 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 advisers to execute non-disclosure agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require employees, consultants and advisers who work on our products to agree to disclose and assign to us all inventions conceived during their work with us that are developed using our property or 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, 2018, we had 21 granted and active U.S. patents with expiration dates ranging from 2020 through 2034, and had 56 additional pending U.S. patent applications. We believe that it will take at least several years 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:

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- 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, such as apps, 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 with the United States Patent and Trademark Office on the Principal Register and in other appropriate jurisdictions. Our trademarks include OMNIPOD(R), DASH™, Omnipod CONTROL™, Omnipod DISPLAY™, Omnipod VIEW™, Omnipod OMNIPOD U-200™, OMNIPOD U-500™, HORIZON™, Pod Pals™ and Podder™.

Government Regulation

United States FDA 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, preclinical 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. We have obtained 510(k) clearance for the Omnipod and Omnipod DASH Systems and expect that PMA approval may 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 our products. Both the 510(k) clearance and PMA processes can be expensive and lengthy and entail significant user fees, unless an exemption is available.

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. 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 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. 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

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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.

Clinical Trials. Clinical trials are almost always required to support a PMA application and sometimes also 510(k) submissions. If the device presents a “significant risk” to human health as defined by the FDA, the FDA requires the device sponsor to submit an investigational device exemption ("IDE") to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a “non-significant risk” device, in which case an IDE approval from the FDA would not be required, although the clinical trial would need to meet other requirements including IRB approval. Clinical trials for a significant risk device may begin once an IDE is approved by the FDA and the appropriate Institutional Review Board ("IRB") at each clinical trial site. Future clinical trials may require that we obtain an IDE from the FDA prior to commencing any such clinical trial and that the trial be conducted with the oversight of an IRB at the clinical trial site.

Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. A clinical trial may be suspended by the FDA or at a specific site by the relevant IRB at any time for various reasons, including a belief that the risks to the trial participants outweigh the benefits of participation in the clinical trial. Even if a clinical trial is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient for us to obtain approval of our product.

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 development and 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 import or 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.

International Product Regulations

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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. The primary regulatory body in Europe is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices, including the Medical Device Directive ("MDD"). Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third party assessment by a “Notified Body.” This third-party assessment may consist of an audit of the manufacturer’s quality system and specific testing of the manufacturer’s product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. Outside of the European Union, regulatory approval needs to be sought on a country-by-country basis in order for us to market our products.

We have obtained the right to affix the CE Mark to the Omnipod and Omnipod DASH Systems. The CE Mark gives us authorization to distribute these products throughout the European Union and in other countries that recognize the CE Mark. In September 2009, we received Health Canada approval to distribute the Omnipod throughout Canada. We have been distributing the Omnipod in certain countries in Europe through intermediaries or directly to end-users since 2010.

Other Regulations

Licensure. Several states require that 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. In order to sell our product through the pharmacy channel, we are required to work with intermediaries who have the appropriate pharmacy license for the applicable market in which we provide customers with access to our product through the pharmacy.

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 healthcare Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration (anything of value) 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, patients, purchasers and formulary managers on the other. Liability under the statute 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 civil False Claims Act, which is addressed below. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common business practices from prosecution and administrative sanctions, 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. For example, 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. We compensate outside diabetes educators for their services at contracted rates deemed to be consistent with the market. We have structured our arrangements with diabetes educators and other business practices to comply with statutory exemptions and regulatory safe harbors whenever possible, but our practices may be subject to scrutiny if they fail to strictly comply with the criteria in the exemption or regulatory safe harbor. Moreover, there are no safe harbors for many common practices such providing reimbursement assistance, coding and billing information or other patient assistance and product support programs. If any of our practices, arrangements or programs are found not to be in compliance with the federal Anti-Kickback Statute, we can be subject to significant criminal, civil and administrative penalties, including imprisonment, fines, damages, and exclusion

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from Medicare, Medicaid or other governmental programs, 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 for the furnishing of certain "designated health services," including 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 for items and services referred by a physician with a noncompliant arrangement, civil damages and penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although there are a number of statutory and regulatory exceptions protecting certain common business practices implicating the Stark Law, and we have structured our arrangements with physicians and other providers to comply with these exceptions, these arrangements may not expressly meet the requirements for applicable exceptions from the law.

Federal civil False Claims Act. The federal civil False Claims Act imposes penalties against any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act are subject to the imposition of significant per claim penalties, three times the amount of damages that the federal government sustained and possible exclusion from participation in federal health care programs like Medicare and Medicaid. We believe that we are in compliance with the federal government's laws and regulations concerning the filing of claims for reimbursement. 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 significant civil money penalties 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. Violations of these statutes can result in significant civil, criminal and administrative penalties, fines, damages, and exclusion from federal health care programs.

State Fraud and Abuse Laws and Marketing Restrictions. Many states have also adopted anti-kickback, anti-referral laws, and false claims laws and regulations analogous to the federal civil Anti-Kickback Statute and federal False Claims Act, and in some cases these state laws apply regardless of the payer, including private payors. We believe that we are in conformance with such laws. Moreover, several states have imposed requirements to disclose payments to health care providers, restrictions on marketing and other expenditures, and requirements to adopt a code of conduct or compliance program with specific elements. 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. If we are found to be in violation of HIPAA, we could be subject to civil or criminal penalties.

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General Data Protection Regulation. The General Data Protection Regulation ("GDPR") is a comprehensive update to the data protection regime in the European Economic Area that is effective in fiscal 2018. The GDPR imposes new requirements relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third party processors. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties for noncompliance with the GDPR.

Patient Protection and Affordable Care Act. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (“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. Some of the provisions of the ACA have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. It is unclear how the ACA and its implementation, as well as efforts to repeal or replace, or invalidate, the ACA, or portions thereof, will affect our business. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible. 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, implemented as the Open Payments program, requires manufacturers of drugs and devices for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value provided to physicians and teaching hospitals, as well as ownership and investment interests held by physician and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. Our failure to disclose reportable payments could subject us to penalties and materially adversely impact our business and financial results.

Additionally, as these laws and regulations continue to evolve, we lack definitive guidance as to the application of certain key aspects of these laws and regulations as they relate to certain of our arrangements and programs, including those with providers with respect to patient training. We cannot predict the final form of these federal and state regulations or the effect that application of those interpretations 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. Moreover, these laws continue to evolve. The Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti Kickback Statute. Most recently, on February 6, 2019, the United States Department of Health and Human Services’ Office of the Inspector General (“OIG”) issued a proposed rule to remove protection from the discount safe harbor to the federal healthcare Anti-Kickback Statute for manufacturers rebates to pharmacy benefit managers (or “PBMs”), Medicare Part D plans, and Medicaid managed care organizations (MCOs). The rule also proposes a new safe harbor for point-of sale-reductions offered by manufacturers to Part D plans, Medicaid MCOs and their PBMs, and a new safe harbor for certain fees manufacturers pay to PBMs for services to the manufacturers. If finalized, the rule will be one of the most significant amendments to the Anti-Kickback Statute regulatory safe harbors in decades and likely will transform manufacturer interactions with Part D plans, Medicaid MCOs and their PBMs.

Ensuring that our business arrangements and interactions with healthcare professionals, third party payors, patients and others comply with applicable healthcare laws and regulations requires substantial resources. Because of the breadth of these laws and the narrowness of the exceptions or safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations. 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.

Employees

As of December 31, 2018, we had 1,169 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 strong.

Company Information

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Insulet Corporation is a Delaware corporation formed in 2000. Our principal office is located at 100 Nagog Park, Acton, Massachusetts, 01720 and 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, 2018.

Item 1A. Risk Factors

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

We generally identify forward looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “con negative of these terms or other similar words. These statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections 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

Although we achieved operating income and net income in 2018, we previously incurred significant operating and net losses since inception and cannot assure you that we will sustain profitability.

Prior to 2018 and since our inception in 2000, we incurred significant operating losses. For the year ended December 31, 2018, we generated operating income of $27.4 million and net income of $3.3 million. Our net losses for the years ended December 31, 2017, 2016 and 2015 were $26.8 million, $28.9 million and $73.52 million, respectively. The extent of any future net losses and the timing of profitability are uncertain, and we may not sustain profitability. As of December 31, 2018, we had an accumulated deficit of $683.6 million.

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

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

- delays in shipping due to capacity constraints;
- practices of health insurance companies and other third-party payors with respect to reimbursement for our current or future products;
- market acceptance of our products;
- our ability to manufacture our products efficiently, or at all;
- transitions in our distribution channel;
- 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 should not be the only indication of our future performance.

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We currently rely on sales of the Omnipod System, and tailored versions of the Omnipod System in our drug delivery product line, to generate nearly all 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 nearly all of our revenue from the sale of this product. Accordingly, our ability to continue to generate revenue is highly reliant on our ability to market and sell the Omnipod System and to retain customers who currently use the product. 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;
- reductions in reimbursement rates or coverage 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;
- the inability of our customers to continue paying for our products;
- 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 sustain profitability may depend on our ability to sustain or further 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.

To sustain profitability, we may need to, among other things, sustain or further reduce the per unit cost of the Omnipod System. If we are unable to sustain or further reduce raw material and manufacturing overhead costs through volume purchase discounts, negotiation of improved pricing and increased productivity and production capacity, our ability to sustain profitability could be negatively affected. The occurrence of one or more factors that negatively impact the manufacturing or sales of the Omnipod System or increase our raw material costs could prevent us from sustaining our desired increase in manufacturing volume, which would prevent us from sustaining and further increasing profitability.

Adverse changes in general economic conditions in the United States and outside of the United States, predominantly in Europe, 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 ability to pay 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, Canada and Europe could be negatively affected in the event of a downturn in economic conditions. For example, U.S. 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.

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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 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.

Sales of certain medical devices are subject to a 2.3% federal excise tax, subject to a suspension through 2019. We believe 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 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.

Some of the provisions of the ACA have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate", effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly known as the “donut hole,” by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%. It is unclear how the ACA and its implementation, as well as efforts to repeal or replace, or invalidate, the ACA, or portions thereof, will affect our business. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible. It is possible that the ACA, 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 our products;
- costs of developing new products or technologies and enhancements to our products;
- 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 of $288.9 million, 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 2019.

We may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. We may need to raise additional debt or equity financing to repay our outstanding Senior Convertible Notes. If we

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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 Convertible Senior Notes. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

As of December 31, 2018, we had outstanding principal amounts due of $747.5 million on our Convertible Senior Notes, which mature between 2021 and 2024. Our ability to make scheduled payments or to refinance the 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 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 Pods and PDMs. 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 all of our suppliers, and, in many cases, we, or Flex on our behalf, make purchases on the basis of individual purchase orders. In some cases 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 our products, cause delays in shipment or negatively affect our reputation;
- 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;
- thefts of our trade secrets and intellectual property could occur with the third-party supply process;
- 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.

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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.

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 U.S. 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.

We sell the Omnipod in Europe, Canada and Israel. 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 are subject to foreign regulatory and import or export requirements.

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, while we expect to begin U.S. production in the first half of 2019, 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.

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Our assumption on July 1, 2018 of the commercial activities for our Omnipod System in Europe (including, among other things, distribution, sales, marketing, training and support) following the expiration of our prior third-party global distribution agreement creates several business and operational risks related to the future sales of our Omnipod System in Europe.

On July 1, 2018, we assumed all commercial activities (including, among other things, distribution, sales, marketing, training and support) of our Omnipod System across Europe following the expiration of our distribution agreement with our European distributor on June 30, 2018. We expect to incur increased operating expenses as we invest in these European operations, and it is possible that the ultimate economic benefits that we derive from these investments could be less than anticipated, or that such expected economic benefits could fail to materialize at all.

In connection with the expiration of this distribution agreement on June 30, 2018, we are required to pay to the former European Distributor a quarterly per-unit fee for Omnipod sales by us between July 1, 2018 and June 30, 2019 to certain customers of the former European Distributor. We are recognizing a liability and an associated intangible asset for this fee as qualifying sales occur. The actual total fee could vary significantly depending on the number of customers who count for purposes of calculating the fee under the terms of the distribution agreement and the methodology applicable for determining this number under the agreement is subject to an active arbitration proceeding between the parties in Switzerland.We estimate that the final aggregate fee for the applicable twelve-month period could be in the range of approximately $10 million to $55 million.

Our establishment of commercial operations in Europe creates risk associated with Brexit

On June 23, 2016, in a referendum vote commonly referred to as “Brexit,” a majority of British voters voted to exit the European Union. In March 2017, the U.K. government officially triggered the process to formally initiate negotiations for the terms of separation from the European Union. In June 2017, the U.K. government began negotiations to leave the European Union. A withdrawal could potentially disrupt the free movement of goods, services and people between the U.K. and the European Union, undermine bilateral cooperation in key geographic areas and significantly disrupt trade between the U.K. and the European Union or other nations as the U.K. pursues independent trade relations. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which European Union laws to replace or replicate. The effects of Brexit will depend on any agreements the U.K. makes to retain access to European Union or other markets either during a transitional period or more permanently. Because this is an unprecedented event, it is unclear what long-term economic, financial, trade and legal implications the withdrawal of the U.K. from the European Union will have and how such withdrawal could affect our business and applicable regulations in the U.K. and Europe. In addition, Brexit may lead other European Union member countries to consider referendums regarding their European Union membership. Any of these events, along with any political, economic and regulatory changes that may occur, could cause political and economic uncertainty in Europe and internationally and harm our business and financial results.

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. Healthcare market initiatives in the United States may also 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. 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.

We are an approved Medicare supplier and, in January 2018, CMS issued guidance clarifying that Medicare Part D Plan Sponsors may provide coverage for products such as the Omnipod System under the Medicare Part D prescription drug program. As a result, we must negotiate with third-party payors in order to provide our product through the pharmacy channel to users who are covered under Medicare Part D. Compliance with administrative procedures or requirements of these third-party payors may result in delays in processing approvals by those payors for patients to obtain Medicare Part D coverage for the use of the Omnipod System. Medicaid coverage decisions are made by the governing authorities in each state. As the Medicaid coverage process and stakeholders are unique to each state, the timeline to gain coverage in each state may vary.

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We expect to sell Omnipod DASH primarily through the pharmacy channel. As such, this may require new or amended agreements with our intermediaries and payors. The availability of Omnipod DASH may be limited or restricted if we are unable to secure the same level of reimbursement we currently have for the Omnipod.

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 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 suppliers we compete with include Tandem Diabetes Care, Inc. and Roche Holdings Ltd.

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 pump 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. While we believe that pump 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 pump 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. 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. 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

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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.

If our efforts to maintain the privacy and security of our customer, patient, third-party payor, employee, supplier or Company information are not successful, we could incur substantial additional costs and become subject to litigation, enforcement actions and reputational damage.

Our business, like that of most medical device manufacturers, involves the receipt, storage and transmission of patient information and payment and reimbursement information, as well as confidential information about third-party payors, our employees, our suppliers and our Company. Our information systems are vulnerable to an increasing threat of continually evolving cybersecurity risks. Unauthorized parties may attempt to gain access to our systems or information through fraud or other means of deceiving our employees or third-party service providers. Hardware, software or applications we develop or obtain from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information and device security. The methods used to obtain unauthorized access, disable or degrade service or sabotage systems are also constantly changing and evolving, and may be difficult to anticipate or detect for long periods of time. We have implemented and regularly review and update processes and procedures to protect against unauthorized access to or use of secured data and to prevent data loss. However, the ever-evolving threats mean we must continually evaluate and adapt our systems and processes, and our efforts may not be adequate to safeguard against all data security breaches, misuse of data or sabotage of our systems. Any future significant compromise or breach of our data security, whether external or internal, or misuse of customer, third-party payor, employee, supplier or Company data, could result in additional significant costs, lost sales, fines, lawsuits and damage to our reputation. In addition, as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could also result in additional costs.

Technological breakthroughs in diabetes monitoring, treatment or prevention could render the Omnipod System obsolete.

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, which was commercially launched in 2017 and 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.

Our own new product development initiatives may prove to be ineffective or not commercially successful.

We 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. 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, which allows us to incorporate a blood glucose meter into the Omnipod, is terminated 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 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 under patents and other relevant technical information relating to the FreeStyle blood glucose meter during the term of

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the agreement. As amended in December 2018, this agreement has been extended through January 2023. The agreement may be terminated prior to 2023 in the event of certain breaches by either party. Breach of the contract by us could lead to damages and result in a loss of the license. Such a loss in the near-term could require us to either remove the blood glucose meter from PDMs sold in the future, which could impair the functionality of the Omnipod, 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 to our customers. These could result in 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 in the United States. 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 or availability of the test strips may make the Omnipod 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 or sell future products without these rights.

Our non-insulin drug delivery product line faces challenges which, if not met, may impair its future success.

Our non-insulin drug delivery product line involves the development, manufacturing and sale of a modified Omnipod System for delivery of a specific drug other than insulin. The majority of our commercialized drug delivery revenue consists of sales of a customized version of our product for use in Amgen's Neulasta Onpro kit. The marketing and sales initiatives driving this product line 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 future results of our non-insulin drug delivery product line 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, or if our agreement with Amgen is terminated, our financial results could be materially and adversely impacted.

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;

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- 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

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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;
•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 claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance or pre-market approval from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. In December 2012 we received 501(k) clearance for our Omnipod. We have since obtained clearance for modified versions of this device, including Omnipod DASH. 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. Some of our future products may 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.

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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 the malfunction recurred. 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 and subsequently, the FDA Reauthorization Act of 2017, 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 is also sold in a number of European countries, Canada and Israel. 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 the Omnipod and in November 2017 we received CE Mark approval for Omnipod DASH. The CE Mark gives us authorization to distribute the Omnipod and Omnipod DASH 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 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 clear or approve 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.

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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, shipping and servicing 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.

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.
Further, under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in

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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.

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, contract laboratories and other third parties 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.

If we were found to be noncompliant with state DME licensure rules, 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.

Several states require that 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.

We are subject to federal, state and foreign 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 and certain patient and product support programs, we

may have with hospitals, physicians, patients or other potential purchasers of medical devices. These laws include, among others, the federal healthcare Anti-Kickback Statute, the federal civil 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 and programs 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, fines, damages, and exclusion

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from participation in federal health care programs. 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 OIG, CMS, and the Department of Justice, or may be subject to whistleblower lawsuits under federal and state false claims laws. 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.

We are subject to complex and evolving U.S. and foreign laws and regulations regarding privacy, data protection, and other matters. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, monetary penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

We are subject to a variety of laws and regulations in the United States and abroad that involve matters central to our business, including laws and regulations relating to privacy and data protection, rights of publicity, content, intellectual property, advertising, marketing, distribution, data security, data retention and deletion, personal information, electronic contracts and other communications, competition, protection of minors, consumer protection, telecommunications, product liability, taxation, economic or other trade prohibitions or sanctions, corrupt practices, fraud, waste and abuse restrictions, and securities law compliance. The introduction of new products or expansion of our activities in certain jurisdictions may subject us to additional laws and regulations. For example, data protection laws passed by the federal government, many states and foreign countries require notification to users when there is a security breach for personal data.

In addition, foreign data protection, privacy, and other laws and regulations can be more restrictive than those in the United States. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and/or processed within that country. We could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, as we continue to grow and expand our operations. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that make our products less useful to our customers, require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways. For example, the General Data Protection Regulation ("GDPR") is a comprehensive update to the data protection regime in the European Economic Area that is effective in fiscal 2018. The GDPR imposes new requirements relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third party processors. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties for noncompliance with the GDPR, and amounts could be significant.

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

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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 customers.

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, competition, 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 could 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 could 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,		
	2018	2017	2016
Amgen, Inc.	12%	15%	17%
Ypsomed Distribution AG and affiliates	*	22%	16%
Cardinal Health Inc. and affiliates	12%	11%	10%

* 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.

Our Omnipod System inventory is produced in a limited number of locations and we maintain our Omnipod System inventory in a limited number of locations globally.

Until our U.S. manufacturing facility is fully operational, all of our manufacturing of complete Omnipod Systems will be 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.

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In addition, substantially all of our domestic Omnipod System inventory is held at a single location in Massachusetts. Additionally, our European Omnipod System inventory is maintained by a third-party logisitcs entity primarily in a single location in the Netherlands. 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 start-up and commissioning of our new 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 are completing the construction of a highly-automated manufacturing facility in Acton, Massachusetts. As we commence operation of this facility for the production of our product, we could experience quality issues and unexpected operational delays that will decrease our gross margins and cause a shortage of product supply.

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

Over the last several 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 and promoted employees. As such, our success will depend on our ability to retain our employees, both domestically and abroad, 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 new and promoted employees and executives be largely seamless. 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 and we may not be able to deliver the Omnipod System in a timely manner, which could harm our results of operations.

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, Canada and Israel. 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, including the European, 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.

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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 intermediaries, our business, prospects and brand may be materially and adversely affected.

We currently promote, market and sell the majority of the Omnipod System through our own direct sales force. However, we also utilize domestic and international intermediaries to distribute our product to end-users. We cannot assure you that we will be able to successfully develop our relationships with third-party intermediaries. 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. Intermediaries that are in the business of selling other medical products may not devote a sufficient level of resources and the support required to generate awareness of our products and grow or maintain product sales. If our intermediaries 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.

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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 our products;
- 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 our products 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 Convertible Senior Notes may dilute the ownership interest of existing stockholders or depress our stock price.

The conversion of some or all of our 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

In December 2018, we substantially completed the construction of our 195,000 square foot U.S. manufacturing and office facility in Acton, Massachusetts. The property serves as our global headquarters. We also lease a total of approximately 149,000 square feet of office, research and development and warehousing space and other related facilities primarily in the U.S., Europe and Canada.

Item 3. Legal Proceedings

The information required by this Item is provided under "Legal Proceedings" in Note 14 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.

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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 2017		
First Quarter	$47.22	$36.98
Second Quarter	$51.31	$39.10
Third Quarter	$59.46	$49.49
Fourth Quarter	$71.80	$55.67
Fiscal Year 2018		
First Quarter	$87.20	$68.49
Second Quarter	$101.93	$83.27
Third Quarter	$108.13	$81.43
Fourth Quarter	$105.19	$73.27

As of February 20, 2019, there were approximately 8 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, 2013 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, 2018. The historical stock price performance of our common stock shown in the performance graph below is not necessarily indicative of future stock price performance.

	2013	2014	2015	2016	2017	2018
Insulet Corporation	$100	$124	$102	$102	$186	$214
NASDAQ Composite	100	115	123	133	172	166
NASDAQ Health Care	100	129	135	111	133	126

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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, 2018.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	2,398,286	$ 40.38	4,439,383
Equity compensation plans not approved by security holders[2]	679,338	$ 34.87	—
Total	3,077,624	$ 39.16	4,439,383

[1] Includes our Amended and Restated 2017 and 2007 Stock Option and Incentive Plans. Outstanding restricted stock units convert to common stock without the payment of consideration. As of December 31, 2018, 752,207 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 $40.38. For more information relating to our equity compensation plans, see Note 15 to our consolidated financial statements.

[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 79,936 non-qualified stock options made to Shacey Petrovic upon being hired by us in February 2015;
- one inducement grant of 58,852 non-qualified stock options made to Michael Levitz upon being hired by us in May 2015;
- one inducement grant of 29,581 non-qualified stock options made to David Colleran (1,849 of which have been exercised as of December 31, 2018) upon being hired by us in June 2015; and
- one inducement grant of 30,511 non-qualified stock options made to Michael Spears (17,161 of which have been exercised as of December 31, 2018) upon being hired by us in July 2015.

These non-qualified stock option awards were granted outside of our Amended and Restated 2007 Stock Option and Incentive Plan in compliance with Nasdaq Listing Rule 5635.

Issuer Repurchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended December 31, 2018, nor issue any securities that were not registered under Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

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Item 6. Selected Financial Data

	Years Ended December 31,				
(In thousands, except share and per share data)	2018	2017	2016	2015	2014
Consolidated Statements of Operations Data:					
Revenue	$563,823	$463,768	$366,989	$263,893	$231,321
Cost of revenue	193,655	186,599	155,903	130,622	104,195
Gross profit	370,168	277,169	211,086	133,271	127,126
Total operating expenses	342,745	284,556	221,790	182,007	136,000
Operating income (loss)	27,423	(7,387)	(10,704)	(48,736)	(8,874)
Interest expense and other, net	(22,197)	(19,187)	(16,114)	(12,654)	(39,006)
Net income (loss) from continuing operations	3,292	(26,831)	(27,210)	(61,602)	(47,940)
Loss from discontinued operations, net of tax	—	—	(1,669)	(11,918)	(3,560)
Net income (loss)	$3,292	$(26,831)	$(28,879)	$(73,520)	$(51,500)
Net income (loss) from continuing operations per share:					
Basic	$0.06	$(0.46)	$(0.48)	$(1.08)	$(0.86)
Diluted	$0.05	$(0.46)	$(0.48)	$(1.08)	$(0.86)
Net loss from discontinued operations per share	—	—	(0.03)	(0.21)	(0.06)
Weighted-average number of shares used in calculating net income (loss) per share					
Basic	58,859,574	58,003,434	57,251,377	56,785,646	55,628,542
Diluted	61,008,024	58,003,434	57,251,377	56,785,646	55,628,542

	As of December 31,				
(In thousands)	2018	2017	2016	2015	2014
Consolidated Balance Sheets Data:					
Cash and cash equivalents	$113,906	$272,577	$137,174	$122,672	$151,193
Short-term investments	$175,040	$167,479	$161,396	$—	$—
Working capital	$345,629	$451,146	$314,263	$125,605	$163,900
Long-term investments	$140,784	$125,549	$—	$—	$—
Total assets	$928,744	$816,744	$456,647	$275,126	$297,182
Current portion of long-term debt and capital lease obligations	$—	$—	$269	$5,519	$3,380
Long-term debt and capital lease obligations	$591,978	$566,173	$332,768	$171,967	$166,283
Other long-term liabilities	$9,010	$6,030	$5,032	$3,952	$2,774
Total stockholders' equity	$212,099	$158,516	$63,150	$34,051	$83,829

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

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

In addition to the diabetes market space, we have partnered with pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of subcutaneous drugs across other therapeutic areas. The majority of our drug delivery revenue currently consists of sales of pods used in Amgen's Neulasta Onpro kit, an innovative delivery system for Amgen's white blood cell booster to help reduce the risk of infection during intense chemotherapy.

We have substantially completed the construction of a highly-automated manufacturing facility in Acton, Massachusetts, with planned production out of the facility beginning in the first half of 2019. The facility also serves as our global headquarters. We expect that, following start up related activities, the new facility will allow us to lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base and support growth. From the purchase of this facility in late 2016 through December 31, 2018, capital expenditures for the construction of the Acton facility and related equipment purchases have been approximately $193 million. In 2019, we expect to invest additional capital in this facility to support our growth funded by our existing cash and investments.

In January 2018, we announced that the Centers for Medicare & Medicaid Services ("CMS") has issued guidance clarifying that Medicare Part D Plan Sponsors may provide coverage for products such as the Omnipod System under the Medicare Part D (prescription drug) program. We have been securing coverage with Medicare Part D carriers to ensure beneficiaries living with diabetes have access to the Omnipod System. Securing Medicare Part D coverage also provides us with a direct pathway to increased Medicaid coverage at the state level, as many state-run Medicaid programs follow CMS prescription drug guidance to determine coverage. This allows access for lower-income individuals and families on Medicaid for whom Omnipod currently is not a covered option. In April 2018, we also significantly increased our market access when we secured in-network coverage of Omnipod with United Healthcare, the largest commercial payer in the United States.

In June 2018, the FDA provided clearance for the commercial distribution of our DASH ™ System, which is our next-generation digital mobile Omnipod platform, featuring a secured Bluetooth enabled Pod and PDM with a touch screen color user interface supported by smartphone connectivity. We commenced a U.S. limited commercial release of Omnipod DASH ™ in the third quarter of 2018 prior to a U.S. full market launch in the first half of 2019.

2018 Revenue Results:

- Total revenue of $563.8 million
- U.S. Omnipod revenue of $323.5 million, a 19% increase year over year
- International Omnipod revenue of $172.0 million, a 43% increase year over year
- Drug Delivery revenue of $68.3 million, a 5% decrease year over year

Our long-term financial objective is to sustain profitable growth. We expect our efforts in 2019 to focus primarily on commissioning our U.S. manufacturing facility, commencing a U.S. full market release of Omnipod DASH, continuing our

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product development efforts, and continuing to work with Medicare, Medicaid and commercial payors and intermediaries to expand access. Achieving these objectives is expected to require additional investments in certain initiatives and personnel, as well as enhancements to our supply chain operation capacity, efficiency and effectiveness.

Components of Financial Operations

Revenue. We derive the majority of our revenue from global sales of the Omnipod System. We also sell devices based on the Omnipod System technology to global pharmaceutical and biotechnology companies for the delivery of their drugs across therapeutic areas.

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

Research and development. Research and development expenses consist primarily of personnel costs, license fees and outside service expenses within our product development, regulatory and clinical functions and well as innovations related to our global supply chain and manufacturing process. Research and development expenses also include engineering and operational costs, such as training and start up activities, associated with our newly constructed U.S. manufacturing facility. We generally expense research and development costs as incurred.

Sales and marketing. Sales and marketing expenses consist primarily of personnel costs within our sales, marketing, reimbursement support and customer care functions, as well as sales commissions paid to our sales representatives, costs associated with promotional activities and participation in industry trade shows. Commission costs that are direct and incremental to obtaining a new customer are capitalized and amortized to sales and marketing expense over the expected period of benefit.

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

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Results of Operations

This section discusses our consolidated results of operations for 2018 compared to 2017, as well as 2017 compared to 2016, and should be read in conjunction with the consolidated financial statements and accompanying notes included under Item 8 of this Form 10-K.

TABLE 1: RESULTS OF OPERATIONS

	Years Ended December 31,				Years Ended December 31,			
			Change				Change	
(In Thousands)	2018	2017	$	%	2017	2016	$	%
Revenue								
U.S. Omnipod	$323,528	$271,597	$51,931	19 %	$271,597	$229,785	$41,812	18 %
International Omnipod	172,020	119,953	52,067	43 %	119,953	71,889	48,064	67 %
Drug Delivery	68,275	72,218	(3,943)	(5)%	72,218	65,315	6,903	11 %
Total Revenue	563,823	463,768	100,055	22 %	463,768	366,989	96,779	26 %
Cost of revenue	193,655	186,599	7,056	4 %	186,599	155,903	30,696	20 %
Gross profit	370,168	277,169	92,999	34 %	277,169	211,086	66,083	31 %
Gross margin	65.7 %	59.8 %			59.8 %	57.5 %		
Operating expenses:								
Research and development	88,606	74,452	14,154	19 %	74,452	55,710	18,742	34 %
Sales and marketing	142,321	121,617	20,704	17 %	121,617	94,483	27,134	29 %
General and administrative	111,818	88,487	23,331	26 %	88,487	71,597	16,890	24 %
Total operating expenses	342,745	284,556	58,189	20 %	284,556	221,790	62,766	28 %
Operating income (loss)	27,423	(7,387)	34,810	471 %	(7,387)	(10,704)	3,317	31 %
Interest expense and other, net	(22,197)	(19,187)	(3,010)	16 %	(19,187)	(16,114)	(3,073)	19 %
Income (loss) from continuing operations before income taxes	5,226	(26,574)	31,800	120 %	(26,574)	(26,818)	(244)	(1)%
Income tax expense	1,934	257	1,677	653 %	257	392	(135)	(34)%
Net income (loss) from continuing operations	3,292	(26,831)	33,477	125 %	(26,831)	(27,210)	(379)	(1)%
Loss from discontinued operations, net of tax	—	—	—		—	(1,669)	1,669	
Net income (loss)	$3,292	$(26,831)	$30,123	112 %	$(26,831)	$(28,879)	$2,048	7 %

Comparison of the Years Ended December 31, 2018 and December 31, 2017

Revenue

Our total revenue increased to $563.8 million, up $100.1 million, or 22%, in 2018 compared to 2017, primarily due to continued growth in our International and U.S. Omnipod revenue. Our International Omnipod revenue increased to $172.0 million, up $52.1 million, or 43%, primarily due to both higher volumes and pricing as a result of our commencement of direct sales of our Omnipod System across Europe following the expiration of our prior distribution agreement with our former European Distributor on June 30, 2018. Our U.S. Omnipod revenue increased to $323.5 million, up $51.9 million, or 19%, as we continue to expand access to and awareness of the Omnipod System. Our drug delivery revenue declined to $68.3 million, down $3.9 million, or 5%, primarily reflecting a lower number of shipments during the year, partially offset by the favorable impact of adoption of new accounting rules that require a portion of our drug delivery revenue to be recognized as the product is produced rather than at time of shipment (as further described in Note 2 to the consolidated financial statements).

For 2019, we expect strong revenue growth driven by continued Omnipod expansion globally, partially offset by lower drug delivery revenue. Internationally, we expect higher revenues primarily due to increasing sales and the full year effect of more favorable pricing as a result of our mid-2018 transition to direct commercial operations in Europe. In the U.S., we expect higher revenues primarily due to increasing sales as a result of expanded payor coverage and greater awareness and availability for the Omnipod.

Cost of Revenue

Cost of revenue increased to $193.7 million, up $7.1 million, or 4%, in 2018 compared to 2017, primarily due to an increase in sales volumes, partially offset by improvements in supply chain operations in 2018.

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Gross Margin

Gross margin increased to 65.7%, up approximately 590 basis points, in 2018 compared to 2017. The increase in gross margin was due primarily to (i) favorable pricing following expiration of our former distributor agreement in Europe and (ii) lower product cost as a result of continued improvements in manufacturing and supply chain operations. For 2019, we expect full-year gross margins to be relatively consistent with 2018, as the benefits of continued improvements in manufacturing and supply chain operations and the full year effect of our mid-2018 assumption of direct commercial operations in Europe is expected to be offset by start-up costs and inefficiencies as we ramp up our new U.S. manufacturing operations.

Research and Development

Research and development expenses increased to $88.6 million, up $14.2 million, or 19%, in 2018 as compared to 2017. The increase in research and development expenses was primarily due to an increase in expenses related to our development projects, including Omnipod DASH, and our Omnipod Horizon automated insulin delivery system. Research and development expenses also increased due to engineering and operational costs, such as training and start up activities, associated with our newly constructed U.S. manufacturing facility, with planned production beginning in the first half of 2019. For 2019, we expect overall research and development spending to increase as compared to 2018 primarily due to the development efforts on our ongoing projects.

Sales and Marketing

Sales and marketing expenses increased to $142.3 million, up $20.7 million, or 17%, in 2018 as compared to 2017. The increase in sales and marketing expenses was primarily due to investments to support our assumption in mid-2018 of direct commercial operations in Europe as well as the expansion of our U.S. sales force and customer support personnel. These increases were partially offset by the capitalization of commission costs related to new customer contracts (as further described in Note 8 to the consolidated financial statements). We expect sales and marketing expenses in 2019 to increase as compared to 2018 due to additional expansion of our U.S. sales force and customer support personnel to support our continued growth and the full year effect of our mid-2018 assumption of direct commercial operations in Europe.

General and Administrative

General and administrative expenses increased to $111.8 million, up $23.3 million, or 26% in 2018 as compared to 2017. General and administrative expenses in the current year include $12.6 million of severance-related charges associated with the retirement of our former CEO, of which $8.2 million related to stock-based compensation for the acceleration of share-based awards and the remainder represented cash severance benefits. General and administrative expenses also increased due to our commencement of direct commercial operations in Europe. For 2019, we expect overall general and administrative expenses to increase as compared to 2018 as we continue to grow the business and make investments in our operating structure to support continued growth as well as the full-year effect of our establishment of direct commercial operations in Europe in 2018.

Interest Expense and Other, Net

Interest expense and other, net, increased to $22.2 million, up $3.0 million, or 16%, for 2018, compared to 2017. Interest expense and other, net, includes $9.8 million of cash interest expense and $29.3 million of non-cash interest expense associated with our convertible debt, partially offset by $10.2 million of interest capitalized as part of the cost of our U.S. manufacturing facility and by $6.7 million of interest income on our investment portfolio. The increase in interest expense and other, net, in the current period as compared to 2017 was primarily due to the full year effect of interest expense associated with our 1.375% Notes, which were issued in November 2017, partially offset by an increase in capitalized interest expense and higher interest income on our investment portfolio in the current period. We expect that our interest expense and other, net, will be relatively consistent in 2019 compared to the prior year.

Income Tax Expense

Income tax expense increased to $1.9 million, up $1.7 million for 2018 compared to 2017. The increase in income tax expense was primarily due to growth in our international operations where we do not have net operating loss carryforwards. For more information on our income tax expense, please refer to Note 17 to the consolidated financial statements.

Comparison of the Years Ended December 31, 2017 and December 31, 2016

Revenue

Our total revenue increased to $463.8 million, up $96.8 million, or 26% in 2017 as compared to 2016, due to strong growth in our International Omnipod revenue and our U.S. Omnipod revenue. Our International Omnipod revenue increased to $120.0 million, up $48.1 million, or 67%, primarily due to growth in distributor sales from continued adoption in existing and newer markets within Europe. Our U.S. Omnipod revenue increased to $271.6 million, up $41.8 million, or 18%, as we continue to expand awareness of the Omnipod System. Our drug delivery revenue increased to $72.2 million, up $6.9 million, or 11%, due to growth in demand for our primary drug delivery device on greater market adoption of Amgen's Neulasta Onpro kit.

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Cost of Revenue

Cost of revenue increased to $186.6 million, up $30.7 million, or 20%, in 2017 as compared to 2016, primarily due to an increase in sales volumes, partially offset by improvements in supply chain operations in 2017.

Gross Margin

Gross margin increased to 59.8%, up approximately 230 basis points, in 2017 as compared to 2016. The increase in gross margin was primarily due to improvements in supply chain operations, partially offset by the unfavorable mix impact of higher distributor sales in Europe.

Research and Development

Research and development expenses increased to $74.5 million, up $18.7 million, or 34%, in 2017 as compared to 2016. The increase was primarily due to an increase in expenses related to our development projects.

Sales and Marketing

Sales and marketing expenses increased to $121.6 million, up $27.1 million, or 29% in 2017 as compared to 2016. The increase was primarily due increased personnel-related expenses associated with the expansion of our customer support, market access and sales force personnel, investments to support our assumption of direct commercial support for Omnipod in Europe in mid-2018, and increased advertising expenses associated with direct to patient marketing activities.

General and Administrative

General and administrative expenses increased to $88.5 million, up $16.9 million, or 24% in 2017 as compared to 2016. The increase was primarily attributable to increased personnel-related costs and fees related to external consultants and professional service providers to support the growth in our business.

Interest Expense and Other, Net

Interest expense and other, net, increased to $19.2 million, up $3.1 million, or 19%, in 2017 as compared to 2016. The increase in interest expense and other, net, was primarily due to a net increase in our outstanding long-term debt, partially offset by lower losses on the extinguishment of debt in 2017. Non-cash interest expense increased $7.9 million and cash interest expense increased $1.8 million in 2017 as compared to 2016. These increases were partially offset by a $1.9 million reduction in losses on the extinguishment of debt in 2017, higher capitalization of interest, and higher interest income.

Income Tax Expense

Income tax expense was not material to our results of operations in the years 2017 or 2016 as we had generated net operating losses and have fully reserved our net operating loss carryforwards. For more information on our income tax expense, refer to Note 17 to the consolidated financial statements.

Liquidity and Capital Resources

As of December 31, 2018, we had $113.9 million in cash and cash equivalents and $315.8 million of investments in marketable securities. We believe that our current liquidity will be sufficient to meet our projected operating, investing and debt service requirements for at least the next twelve months.

To lower our manufacturing costs, increase supply redundancy, add capacity closer to our largest customer base and support growth, we have been constructing a highly-automated manufacturing facility in Acton, Massachusetts, which serves as our corporate headquarters. The facility was substantially complete in December 2018, with planned production out of the facility beginning in the first half of 2019. Our capital expenditures have increased above historic levels to fund the construction of this facility and related equipment purchases. As of December 31, 2018, cumulative investments related to the Acton facility were approximately $193 million. While we expect to continue to invest in this facility in 2019 to support our growth, we expect capital expenditures to be substantially lower in 2019 than in 2018.

In connection with our assumption on July 1, 2018 of all commercial activities of our Omnipod System across Europe following the expiration of our distribution agreement with our European Distributor on June 30, 2018, we are required to pay to the former European Distributor a per-unit fee for Omnipod sales by us between July 1, 2018 and June 30, 2019 to certain customers of the former European Distributor. We are recognizing a liability and an associated intangible asset for this fee as qualifying sales occur. The actual total fee could vary significantly

depending on the number of customers who count for purposes of calculating the fee under the terms of the distribution agreement, and the methodology applicable for determining this number under the agreement is subject to an active arbitration proceeding between the parties in Switzerland. We estimate that the final aggregate fee for the applicable twelve-month period could be in the range of approximately $10 million to $55 million.

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Convertible Senior Notes

To finance our operations and global expansion, we have periodically issued and sold Convertible Senior Notes, which are convertible into our common stock. As of December 31, 2018, the following Notes were outstanding:

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

We called our 2% Notes in March 2018 and settled the outstanding notes in May 2018. Additional information regarding our debt issuances is provided in Note 13 to the consolidated financial statements included under Item 8 of this Form 10-K.

Summary of Cash Flows	Years Ended December 31,		
(In thousands)	2018	2017	2016
Cash provided by (used in):			
Operating activities	$35,899	$41,207	$15,911
Investing activities	(184,504)	(210,797)	(178,010)
Financing activities	(8,665)	304,547	176,567
Effect of exchange rate changes on cash	(1,401)	446	34
Net (decrease) increase in cash and cash equivalents	$(158,671)	$135,403	$14,502

Included in our summary of cash flows for the years ended December 31, 2016 are the results of our discontinued operations. Additional information regarding our discontinued operations is provided in Note 19 to the consolidated financial statements included under Item 8 of this Form 10-K.

Operating Activities

Our net cash provided by operating activities for the year ended December 31, 2018 was $35.9 million compared to net cash provided by operating activities of $41.2 million in 2017, a decrease of $5.3 million year over year. The decrease in cash provided by operating activities in the current year is primarily due to investments in working capital, including increases in inventory levels to ensure we can meet the growing global demand for our products and in anticipation of the start-up of our U.S. manufacturing facility in the first half of 2019. These increases in working capital were partially offset by increases in our operating income due to growth in our business.

Our net cash provided by operating activities was $41.2 million for the year ended December 31, 2017 compared to net cash provided by operating activities of $15.9 million in the same period in 2016. The increase was primarily due to a decline in working capital in 2017 as compared to increases in working capital in 2016 primarily associated with inventory.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2018 was $184.5 million compared to $210.8 million in 2017, a decrease of $26.3 million. The decrease in investing activities in the current year is primarily due to lower net purchases of marketable securities, partially offset by an increase in capital expenditures in the current period, which were $162.4 million in 2018 compared to $77.2 million in 2017, primarily associated with the construction of our manufacturing and corporate headquarters facility in Acton, Massachusetts.

Net cash used in investing activities in 2017 increased $32.8 million as compared to 2016 due to higher capital expenditures, partially offset by fewer net investments in marketable securities.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2018 was $8.7 million compared to cash provided by financing activities of $304.5 million in 2017, a decrease of $313.2 million. The decrease was primarily attributable to net proceeds in 2017 from the issuance of our 1.375% Notes, offset by repayments to retire previously outstanding debt. No such financing took place in 2018.

Net cash provided by financing activities in the year ended December 31, 2017 was $304.5 million compared to $176.6 million in net cash provided by financing activities in 2016, an increase of $127.9 million. The increase was primarily attributable to

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net proceeds of $391.6 million from the issuance of our 1.375% Notes in 2017 as compared to net proceeds of $333.7 million from the issuance in 2016 of our 1.25% Notes, and lower repayments to retire outstanding debt in the 2017 as compared to 2016.

Commitments and Contingencies

Our lease commitments related to facility operating leases are shown in the table below.

The following table summarizes our principal obligations as of December 31, 2018:

(In millions)

Contractual Obligations [3]	Total	2019	2020	2021	2022	2023	Later
Operating lease obligations	$12.5	$3.3	$2.9	$2.9	$2.6	$0.3	$0.5
Debt obligations: principal [1]	747.5	—	—	345.0	—	—	402.5
Debt obligations: cash interest [1]	44.0	9.8	9.8	8.6	5.5	5.5	4.8
Purchase obligations[2]	185.2	162.8	22.4	—	—	—	—
Total contractual obligations	$989.2	$175.9	$35.1	$356.5	$8.1	$5.8	$407.8

(1) Debt obligations include principal and cash interest.

(2) Our purchase obligations include commitments with certain of our suppliers, primarily for the purchase of Omnipod System components 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. Purchase obligations also include approximately $80 million of commitments related to our Acton, Massachusetts manufacturing facility.

(3) The contractual obligations table excludes fees that we are required to pay to our former European distributor following the expiration of our global distribution agreement on June 30, 2018. The actual amount of the fee is uncertain and is dependent on a number of factors.

Legal Proceedings

The significant estimates and judgments related with establishing litigation reserves are discussed under "Legal Proceedings" in Note 14 of the consolidated financial statements included under Item 8 of this Form 10-K.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet financing arrangements.

Critical Accounting Policies and Estimates

Our financial statements are based on the selection and application of generally accepted accounting principles, which require us to make estimates and assumptions about future events that affect the amounts reported in our financial statements and the accompanying 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
- Fair value measurements
- Accounts receivable and allowance for doubtful accounts
- Inventories
- Product warranty costs
- Convertible debt
- Commitments and contingencies
- Stock-based compensation

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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.

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Item 7A. Quantitative and Qualitative Disclosures about Market Risk

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

As of December 31, 2018, we had outstanding debt related to our convertible senior notes recorded on our consolidated balance sheet of $592.0 million, net of unamortized discount and issuance costs totaling $155.5 million. Changes in the fair value of our outstanding debt, which could be impacted by changes in interest rates, are not recorded in these consolidated financial statements as the debt is accounted for at cost less unamortized discount and issuance costs. The fair value of the debt, which is disclosed in Note 4 to the consolidated financial statements, is also impacted by changes on our stock price.

Our business is subject to risks, including, but not limited to: unique economic conditions, changes in political climate, differing tax structures, other regulations and restrictions, and foreign exchange rate volatility. A substantial portion of our operations are located in the United States, and the majority of our sales since inception have been made in United States dollars. During 2018, following the assumption of direct operations in Europe, our business became more exposed to foreign currency exchange rate fluctuations. Fluctuations in the rate of exchange between the United States dollar and foreign currencies, primarily the Euro and the British Pound, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

Item 8. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2018 and 2017 and for each of the three years in the period ended December 31, 2018, and the Report of the Registered Independent Public Accounting Firm are included in this report as listed in the index.

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Report of Independent Registered Public Accounting Firm

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Insulet Corporation
Opinion on the financial statements
We have audited the accompanying consolidated balance sheets of Insulet Corporation (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and schedule (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.
We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company’s internal control over financial reporting as of December 31, 2018, 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 25, 2019 expressed an unqualified opinion.
Basis for opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP
We have served as the Company's auditor since 2016.

Boston, Massachusetts
February 25, 2019

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INSULET CORPORATION
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)	December 31, 2018	December 31, 2017
ASSETS		
Current Assets		
Cash and cash equivalents	$ 113,906	$ 272,577
Short-term investments	175,040	167,479
Accounts receivable, net	63,294	53,373
Unbilled receivable	13,378	—
Inventories	71,414	33,793
Prepaid expenses and other current assets	24,254	9,949
Total current assets	461,286	537,171
Long-term investments	140,784	125,549
Property and equipment, net	258,379	107,864
Other intangible assets, net	10,383	4,351
Goodwill	39,646	39,840
Other assets	18,266	1,969
Total assets	$ 928,744	$ 816,744
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 25,500	$ 24,413
Accrued expenses and other current liabilities	88,973	59,256
Deferred revenue	1,184	2,356
Total current liabilities	115,657	86,025
Long-term debt, net	591,978	566,173
Other long-term liabilities	9,010	6,030
Total liabilities	716,645	658,228
Commitments and contingencies (Note 14)		
Stockholders' Equity		
Preferred stock, $.001 par value: Authorized: 5,000,000 shares at December 31, 2018 and 2017. Issued and outstanding: zero shares at December 31, 2018 and 2017	—	—
Common stock, $.001 par value: Authorized: 100,000,000 shares at December 31, 2018 and 2017. Issued and outstanding: 59,188,758 and 58,319,348 shares at December 31, 2018 and 2017, respectively	59	58
Additional paid-in capital	898,559	866,206
Accumulated other comprehensive loss	(2,905)	(493)
Accumulated deficit	(683,614)	(707,255)
Total stockholders' equity	212,099	158,516
Total liabilities and stockholders' equity	$ 928,744	$ 816,744

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

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INSULET CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
(In thousands, except share and per share data)	2018	2017	2016
Revenue	$563,823	$463,768	$366,989
Cost of revenue	193,655	186,599	155,903
Gross profit	370,168	277,169	211,086
Operating expenses:			
Research and development	88,606	74,452	55,710
Sales and marketing	142,321	121,617	94,483
General and administrative	111,818	88,487	71,597
Total operating expenses	342,745	284,556	221,790
Operating income (loss)	27,423	(7,387)	(10,704)
Interest expense	28,902	21,211	14,388
Interest income and other, net	6,705	2,633	825
Loss on extinguishment of long-term debt	—	609	2,551
Interest and other income (expense), net	(22,197)	(19,187)	(16,114)
Income (loss) from continuing operations before income taxes	5,226	(26,574)	(26,818)
Income tax expense	1,934	257	392
Net income (loss) from continuing operations	3,292	(26,831)	(27,210)
Loss from discontinued operations, net of tax	—	—	(1,669)
Net income (loss)	$3,292	$(26,831)	$(28,879)
Net income (loss) from continuing operations per share:			
Basic	$0.06	$(0.46)	$(0.48)
Diluted	$0.05	$(0.46)	$(0.48)
Net loss from discontinued operations per share basic and diluted	$—	$—	$(0.03)
Weighted-average number of shares used in calculating net income (loss) per share:			
Basic	58,859,574	58,003,434	57,251,377
Diluted	61,008,024	58,003,434	57,251,377

The accompanying notes are an integral part of these consolidated financial statements.
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INSULET CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Years Ended December 31,		
(In thousands)	2018	2017	2016
Net income (loss)	$3,292	$(26,831)	$(28,879)
Other comprehensive (loss) income, net of tax			
Foreign currency translation adjustment, net of tax	(2,174)	565	135
Unrealized loss on available-for-sale securities, net of tax	(238)	(332)	(207)
Total other comprehensive (loss) income, net of tax	(2,412)	233	(72)
Total comprehensive income (loss)	$880	$(26,598)	$(28,951)

The accompanying notes are an integral part of these consolidated financial statements.
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INSULET CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share data)	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
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
Exercise of options to purchase common stock	505,207	1	13,987			13,988
Issuance for employee stock purchase plan	59,134	—	1,817			1,817
Stock-based compensation expense			31,941			31,941
Restricted stock units vested, net of shares withheld for taxes	297,040	—	(4,054)			(4,054)
Allocation to equity for conversion feature on 1.375% Notes, net of issuance costs			117,458			117,458
Extinguishment of conversion feature on 2% Notes, net of issuance costs			(39,186)			(39,186)
Net loss				(26,831)		(26,831)
Other comprehensive income					233	233
Balance, December 31, 2017	58,319,348	58	866,206	(707,255)	(493)	158,516
Exercise of options to purchase common stock, net of shares withheld and retired to satisfy cashless exercises	409,428	1	12,798			12,799
Issuance for employee stock purchase plan	46,343	—	3,029			3,029
Stock-based compensation expense			37,521			37,521
Restricted stock units vested, net of shares withheld for taxes	413,639	—	(17,785)			(17,785)
Extinguishment of conversion feature on 2% Notes, net of issuance costs			(3,210)			(3,210)
Adoption of ASC 606 (Note 2)				20,349		20,349
Net income				3,292		3,292
Other comprehensive loss					(2,412)	(2,412)
Balance, December 31, 2018	59,188,758	$ 59	$ 898,559	$ (683,614)	$ (2,905)	$ 212,099

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

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INSULET CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Years Ended December 31, 2018	2017	2016
Cash flows from operating activities			
Net income (loss)	$3,292	$(26,831)	$(28,879)
Adjustments to reconcile net income (loss) to net cash provided by operating activities			
Depreciation and amortization	15,646	13,854	13,833
Non-cash interest expense	29,282	18,008	10,068
Stock-based compensation expense	37,521	31,941	23,617
Loss on extinguishment of long-term debt	—	609	2,551
Provision for bad debts	3,382	1,922	2,070
Impairments and other	(401)	89	6,234
Changes in operating assets and liabilities:			
Accounts receivable	(22,879)	(26,322)	12,551
Inventories	(38,826)	1,689	(24,103)
Deferred revenue	(3,787)	1,061	(849)
Prepaid expenses and other assets	(11,601)	(3,328)	(2,621)
Accounts payable, accrued expenses and other current liabilities	21,187	27,313	639
Other long-term liabilities	3,083	1,202	800
Net cash provided by operating activities[1]	35,899	41,207	15,911
Cash flows from investing activities			
Purchases of property, equipment and intangible assets [2]	(162,354)	(77,226)	(22,115)
Purchases of investments	(191,424)	(297,965)	(177,654)
Receipts from the maturity or sale of investments	169,274	164,394	16,045
Proceeds from divestiture of business, net	—	—	5,714
Net cash used in investing activities	(184,504)	(210,797)	(178,010)
Cash flows from financing activities			
Principal payments of capital lease obligations	—	(269)	(5,518)
Proceeds from issuance of convertible notes, net of issuance costs	—	391,638	333,725
Repayment of convertible notes	(6,699)	(98,572)	(153,628)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	15,815	15,804	4,854
Payment of withholding taxes in connection with vesting of restricted stock units	(17,781)	(4,054)	(2,866)
Net cash (used in) provided by financing activities	(8,665)	304,547	176,567
Effect of exchange rate changes on cash	(1,401)	446	34
Net (decrease) increase in cash, cash equivalents and restricted cash	(158,671)	135,403	14,502
Cash, cash equivalents and restricted cash, beginning of year [3]	272,577	137,174	122,672
Cash, cash equivalents and restricted cash, end of year [3]	$113,906	$272,577	$137,174
Supplemental disclosure of cash flow information			
Cash paid for interest, net of amount capitalized	$—	$2,476	$3,687
Cash paid for taxes	$795	$462	$932
Non-cash investing and financing activities			
Allocation to equity for conversion feature for issuance of 1.375% convertible notes	$—	$120,710	$—
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	$—	$(39,186)	$(32,865)

(1) Includes activity related to discontinued operations for the year ended December 31, 2016. See Note 19 to the consolidated financial statements for discussion of discontinued operations.
(2) Cash outflows from purchases of property, equipment and intangible assets for the years ended December 31, 2018 and 2017 include $4.0 million and $2.0 million, respectively, of purchases made in prior periods that were included in accounts payable and accrued expenses as of December 31, 2017 and 2016, respectively, and exclude $11.5 million and $4.0 million of purchases made during the year ended December 31, 2018 and 2017, respectively, that were included in accounts payable and accrued expenses as of December 31, 2018 and 2017, respectively.
(3) Cash and cash equivalents includes restricted cash amounts totaling $2.7 million, $0.5 million and $1.2 million as of December 31, 2018, 2017 and 2016, respectively. See Note 2 to the consolidated financial statements.

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

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 System, an innovative, discreet and easy-to-use continuous insulin delivery system for people with insulin-dependent diabetes. There are two primary types of insulin therapy practiced today: multiple daily injection (“MDI”) therapy using syringes or insulin pens; and pump therapy using insulin pumps. Insulin pumps are used to perform continuous subcutaneous insulin infusion, or insulin pump therapy, and typically use a programmable device and an infusion set to administer insulin into the person’s body. Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. The Company estimates that approximately one-third of the Type 1 diabetes population in the United States and less than one fifth of the Type 1 diabetes population outside the United States uses insulin pump therapy. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod device, which is worn on the body for approximately three days at a time (the "Pod"), and its wireless companion, the handheld Personal Diabetes Manager ("PDM"). The Omnipod System, which features two discreet, easy-to-use devices, communicates wirelessly, provides for virtually pain-free automated cannula insertion and eliminates the need for traditional MDI therapy or the use of traditional pump and tubing. The Company believes that the Omnipod System’s unique proprietary design and features allow people with insulin-dependent diabetes to manage their diabetes with unprecedented freedom, comfort, convenience, and ease.

Commercial sales of the Omnipod Insulin Management System ("Omnipod") began in the United States in 2005. The Company sells the Omnipod through direct sales to customers or through intermediaries. The Omnipod is also currently available in multiple countries in Europe, as well as in Canada and Israel. On July 1, 2018, the Company commenced direct commercial operations for the Omnipod in Europe following the expiration of its distribution agreement on June 30, 2018 with Ypsomed Distribution AG ("Ypsomed" or the "European Distributor"). In June 2018, the FDA cleared for commercial sale the Company's Omnipod DASH™ Insulin Management System ("Omnipod DASH" or "DASH"), which is its next-generation digital mobile Omnipod platform within the Omnipod System family, featuring secured Bluetooth wireless technology for connectivity between the Pod and the color touchscreen smartphone PDM. The Company commenced a limited commercial release of Omnipod DASH in 2018 prior to a planned full market launch in the U.S. in the first half of 2019.

In addition to using the Omnipod System for insulin delivery, the Company also partners with global pharmaceutical and biotechnology companies to tailor the Omnipod System technology platform for the delivery of their drugs across other therapeutic areas. The majority of the Company's drug delivery revenue currently consists of sales of Amgen's Neulasta Onpro kit, an innovative delivery system for Amgen’s white blood cell booster to help reduce the risk of infection during intense chemotherapy.

To lower manufacturing costs, increase supply redundancy, add capacity closer to the Company's largest customer base and support growth, the Company has been constructing a highly-automated manufacturing facility in Acton, Massachusetts, which serves as its corporate headquarters. The facility was substantially complete in December 2018, with planned production out of the facility beginning in the first half of 2019.

In February 2016, the Company sold its Neighborhood Diabetes business, through which the Company provided customers with blood glucose testing supplies, traditional insulin pumps, pump supplies and pharmaceuticals. Additional information regarding the disposition and treatment of the Neighborhood Diabetes business as discontinued operations is provided in Note 19 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 accounting principles generally accepted in the United States ("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; the fair value of intangible assets; the valuation of inventory; the valuation of variable transaction price in its contracts with customers, such as rights of return, discounts and rebates; the valuation of deferred revenue associated with undelivered performance obligations in contracts with customers; the calculation of gains and losses, if any, on the retirement or conversion of convertible debt; the estimated useful lives of property and equipment and intangible assets; the amount of internal use software development costs that qualify for capitalization; the fair value of liabilities associated with leased facilities; the valuation allowance related to deferred income taxes; the estimated amount, if any, of accrued contingent liabilities as well as warranty and doubtful accounts allowance reserve calculations. Actual results may differ from those estimates.

Principles of Consolidation and Basis of Presentation

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.

Foreign Currency Translation

For the foreign subsidiaries of the Company, assets and liabilities 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 income (loss), a separate component of stockholders' equity. For the year ended December 31, 2018, net foreign currency realized and unrealized losses were approximately $1.0 million and were not material for the years 2017 and 2016.

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 and U.S. government and agency bonds, which are carried at cost which approximates their fair value. Included in the Company's cash and cash equivalents are restricted cash amounts set aside for collateral on outstanding letters of credit totaling $2.7 million as of December 31, 2018 and $0.5 million as of December 31, 2017.

Investments in Marketable Securities

Short-term and long-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 income (loss) in stockholders' equity. Investments with a stated maturity date of more than one year from the balance sheet date and that are not expected to be used in current operations, are classified as long-term investments. Short-term and long-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.

Fair Value Measurements

Fair value is defined 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 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 of assets and liabilities required to be measured or disclosed at fair value, the Company uses the following fair value hierarchy based on three levels of inputs of which the first two are considered observable and the last unobservable:

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

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

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

Property and Equipment and Intangible Assets

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful life of the respective assets. Intangible assets, such as internal use software or customer relationships acquired outside of a business combination, are recorded at cost and amortized over their expected period of benefit. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. Maintenance and repair costs are expensed as incurred.

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.

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 its Chief Executive Officer is the CODM as the CEO is the ultimate decision maker for key operating decisions, determining the allocation of resources and assessing the financial performance of the Company. These decisions, allocations and assessments are performed by the CODM using consolidated financial information. Consolidated financial information is utilized by the CODM as the Company's current product offering primarily consists of the Omnipod System and drug delivery devices based on the Omnipod platform. 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.

Goodwill

The Company performs an assessment of its goodwill for impairment annually on October 1 or whenever events or changes in circumstances indicate there might be impairment. Goodwill is evaluated for impairment at the reporting unit level. The Company has concluded that it operates in one segment that contains one reporting unit. In reaching this conclusion, the Company considered how components of the business are managed, whether discrete financial information at the component level is reviewed on a regular basis by segment management and whether components may be aggregated based on economic similarity. In performing its annual goodwill test, the Company utilizes a two-step approach. The first step compares the carrying value of the reporting unit to its fair value. If the reporting unit's carrying value exceeds its fair value, the Company would perform the second step and record an impairment loss to the extent that the carrying value of the reporting unit's goodwill exceeds its implied fair value.

Accumulated Other Comprehensive Income (Loss)

Comprehensive income (loss) combines net income (loss) and other comprehensive items, which are reported as components of stockholders' equity, including foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable securities.

Changes in each element of accumulated other comprehensive income (loss), net of tax, were as follows:

(in thousands)	Foreign Currency Translation Adjustment	Unrealized losses on available-for-sale securities	Accumulated Other Comprehensive Items
Balance at December 31, 2017	$ 46	$ (539)	$ (493)
Other comprehensive income (loss)	(2,174)	(238)	(2,412)
Balance at December 31, 2018	$ (2,128)	$ (777)	$ (2,905)

Revenue Recognition

The Company adopted Accounting Standards Codification 606 ("ASC 606") on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results in 2018 reflect the application of ASC 606 guidance while the reported results for 2017 and 2016 were prepared under the guidance of

ASC 605, Revenue Recognition ("ASC 605"), which is also referred to as the "previous guidance". In accordance with the previous guidance, revenue was recognized when persuasive evidence of a sales arrangement existed, delivery of goods occurred through transfer of title and risk and rewards of ownership, the selling price was fixed or determinable and collectability was reasonably assured. In accordance with ASC 606, revenue is recognized when a customer obtains control of the promised products. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products. To achieve this core principle, the Company applies the following five steps as outlined in ASC 606:

1) Identify the contract with a customer;
2) Identify the performance obligations in the contract;
3) Determine the transaction price;
4) Allocate the transaction price to performance obligations in the contract;
5) Recognize revenue when or as the Company satisfies a performance obligation.

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

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

The Company's drug delivery product line includes sales of a modified version of the Omnipod to pharmaceutical and biotechnology companies who use the Company’s technology as a delivery method for their drugs. Under ASC 606, for the majority of this product line, revenue is recognized as the product is produced pursuant to the customer’s firm purchase commitments as the Company has an enforceable right to payment for performance completed to date and the inventory has no alternative use to the Company. Judgment is required in the assessment of progress toward

completion of in-process inventory. The Company recognizes revenue over time using a blend of costs incurred to date relative to total estimated costs at completion and time incurred to date relative to total production time to measure progress toward the satisfaction of its performance obligations. The Company believes that both incurred cost and elapsed time reflect the value generated, which best depicts the transfer of control to the customer. Contract costs include third party costs as well as an allocation of manufacturing overhead. Changes from quarter to quarter in quantity and stage of production of in-process inventory could have a significant quarterly impact on revenue.

The Company had deferred revenue of $2.1 million and $3.2 million as of December 31, 2018 and 2017, respectively. Deferred revenue included $0.9 million and $0.9 million classified in other long-term liabilities as of December 31, 2018 and 2017, respectively. Deferred revenue represents the value of performance obligations that are not yet delivered for which cash has been received or for which the Company has an unconditional right to invoice. The Company recognized $2.4 million of revenue during the year ended December 31, 2018 that was included in deferred revenue at the beginning of the period.

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, the following more notable alliance is 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 System specifically designed to deliver Eli Lilly's 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 the Omnipod System, specifically designed to deliver Eli Lilly's Humalog ® 200 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 Eli Lilly's Humalog ® U-100 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 $6.6 million, $5.0 million and $4.1 million in the years ended December 31, 2018, 2017 and 2016, respectively.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, short-term and long-term investments in marketable securities and accounts receivable. The Company maintains the majority of its cash and short-term and long-term investments with a limited number of financial institutions. 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, 2018 and December 31, 2017, liabilities to this vendor represented approximately 10% and 20%, respectively, of the combined balance of accounts payable, accrued expenses and other current liabilities.

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

	Twelve Months Ended December 31,		
	2018	2017	2016
Amgen, Inc.	12%	15%	17%
Ypsomed	*	22%	16%
Cardinal Health Inc. and affiliates	12%	11%	10%

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

Recently Adopted Accounting Standards

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers, and its related amendments (collectively referred to as ASC 606),

which requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. Under this method, the new guidance was applied to contracts that were not yet completed as of January 1, 2018 with the cumulative effect of initially applying the guidance recognized through accumulated deficit as of the date of initial application. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price, which did not have a material effect on the adjustment to accumulated deficit.

The adoption of ASC 606 represents a change in accounting principle that primarily impacts how revenue is recognized for the Company's drug delivery product line and how the Company accounts for contract acquisition costs such as commissions. The following table shows the adjustments made to accounts on the consolidated balance sheet as of January 1, 2018 as a result of adopting the new guidance. The table also compares the reported consolidated balance sheet accounts as of December 31, 2018 that were impacted by the new guidance to pro forma balance sheet amounts had the previous guidance been in effect.

(in thousands)	As Reported under ASC 605 12/31/2017	Adjustments 1/1/2018	As Adjusted under ASC 606 1/1/2018	As Reported under ASC 606 12/31/2018	Adjustments 12/31/2018	Pro forma under ASC 605 12/31/2018
Assets						
Unbilled receivable (a)	$—	$ 5,119	$5,119	$13,378	$ (13,378)	$—
Inventories	$33,793	$ (753)	$33,040	$71,414	$ 1,777	$73,191
Prepaid expenses and other current assets (b)	$9,949	$ 5,568	$15,517	$24,254	$ (7,277)	$16,977
Total current assets	$537,171	$ 9,934	$547,105	$461,286	$ (18,878)	$442,408
Other assets (b)	$1,969	$ 13,326	$15,295	$18,266	$ (15,988)	$2,278
Total assets	$816,744	$ 23,260	$840,004	$928,744	$ (34,866)	$893,878
Liabilities and Stockholder's Equity						
Deferred revenue (c)	$2,356	$ 2,625	$4,981	$1,184	$ (779)	$405
Total current liabilities	$86,025	$ 2,625	$88,650	$115,657	$ (779)	$114,878
Other long-term liabilities	$6,030	$ 271	$6,301	$9,010	$ (271)	$8,739
Total liabilities	$658,228	$ 2,896	$661,124	$716,645	$ (1,050)	$715,595
Accumulated deficit	$(707,255)	$ 20,349	$(686,906)	$(683,614)	$ (33,800)	$(717,414)
Total stockholders' equity	$158,516	$ 20,364	$178,880	$212,099	$ (33,816)	$178,283
Total liabilities and stockholders' equity	$816,744	$ 23,260	$840,004	$928,744	$ (34,866)	$893,878

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

(b) Prepaid expenses and other current and non-current assets include contract acquisition costs, such as commissions, related to the sale of the Omnipod. These costs are amortized over the estimated period of benefit.

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

The following summarizes the significant changes on the Company’s consolidated statement of operations for the year ended December 31, 2018 as a result of the adoption of ASC 606 on January 1, 2018 compared to if the Company had continued to recognize revenue under ASC 605:

	Year ended December 31, 2018		
(in thousands, except per share amounts)	As reported under ASC 606	Adjustments	Pro forma under ASC 605
U.S. Omnipod	$323,528	$ (59)	$323,469
International Omnipod (a)	172,020	(1,787)	170,233
Drug Delivery (b)	68,275	(8,259)	60,016
Revenue	$563,823	$ (10,105)	$553,718
Cost of revenue	$193,655	$ (1,024)	$192,631
Gross profit	$370,168	$ (9,081)	$361,087

Sales and marketing (c)	$142,321	$ 4,370	$146,691
Total operating expenses	$342,745	$ 4,370	$347,115
Operating income	$27,423	$ (13,451)	$13,972
Income (loss) before income taxes	$5,226	$ (13,451)	$(8,225)
Net income (loss)	$3,292	$ (13,451)	$(10,159)
Net income (loss) per share: basic	$0.06	$ (0.23)	$(0.17)
Net income (loss) per share: diluted	$0.05	$ (0.23)	$(0.18)

(a) International Omnipod revenue under ASC 606 includes the amortization of a material right associated with a volume-based pricing discount granted to the Company's European Distributor at the outset of the distribution contract in 2010. The deferred revenue was recognized as revenue through the completion of the distributor contract during the first half of 2018.
(b) ASC 606 accelerated the recognition of revenue and fulfillment costs related to certain drug delivery contracts for which recognition was previously recorded when the product was shipped to the customer and is recorded as the product is produced under ASC 606. During the year ended December 31, 2018, $8.3 million of revenue was recognized due to changes in quantity and stage of production of in-process inventory during the year.
(c) ASC 606 resulted in the amortization of capitalized commission costs that were recorded as part of the cumulative effect adjustment upon adoption and during the twelve months ended December 31, 2018. Amortization of these capitalized costs to selling and marketing expenses, net of commission costs that were capitalized during the year, reduced sales and marketing expenses during the period.

	Year Ended December 31, 2018		
Statement of Cash Flows (in thousands)	As Reported under ASC 606	Adjustments	Pro Forma under ASC 605
Net income (loss)	$3,292	$ (13,451)	$(10,159)
Adjustments to reconcile net loss to net cash used in operating activities			
Non-cash items	85,430	—	85,430
Changes in operating assets and liabilities:			—
Accounts receivable and unbilled receivable	(22,879)	8,259	(14,620)
Inventories	(38,826)	(1,024)	(39,850)
Prepaid expenses and other assets	(11,601)	4,370	(7,231)
Accounts payable, accrued expenses and other current liabilities	21,187	—	21,187
Deferred revenue	(3,787)	1,846	(1,941)
Other long-term liabilities	3,083	—	3,083
Net cash provided by operating activities	$35,899	$ —	$35,899

The adoption of ASC 606 had no net impact on the Company’s cash used in operating, investing or financing activities.

Other Accounting Standards Adopted in 2018
Effective January 1, 2018, the Company adopted ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 changed the GAAP model for the accounting of equity investments, whereby equity investments with readily determinable fair value are carried at fair value with changes reported in net income as opposed to other comprehensive income. The Company adopted ASU 2016-01 as of the required effective date of January 1, 2018. There was no impact on the consolidated financial statements upon the adoption of ASU 2016-01 as of the effective date or as of and for the year ended December 31, 2018.
Effective January 1, 2018, the Company retrospectively adopted ASU 2016-15, Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force) ("ASU 2016-15"). ASU 2016-15 clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows. The guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. There was no impact on the consolidated statements of cash flows upon the adoption of ASU 2016-15.
Effective January 1, 2018, the Company adopted ASU 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting. ("ASU 2017-09"). ASU 2017-09 specifies the types of changes to the terms or conditions of a share-based payment award that require an entity to apply modification accounting in accordance with Topic 718. The adoption of ASU 2017-09 did not have an impact on the Company's consolidated financial statements.
Effective January 1, 2018, the Company adopted ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory ("ASU 2016-16"). ASU 2016-16 requires that an entity recognized the income tax effects of an intra-entity transfer of an asset, other than inventory, when the transfer occurs as opposed to when the

asset is sold to a third party. The adoption of this guidance did not have an impact on the Company's consolidated financial statements.

Accounting Pronouncements Issued and Not Yet Adopted as of December 31, 2018

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 and its related amendments (collectively referred to as ASC 842) requires entities to recognize the assets and liabilities on their balance sheet for the rights and obligations created by most leases and to recognize expense on their income statements over the lease term. ASC 842 will also require disclosures designed to give financial statement users information on the amount, timing, and uncertainty of cash

flows arising from leases. The guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those years. The Company adopted ASC 842 on January 1, 2019 using the modified retrospective method, whereby the new guidance will be applied prospectively as of the date of adoption and prior periods will not be restated. While the Company continues to calculate all potential impacts of the standard, the Company expects to record right-of-use assets of approximately $7 million to $9 million, and associated lease obligations of approximately $9 million to $11 million, on its balance sheet primarily related to its leased office and warehousing space. The difference between the approximate value of the right-of-use assets and the approximate value of the lease obligations is attributable to deferred rent and a cease-use liability, as further described in Note 12, which will be reclassified against the right-of-use assets upon adoption of ASC 842. The Company expects to elect certain available practical expedients upon adoption of the new guidance, including practical expedients that provide that an entity need not reassess whether an existing contract contains a lease and allows entities to carry forward the classification of current operating and capital leases into the new operating and financing classifications. The Company will also exclude leases with an expected term of less than one year from the application of ASC 842. In determining the estimated value of the right-use assets and lease liabilities provided above, the Company considered the remaining contractual term of the lease as well as the likelihood that the lease will be renewed. The Company discounted the estimated lease liability using its incremental borrowing rate, which is based on its unsecured borrowing rate as observed in recent convertible note transactions, adjusted for the estimated impact of collateralization.

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

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

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

In August 2018, the FASB issued ASU 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract ("ASU 2018-15"). ASU 2018-15 requires that entities capitalize certain costs to implement a cloud computing arrangement that is service contract consistent with the rules applicable to internal use software capitalization projects. The Company adopted this new guidance effective January 1, 2019 prospectively. Upon adoption, the Company will defer eligible costs related to the implementation of cloud computing arrangements within other current and non-current assets and will amortize these costs to the same income statement line as the associated cloud operating expenses.

In June 2016, the FASB issued ASU 2016-13, Credit Losses (Topic 326) ("ASU 2016-13"). ASU 2016-13 requires that financial assets measured at amortized cost, such as trade receivables and contract assets, be presented net of expected credit losses, which may be estimated based on relevant information such as historical experience, current conditions, and future expectation for each pool of similar financial asset. The new guidance requires enhanced disclosures related to trade receivables and associated credit losses. The guidance is effective beginning January 1,

2020. The adoption of this guidance is expected to increase the level of disclosures related to the Company's trade receivables and is not expected to have a material impact 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.

Note 3. Segment Reporting
As further described in Note 2, the Company has concluded that it operates as one segment. The following table summarizes revenue from contracts with customers:

	Years Ended December 31,		
(in thousands)	2018	2017	2016
U.S. Omnipod	$323,528	$271,597	$229,785
International Omnipod	172,020	119,953	71,889
Drug Delivery	68,275	72,218	65,315
Total	$563,823	$463,768	$366,989

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

	Years Ended December 31,		
(in thousands)	2018	2017	2016
United States	$391,803	$343,815	$295,100
All other	172,020	119,953	71,889
Total	$563,823	$463,768	$366,989

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

(in thousands)	December 31, 2018	December 31, 2017
United States	$ 232,263	$ 89,404
China	25,626	18,217
Other	861	434
Total	$ 258,750	$ 108,055

Note 4. Fair Value Measurements
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.
Asset and Liabilities Measured at Fair Value on a Recurring Basis.
The following tables provide a summary of assets that are measured at fair value on a recurring basis as of December 31, 2018 and 2017, aggregated by the level in the fair value hierarchy within which those measurements fall:

December 31, 2018	Fair Value Measurements			
(in thousands)	Total	Level 1	Level 2	Level 3
Money market mutual funds	$47,199	$47,199	$—	$ —
Total cash equivalents	$47,199	$47,199	$—	$ —
U.S. government and agency bonds	$112,509	$69,605	$42,904	$ —
Corporate bonds	56,025	—	56,025	—
Certificates of deposit	6,506	—	6,506	—
Total short-term investments	$175,040	$69,605	$105,435	$ —
U.S. government and agency bonds	$90,402	$64,086	$26,316	$ —
Corporate bonds	46,718	—	46,718	—
Certificates of deposit	3,664	—	3,664	—
Total long-term investments	$140,784	$64,086	$76,698	$ —

December 31, 2017	Fair Value Measurements			
(in thousands)	Total	Level 1	Level 2	Level 3
Money market mutual funds	$236,936	$236,936	$—	$ —
U.S. government and agency bonds	5,000	5,000	—	—
Total cash equivalents	$241,936	$241,936	$—	$ —
U.S. government and agency bonds	$112,076	$90,703	$21,373	$ —
Corporate bonds	47,681	—	47,681	—
Certificates of deposit	7,722	—	7,722	—
Total short-term investments	$167,479	$90,703	$76,776	$ —
U.S. government and agency bonds	$92,464	$49,651	$42,813	$ —
Corporate bonds	27,812	—	27,812	—
Certificates of deposit	5,273	—	5,273	—
Total long-term investments	$125,549	$49,651	$75,898	$ —

Fair Value of Assets and Liabilities Disclosed on a Recurring Basis.
The Company discloses the fair value of its outstanding convertible debt. The carrying amount and the estimated fair value of the Company's convertible debt, which is based on the Level 2 quoted market prices as of December 31, 2018 and 2017 are as follows:

	As of December 31, 2018		December 31, 2017	
(in thousands)	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
2% Convertible Senior Notes	$—	$—	$3,421	$5,467
1.375% Convertible Senior Notes	290,972	426,026	276,172	407,652
1.25% Convertible Senior Notes	301,006	483,851	286,580	450,881
Total	$591,978	$909,877	$566,173	$864,000

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

As further described in Note 12, during the year ended December 31, 2018 the Company recorded a liability in the amount of $1.1 million related to a leased facility that has been partially vacated as a result of the Company's relocation of its global headquarters to Acton, Massachusetts. The fair value of the liability, a Level 3 measurement, was based on the lease payments that will continue to be incurred less an estimate of sublease income, which took into account the current market rates for similar office space and the risks related to obtaining a subtenant. The Company had no Level 3 assets or liabilities as of December 31, 2017.

Note 5. Investments

As of December 31, 2018, The Company's short-term and long-term investments in debt securities had maturity dates that range from 15 days to 23 months and included 64 available-for-sale debt securities that had insignificant unrealized loss positions. The Company has the intent and ability to hold these investments until maturity whereby unrealized losses are expected to be recovered. There were no charges recorded during the three years ended December 31, 2018 for other-than-temporary declines in the fair value of the Company's investments. Realized gains or losses in each of the three years ended December 31, 2018 were insignificant.

Amortized costs, gross unrealized holding gains and losses, and fair values at December 31, 2018 and 2017 are as follows:

(in thousands)	Amortized cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2018				
U.S. government and agency bonds	$112,995	$ —	$ (486)	$112,509
Corporate bonds	56,235	—	(210)	56,025
Certificates of deposit	6,506	—	—	6,506
Total short-term investments	$175,736	$ —	$ (696)	$175,040
U.S. government and agency bonds	$90,458	$ 99	$ (155)	$90,402
Corporate bonds	46,743	43	(68)	46,718
Certificates of deposit	3,664	—	—	3,664
Total long-term investments	$140,865	$ 142	$ (223)	$140,784

(in thousands)	Amortized cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2017				
U.S. government and agency bonds	$112,311	$ —	$ (235)	$112,076
Corporate bonds	47,713	3	(35)	47,681
Certificates of deposit	7,722	—	—	7,722
Total short-term investments	$167,746	$ 3	$ (270)	$167,479
U.S. government and agency bonds	$92,677	$ —	$ (213)	$92,464
Corporate bonds	27,871	—	(59)	27,812
Certificates of deposit	5,273	—	—	5,273
Total long-term investments	$125,821	$ —	$ (272)	$125,549

Note 6. Accounts Receivable, Net

Accounts receivable consist of amounts due from third-party payors, patients, and intermediaries. The Company records an allowance for doubtful accounts at the time potential collection risk is identified. The Company estimates its allowance based on historical experience, assessment of specific risk, and discussions with individual customers. The Company believes the reserve is adequate to mitigate current collection risk. No customer accounted for more than 10% of gross accounts receivable as of December 31, 2018.

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Customers that represented 10% or greater of gross accounts receivable as of December 31, 2017 were as follows:

	As of December 31, 2017
Amgen, Inc.	10 %
Ypsomed	31 %

The components of accounts receivable are as follows:

(in thousands)	As of December 31, 2018	December 31, 2017
Trade receivables	$66,904	$55,914
Allowance for doubtful accounts	(3,610)	(2,541)
Total accounts receivable	$63,294	$53,373

Note 7. Inventories

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

The components of inventories are as follows:

(in thousands)	As of December 31, 2018	December 31, 2017
Raw materials	$10,347	$ 2,146
Work-in-process	30,222	23,918
Finished goods	30,845	7,729
Total inventories	$71,414	$ 33,793

Note 8. Prepaid Expenses and Other Assets

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

(in thousands)	As of December 31, 2018	December 31, 2017
Prepaid expenses and other current assets	$16,977	$ 9,949
Capitalized contract acquisition costs, current portion	7,277	—
Total prepaid expenses and other current assets	$24,254	$ 9,949

The components of other assets are as follows:

(in thousands)	As of December 31, 2018	December 31, 2017
Other assets	$2,278	$ 1,969
Capitalized contract acquisition costs, net of current portion	15,988	—
Total other assets	$18,266	$ 1,969

Effective with the adoption of ASC 606 on January 1, 2018, the Company capitalizes commission costs that are related to new patient starts. These costs are deferred in other assets, net of the short term portion included in prepaid and other current assets. Costs to obtain a contract are amortized as sales and marketing expense on a straight line basis over the expected period of benefit, which considers future product upgrades for which a commission would be

paid. These capitalized costs are periodically reviewed for impairment. The Company recognized $6.9 million of amortization of capitalized commission costs during the year ended December 31, 2018. There were no impairments to capitalized costs to obtain a contract recorded during the period.

Note 9. 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, 2018	December 31, 2017
Land	n/a	$2,525	$ 2,525
Building	39	35,543	—
Machinery and equipment	2-10	85,163	60,878
Lab equipment	3-7	1,446	1,038
Computers and hardware	3-5	6,623	3,659
Office furniture and fixtures	3-5	14,963	2,521
Leasehold improvements	*	1,443	1,425
Construction in process	—	176,101	87,397
Total property and equipment		$323,807	$ 159,443
Less: accumulated depreciation		(65,428)	(51,579)
Total property and equipment, net		$258,379	$ 107,864

* Lesser of lease term or useful life of asset.

Depreciation expense related to property and equipment was $13.8 million, $12.7 million and $12.6 million for the years ended December 31, 2018, 2017 and 2016, respectively. The Company capitalized $10.2 million, $3.1 million and $0.5 million of interest in the years ended December 31, 2018, 2017 and 2016. Construction in process mainly consists of highly-automated manufacturing equipment located at the Company's U.S. manufacturing facility in Acton, Massachusetts. The majority of the equipment is expected to be placed into service during 2019.

Note 10. Goodwill and Other Intangible Assets, Net

Goodwill

The Company has $39.6 million of goodwill on its balance sheet from prior business acquisitions. There were no impairments of goodwill during the years ended December 31, 2018, 2017 or 2016.

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

	Years Ended December 31,	
	2018	2017
(In thousands)		
Beginning balance	$39,840	$39,677
Foreign currency adjustment	(194)	163
Ending balance	$39,646	$39,840

Intangible Assets, Net

The Company’s finite-lived intangible assets are stated at cost less accumulated amortization. Intangible assets include customer relationships acquired in prior business acquisitions and from the Company's former European Distributor. See Note 14 for a discussion of the Company's accounting for estimated fees owed to its former European Distributor following the expiration of its distribution agreement on June 30, 2018.

The components of other intangible assets are as follows:

	As of December 31, 2018			December 31, 2017		
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Customer and contractual relationships	$6,109	$ (1,880)	$4,229	$2,135	$ (1,764)	$371
Internal-use software	11,262	(5,108)	6,154	7,545	(3,565)	3,980
Total intangible assets	$17,371	$ (6,988)	$10,383	$9,680	$ (5,329)	$4,351

Amortization expense for intangible assets was approximately $1.8 million, $1.2 million and $1.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. Amortization expense is recorded in operating expenses in the consolidated statements of operations.

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

(in thousands)

Years Ending December 31,	Customer and Contractual Relationships	Internal-Use Software	Total
2019	$ 552	$ 2,184	$2,736
2020	488	1,965	2,453
2021	425	1,573	1,998
2022	425	391	816
2023	425	39	464
Thereafter	1,914	2	1,916
Total	$ 4,229	$ 6,154	$10,383

As of December 31, 2018, the weighted average amortization periods of the Company’s customer and contractual relationships intangible assets and internal use software intangible assets are approximately 9 years and 3 years, respectively.

Note 11. Accrued Expenses and Other Current Liabilities

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

	Years Ended December 31,	
(in thousands)	2018	2017
Employee compensation and related costs	$37,822	$34,942
Professional and consulting services	14,925	9,273
Supplier charges	7,742	3,542
Value added taxes payable	8,463	—
Warranty	2,701	1,653
Other	17,320	9,846
Total accrued expenses and other current liabilities	$88,973	$59,256

Product Warranty Costs

The Company generally provides a four-year warranty on its PDMs sold in the United States and Europe and a five-year warranty on its PDMs sold in Canada and may replace any Omnipod that does not function in accordance with product specifications. The Company estimates its warranty obligation 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. Warranty claims settled reflects the current product cost. As these estimates are based on historical experience, and the Company continues to introduce new products and versions, the Company also considers the anticipated performance of the product over its warranty period in estimating warranty reserves.

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

(in thousands)	Years Ended December 31, 2018	2017
Product warranty liability at the beginning of the period	$5,337	$4,388
Warranty expense	7,779	6,127
Warranty claims settled	(6,737)	(5,178)
Product warranty liability at the end of the period	$6,379	$5,337

(in thousands)	As of December 31, 2018	December 31, 2017
Composition of balance:		
Short-term	$2,701	$ 1,653
Long-term	3,678	3,684
Product warranty liability at the end of the period	$6,379	$ 5,337

Note 12. Lease Exit Liability

In December 2018, the Company relocated its global headquarters to its newly constructed and owned facility in Acton, Massachusetts. As a result of the relocation of employees and operations, a significant portion of its leased facility in Billerica, Massachusetts, previously serving as the Company's global headquarters, was vacated and ceased to be utilized by the Company. The lease had a remaining term of approximately four years as of the cease-use date. Accordingly, management recorded an exit charge of $1.1 million, representing the fair value of the liability associated with vacated space, net of deferred rent. In addition, the Company recorded $0.3 million of impairments related to the remaining net book value of leasehold improvements and furniture and fixtures associated with the vacated space. The exit and impairment charges are included in general and administrative expenses.

The following table rolls forward the lease exit liability:

(in thousands)	Year Ended December 31, 2018
Beginning balance at December 31, 2017	$ —
Lease exit charge	1,090
Cash payments	—
Ending balance at December 31, 2018	$ 1,090

Note 13. Convertible Debt, Net

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

(in thousands)	As of December 31, 2018	December 31, 2017
Principal amount of 2.0% Convertible Senior Notes	$ —	$ 3,664
Principal amount of 1.25% Convertible Senior Notes, due September 2021	344,992	345,000

Principal amount of 1.375% Convertible Senior Notes, due November 2024	402,500			402,500		
Unamortized debt discount	(143,616		)	(170,448		)
Debt issuance costs	(11,898		)	(14,543		)
Total convertible debt, net	$	591,978		$	566,173	

Interest expense related to the convertible debt is as follows:

	Years Ended December 31,		
(in thousands)	2018	2017	2016
Contractual coupon interest	$9,844	$6,282	$4,467
Accretion of debt discount	26,663	15,931	8,800
Amortization of debt issuance costs	2,619	2,077	1,270
Total interest expense related to convertible debt	$39,126	$24,290	$14,537

Interest expense related to convertible debt for the year ended December 31, 2018 is as follows:

(in thousands)	1.375%	1.25%	2.0%	Total
Contractual coupon interest	$5,512	$4,313	$ 19	$9,844
Amortization of debt discount and issuance costs	14,789	14,433	60	29,282
Total interest expense	$20,301	$18,746	$ 79	$39,126

1.375% Convertible Senior Notes

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

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

The 1.375% 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 Securities and Exchange Commission ("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 1.375% 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 nominal value at the balance sheet date.

As of December 31, 2018, the Company included $291.0 million, net of unamortized discount and issuance costs, on its consolidated balance sheet in long-term debt related to the 1.375% Notes.

1.25% Convertible Senior Notes

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

business day immediately preceding June 15, 2021 only under certain circumstances and during certain periods, and will be convertible on or after June 15, 2021 until the close of business on the second scheduled trading day immediately preceding September 15, 2021, regardless of those circumstances.

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

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 a nominal value at the balance sheet date.

As of December 31, 2018, the Company has $301.0 million, net of discounts and issuance costs, on its consolidated balance sheet in long-term debt related to the 1.25% Notes.

2% Convertible Senior Notes

In June 2014, the Company issued and sold $201.3 million in principal amount of 2% Convertible Senior Notes due June 15, 2019 (the “2% Notes”). The 2% Notes were convertible into the Company’s common stock at an initial conversion rate of 21.5019 shares of common stock per $1,000 principal amount of the 2% Notes, which is equivalent to a conversion price of approximately $46.51 per share. In separately negotiated transactions, the Company repurchased $134.2 million in principal of the notes in September 2016 and $63.4 million in principal of the notes in November 2017. The Company elected to call the remaining notes in March 2018 and settled the outstanding principal and conversion feature of the notes for $6.7 million in cash in the second quarter of 2018. The Company allocated approximately $3.2 million of the settlement to the fair value of the equity component and $3.5 million to the debt component, which was consistent with the carrying value of the notes as of the settlement date, resulting in no gain or loss on extinguishment.

Note 14. 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.

Operating Leases

The Company leases warehousing space in the U.S. and office space globally under leases expiring from April 2019 to January 2026. Rental expense under operating leases was $3.3 million, $2.8 million and $2.5 million in the years ended December 31, 2018, 2017 and 2016, respectively. The aggregate future minimum lease payments related to these leases as of December 31, 2018 are as follows:

(in thousands)

Years Ending December 31,	Minimum Lease Payments
2019	$ 3,311
2020	2,947
2021	2,892
2022	2,568
2023	263
Thereafter	548
Total	$ 12,529

Legal Proceedings

Between May 5, 2015 and June 16, 2015, three class action lawsuits were filed by shareholders in the U.S. District Court, for the District of Massachusetts, against the Company and certain individual current and former executives of the Company. Two

suits subsequently were voluntarily dismissed. Arkansas Teacher Retirement System v. Insulet, et al., 1:15-cv-12345, ("ATRS") alleged that the Company (and certain executives) committed violations of Sections 10(b) and 20(a) and Rule 10b-5 of the Securities Exchange Act of 1934 by making allegedly false and misleading statements about the Company's business, operations, and prospects. On February 8, 2018, the parties executed a binding stipulation of settlement, under which all claims were released and a payment was made to the plaintiffs and the class they purport to represent. On August 6, 2018, the Court issued an order approving the settlement. The Company had previously accrued fees and expenses in connection with this matter for the amount of the final settlement liability that was not covered by insurance, which amount was not material to the Company's consolidated financial statements.

In addition, on April 26, 2017, a derivative action (Walker v. DeSisto, et al., 1:17-cv-10738) ("Walker") was filed, and on October 13, 2017, a second derivative action (Carnazza v. DeSisto, et al., 1:17-cv-11977) ("Carnazza") was filed, both on behalf of the Company, each by a shareholder in the U.S. District Court for the District of Massachusetts against the Company (as a nominal defendant) and certain individual current and former officers and directors of the Company. The allegations in the actions are substantially similar to those alleged in the securities class action. The actions seek, among other things, damages, disgorgement of certain types of compensation or profits, and attorneys' fees and costs. On July 11, 2018, the parties executed a binding stipulation of settlement, under which all claims were released and a payment of attorneys' fees and reimbursement of expenses will be paid to plaintiffs' counsel, subject to the Court's approval. On July 13, 2018, the plaintiffs filed a motion for preliminary approval of the settlement, which is pending. The Company expects that such fees and expenses payable to plaintiff's counsel will be covered by the Company's insurance.

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

Fees To Former European Distributor

Following the expiration of its distribution agreement on June 30, 2018, the Company is required to pay to its former European Distributor a quarterly per-unit fee for Omnipod sales by the Company between July 1, 2018 and June 30, 2019 to certain customers of the former European Distributor. The Company is recognizing a liability and an associated intangible asset for this fee as qualifying sales occur. The actual total fee could vary significantly depending on the number of customers who count for purposes of calculating the fee under the terms of the distribution agreement, and the methodology applicable for determining this number under the agreement is subject to an active arbitration proceeding between the parties in Switzerland. The Company estimates that the final aggregate fee for the applicable twelve-month period could be in the range of approximately
$10 million to $55 million. As of December 31, 2018, the Company has recognized approximately $4.1 million for fees related to Omnipod devices sold to qualifying customers from the period July 1, 2018 through December 31, 2018.

Note 15. Stock-Based Compensation

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718-10, Compensation — Stock Compensation ("ASC 718-10"), which requires share-based payments provided to employees and directors, including grants of stock options and restricted stock units, to be recognized in the income statement at fair value. Share-based payments that contain performance conditions are recognized when such conditions are probable of being achieved. 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.

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Stock-based compensation related to share-based awards recognized in the years ended December 31, 2018, 2017 and 2016 was as follows:

	Year Ended December 31,			Unamortized Expense	Weighted Average Remaining Expense Period (Years)
($ in thousands)	2018	2017	2016	At December 31, 2018	
Stock options	$10,569	$11,647	$9,923	$11,668	2.3
Restricted stock units	25,737	19,718	13,628	20,927	1.7
Employee stock purchase plan	1,215	576	226	666	0.4
Total	$37,521	$31,941	$23,777	$33,261	

Equity Award Plans

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 were granted to persons who were, at the time of grant, employees, officers, non-employee directors or key persons of the Company or the Company's subsidiaries. The 2007 Plan provided for the grant 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. In May 2017, the Company adopted the 2017 Stock Option and Incentive Plan (the "2017 Plan"), which has replaced the 2007 Plan as the means by which the Company makes equity and cash awards. Effective May 18, 2017, the 2017 Plan became effective (the "2017 Plan Effective Date") and the Company ceased granting awards from the 2007 Plan. Outstanding awards under the 2007 Plan remain subject to the terms of the 2007 Plan. Under the 2017 Plan, awards may be granted to persons who are, at the time of grant, employees, officers, non-employee directors, consultants, or advisers of the Company or the Company's subsidiaries and affiliates. The 2017 Plan provides for the grant 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. Stock options granted under the 2017 Plan generally vest over a period of four years and expire ten years from the date of grant. Shares of stock subject to awards granted under the 2007 Plan and the 2017 Plan that are forfeited, expire or otherwise terminate without delivery generally become available for future issuance under the 2017 Plan. As of December 31, 2018, 4.4 million shares remain available for future issuance under the 2017 Plan.

Stock Options

The calculation of the fair value of stock options is affected by the stock price on the grant date, the expected volatility of the Company's stock over the expected term of the award, the expected life of the award, the risk-free interest rate, and the dividend yield. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

The estimated grant date fair values of stock options were based on the following assumptions:

	Years Ended December 31,		
	2018	2017	2016
Risk-free interest rate	2.22% - 2.95%	1.66% - 1.85%	0.99% - 1.91%
Expected term (in years)	4.5 - 5.4	4.7 - 5.3	5.1 - 5.4
Dividend yield	—	—	—
Expected volatility	39% - 41%	38% - 39%	38% - 40%

The weighted average grant date fair value per share of options granted for the years ended December 31, 2018, 2017 and 2016 was $30.34, $17.28 and $11.60, respectively.

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

	Number of Options (#)	Weighted Average Exercise Price ($)	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($)
				(In thousands)
Outstanding at December 31, 2017	3,377,220	$ 35.10		
Granted	292,389	77.27		
Exercised	(421,588)	32.61		$ 23,482
Canceled	(170,397)	40.44		
Outstanding at December 31, 2018	3,077,624	$ 39.16	5.7	$ 124,174
Vested, December 31, 2018	2,318,684	$ 35.26	4.9	$ 102,168
Vested or expected to vest, December 31, 2018[1]	3,001,343	$ 38.69	5.6	$ 122,407

[1] Represents total outstanding stock options as of December 31, 2018, adjusted for estimated forfeitures.

The aggregate intrinsic value of stock options exercised was calculated based on the positive difference between the estimated fair value of the Company's common stock and the exercise price of the underlying options. The aggregate intrinsic value of options exercised in the years ended December 31, 2017 and 2016 was $11.8 million and $4.6 million, respectively.

The aggregate intrinsic value for outstanding awards as of December 31, 2018 was calculated based on the positive difference between the Company's closing stock price of $79.32 on December 31, 2018 and the exercise price of the underlying options.

Restricted Stock Units

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

	Number of Shares (#)	Weighted Average Fair Value ($)
Outstanding at December 31, 2017	994,364	$ 38.08
Granted	332,677	75.70
Adjustment for performance achievement	147,301	29.54
Vested	(640,104)	34.81
Forfeited	(82,031)	45.55
Outstanding at December 31, 2018	752,207	$ 55.02

The restricted stock units granted during the year ended December 31, 2018 were valued at approximately $25.2 million on their grant date. The Company recognizes compensation expense for restricted stock units over the vesting period. Restricted stock units granted during 2018 include 114,569 awards subject to the achievement of performance conditions (performance-based restricted stock units). These performance-based restricted stock units generally vest over a three-year period from the grant date and include both a service and performance component. Certain of these restricted stock units could ultimately vest at up to 200% of the target award depending on the achievement of the performance criteria. During 2018, the Compensation Committee of the Board of Directors determined that the performance criteria was achieved at 200% for certain performance-based awards issued in 2016, resulting in an adjustment to the shares that will ultimately vest for these awards. The Company records stock-based compensation for these awards based on its estimate of the number of awards that will ultimately vest.

The following table provides further information related to the Company's restricted stock units:

	Year ended December 31,		
($ in thousands)	2018	2017	2016
Stock-based compensation:			
Performance-based restricted stock units	$11,750	$6,420	$3,393
Time-based restricted stock units	13,987	13,298	10,235
Total stock-based compensation for restricted stock units	$25,737	$19,718	$13,628

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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 makes one or more offerings each year to eligible employees to purchase stock under the ESPP. Offering periods begin on the first business day occurring on or after each December 1 and June 1 and end on the last business day occurring on or before the following May 31 and November 30, respectively.

Each employee who is a participant in the Company’s ESPP may annually 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, 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. The purchase price for each share purchased is 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 Company issued 46,343, 59,134 and 30,949 shares of common stock in 2018, 2017 and 2016, respectively, to employees participating in the ESPP. The Company recorded approximately $1.2 million, $0.6 million and $0.2 million of stock-based compensation expense related to the ESPP in each of the years ended December 31, 2018, 2017 and 2016, respectively.

Note 16. 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. The Company offers 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. In addition, the Company offers similar defined contribution plans for eligible employees in its foreign subsidiaries. The total amount contributed by the Company to these defined contribution plans was $3.6 million, $3.0 million and $1.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Note 17. Income Taxes

The Company accounts for income taxes in accordance with ASC 740-10, Income Taxes (“ASC 740-10”), 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 enacted tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. As of December 31, 2018, the Company had no uncertain tax positions.

The Tax Cuts and Jobs Act ("Tax Reform Act") that was signed into law on December 22, 2017, significantly changed the U.S tax law by, among other things, lowering the corporate income tax rates, implementing a territorial tax system, expanding the tax base, imposing a tax on deemed repatriated earnings of foreign subsidiaries, taxing certain foreign earnings to the U.S. through global intangible low-taxed income ("GILTI"), modifying officer's compensation limitations and creating new limitations on deductible interest expense. The Company recognized the impact of the Tax Reform Act in its consolidated financial statements for the year ended December 31, 2017. In accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), the Company had a measurement period up to one year beginning on December 22, 2017 to obtain, analyze and prepare the information needed to complete the accounting requirements of the Tax Reform Act. The Company completed the analysis allowed under SAB 118 when it finalized the deemed repatriation tax computation in conjunction with the filing of the Company's 2017 federal and state tax returns. There was no change in the provision amount recorded of $0.8 million.

For the year ended December 31, 2018, the Company calculated both the new limitation on interest expense and the modified officer’s compensation limitation. However, there was no impact on the Company’s income tax expense or effective tax rate in the period due to the full valuation allowance applied to the U.S. entity.

The Company has elected to recognize the income tax related to GILTI as a period expense in the period the tax is incurred or expected to occur for the year ended December 31, 2018. The inclusion of GILTI had no impact on the Company's income tax expense or effective tax rate in the period due to the full valuation allowance applied to the U.S. entity.

The Company files federal, state and foreign tax returns. These returns are generally open to examination by the relevant tax authorities from two to four years from the date they are filed or, in certain circumstances, from the end of the accounting

period. The tax filings relating to the Company's federal and state tax returns are currently open to examination for tax years 2015 through 2017 and 2014 through 2017, respectively. In addition, the Company has generated tax losses from inception in 2000 until 2017 and beginning 2018, the Company is expected to generate taxable income. These years may be subject to examination if the losses are carried forward and utilized in future years.

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

Income tax expense from continuing operations consists of the following:

	Years Ended December 31,		
(in thousands)	2018	2017	2016
Current:			
Federal	$—	$—	$—
State	209	151	52
Non-U.S.	2,094	603	539
Total current expense	2,303	754	591
Deferred:			
Federal	3	(347)	—
State	(12)	91	—
Non-U.S.	(360)	(241)	(199)
Total deferred expense	(369)	(497)	(199)
Total income tax expense	$1,934	$257	$392

Income tax expense from discontinued operations was $0.4 million for the year ended December 31, 2016 and was primarily generated from federal deferred taxes.

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

	Year Ended December 31,		
	2018	2017	2016
Tax at U.S. statutory rate	21.00 %	34.00 %	34.00 %
Changes from statutory rate:			
Foreign rate differential	(2.39)	0.34	(0.23)
State taxes, net of federal benefit	2.88	10.21	(10.86)
Tax credits	(13.70)	13.28	0.03
Share-based compensation	(159.10)	33.61	(14.02)
Non-deductible officer's compensation	81.29	(20.18)	(12.95)
Permanent items	16.79	(13.98)	15.93
Foreign income taxed in the U.S.	26.09	—	—
Change in enacted rates	—	0.98	—
Change in valuation allowance	67.03	(57.91)	(13.45)
Other	(2.88)	(1.32)	(0.37)
Effective income tax rate	37.01 %	(0.97)%	(1.46)%

Pre-tax income attributable to the Company's operations located outside the U.S. was approximately $8.2 million, $1.1 million and $0.8 million for 2018, 2017 and 2016, 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, 2018, the Company has chosen to indefinitely reinvest approximately $13.6 million of earnings of certain of its non-U.S. subsidiaries. To the extent the Company repatriates its foreign earnings, certain withholding taxes and state taxes may apply. No provision has been recorded for taxes that could be incurred upon repatriation. The deferred tax liability related to repatriation of these earnings would not be material to the company's consolidated financial statements.

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

	Year Ended December 31,	
(in thousands)	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$124,871	$129,184
Start up expenditures	288	462
Tax credits	13,041	12,705
Provision for bad debts	1,105	824
Depreciation and amortization	3,463	3,068
Capital loss carryforwards	12,620	12,850
Stock-based compensation	9,339	9,799
Other	6,066	4,449
Total deferred tax assets	$170,793	$173,341
Deferred tax liabilities:		
Prepaid assets	$(1,977)	$(1,326)
Amortization of debt discount	(35,648)	(43,083)
Goodwill	(642)	(633)
Capitalized contract acquisition costs	(5,801)	—
Other	(218)	(264)
Total deferred tax liabilities	$(44,286)	$(45,306)
Valuation allowance	$(126,314)	$(127,927)
Net deferred taxes	$193	$108

The Company has recorded a deferred tax liability related to the tax basis in acquired goodwill that is not amortized for financial reporting purposes. The deferred tax liability will only reverse at the time of further impairment of the goodwill. 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 deferred tax liability cannot be used to offset the deferred tax asset related to the net operating loss carryforward for tax purposes. The U.S. Tax Reform Act limits certain deductions and these limitations may impact the value of existing deferred tax assets. The Company will continue to review the impact of these limitations as regulatory guidance is issued.

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 U.S. deferred tax assets will not be realized. After consideration of the available evidence, both positive and negative, the Company has determined that a $126.3 million valuation allowance at December 31, 2018 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, 2018 and 2017 because it is not more likely than not that the future tax benefit will be realized. In the year ended December 31, 2018, the Company’s valuation allowance decreased to $126.3 million from the balance at December 31, 2017 of $127.9 million.

At December 31, 2018, the Company had approximately $528.1 million, $246.4 million and $13.0 million of gross 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 2037, and the state carryforwards will continue to expire through 2037. At December 31, 2017, the Company had approximately $543.6 million, $250.6 million and $12.7 million of federal net operating loss carryforwards, state net operating loss carryforwards and research and development and other tax credits, respectively. The utilization of such net operating loss carryforwards and the realization of tax benefits in future years depends predominantly upon the Company's ability to generate 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 whereby there would 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.

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Note 18. Net Income (Loss) Per Share

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

The following table sets forth the components used in the computation of basic and diluted net income (loss) per share for the three years ended December 31, 2018:

(in thousands, except share and per share data)	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Numerator:			
Net income (loss) from continuing operations [1]	$ 3,292	$ (26,831)	$ (27,210)
Denominator:			
Weighted average common shares outstanding	58,859,574	58,003,434	57,251,377
Effective of dilutive potential common share equivalents			
Stock options	1,678,535	—	—
Restricted stock units	469,915	—	—
Shares used for diluted net income (loss) per share	61,008,024	58,003,434	57,251,377
Net income (loss) per share:			
Basic	$ 0.06	$ (0.46)	$ (0.48)
Diluted	$ 0.05	$ (0.46)	$ (0.48)

[1] In 2016, the Company reported a net loss from discontinued operations of $1.7 million, which generated net loss per basic and diluted share of $0.03.

For the year ended December 31, 2018, certain potential dilutive common shares from stock options, restricted stock units and convertible debt were excluded from the computation of diluted net income per share because the effect of including these items was anti-dilutive. In addition, certain performance-based restricted stock units were excluded from the computation of diluted net income per share because the underlying performance conditions for such restricted stock units had not been met as of the end of the year.

As the Company reported net losses for the years ended December 31, 2017 and 2016, all potential dilutive common shares have been excluded from the computation of diluted net loss per share in those periods as the effect would have been anti-dilutive.

The number of potential common share equivalents excluded from the computation of diluted net income (loss) per share for the years ended December 31, 2018, 2017 and 2016 are as follows:

	Years Ended December 31,		
	2018	2017	2016
1.375% Convertible Senior Notes	4,319,429	4,319,429	—
2.00% Convertible Senior Notes	—	78,783	1,442,433
1.25% Convertible Senior Notes	5,910,954	5,910,954	5,910,954
Unvested restricted stock units	289,974	994,364	962,219
Outstanding stock options	236,648	3,377,220	3,441,303
Total potential common share equivalents excluded from computation of diluted net income (loss) per share	10,757,005	14,680,750	11,756,909

Note 19. Discontinued Operations

In February 2016, the Company sold Neighborhood Diabetes to Liberty Medical LLC ("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.

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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 various services were provided to Liberty Medical on an interim transitional basis. Total expenses incurred for such transition services were $0.9 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:

	December 31, 2016
(In thousands)	
Discontinued operations:	
Revenue [1]	$ 7,730
Cost of revenue	5,468
Gross profit	2,262
Operating expenses:	
Sales and marketing	1,542
General and administrative	1,853
Total operating expenses	3,395
Operating loss	(1,133)
Interest and other income (expense), net	(128)
Loss from discontinued operations before taxes	(1,261)
Income tax expense	408
Net loss from discontinued operations	$ (1,669)

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

There were no assets or liabilities presented as discontinued operations as of December 31, 2018 or December 31, 2017. Net operating cash flows used in discontinued operations in the year ended December 31, 2016 were $2.0 million.

Note 20. Quarterly Data (Unaudited)

	2018 Quarters Ended			
	December 31	September 30 [1]	June 30	March 31
(In thousands, except per share data)				
Revenue	$164,907	$ 151,076	$124,262	$123,578
Gross profit	$110,312	$ 101,969	$82,072	$75,815
Operating income	$16,233	$ 6,865	$4,325	$—
Net income (loss)	$9,893	$ 1,659	$(1,691)	$(6,569)
Net income (loss) per share:				
Basic	$0.17	$ 0.03	$(0.03)	$(0.11)
Diluted	$0.16	$ 0.03	$(0.03)	$(0.11)

[1] Included in operating income and net income from continuing operations for the third quarter of 2018 was a charge of $12.6 million for severance-related costs associated with the retirement of the Company's former CEO, of which $8.2 million related to stock-based compensation for the acceleration of share-based awards and the remainder represented cash severance benefits.

	2017 Quarters Ended			
	December 31	September 30	June 30	March 31
(In thousands, except per share data)				
Revenue	$130,524	$ 121,775	$109,756	$101,713
Gross profit	$79,508	$ 73,624	$64,639	$59,398
Operating (loss) income	$(768)	$ 2,047	$(3,358)	$(5,308)
Net loss	$(6,860)	$ (2,227)	$(7,767)	$(9,977)
Net loss per share	$(0.12)	$ (0.04)	$(0.13)	$(0.17)

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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, 2018				
Allowance for doubtful accounts	$ 2,541	$ 3,382	$ 2,314	$ 3,609
Deferred tax valuation allowance	$ 127,927	$ 13,938	$ 15,551	$ 126,314
Year Ended December 31, 2017				
Allowance for doubtful accounts	$ 2,911	$ 1,923	$ 2,293	$ 2,541
Deferred tax valuation allowance	$ 191,922	$ 14,232	$ 78,227	$ 127,927
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

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

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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, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2018 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, 2018. 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, 2018, 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, 2018 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their report which appears below.

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Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Insulet Corporation
Opinion on internal control over financial reporting
We have audited the internal control over financial reporting of Insulet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in the 2013 Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, 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) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 31, 2018, and our report dated February 25, 2019 expressed an unqualified opinion on those financial statements.
Basis for opinion
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 Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audit in accordance with the standards of the PCAOB. 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.
Definition and limitations of internal control over financial reporting
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.
/s/ GRANT THORNTON LLP
Boston, Massachusetts
February 25, 2019

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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 2019 Annual Meeting of Stockholders, which Proxy Statement will be filed with the SEC not later than 120 days after the close of our year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders, which Proxy Statement will be filed with the SEC not later than 120 days after the close of our year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders, which Proxy Statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2018. 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 2019 Annual Meeting of Stockholders, which Proxy Statement will be filed with the SEC not later than 120 days after the close of our year ended December 31, 2018.

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 2019 Annual Meeting of Stockholders, which Proxy Statement will be filed with the SEC not later than 120 days after the close of our year ended December 31, 2018.

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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, 2018 and 2017

Consolidated Statements of Operations - Years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Comprehensive Income (Loss) - Years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Stockholders' Equity - Years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Cash Flows - Years ended December 31, 2018, 2017 and 2016
Notes to Consolidated Financial Statements

(A)(2) FINANCIAL STATEMENT SCHEDULES

For the years ended December 31, 2018, 2017 and 2016, Schedule II – Valuation and Qualifying Accounts
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 25, 2019 /s/ Shacey Petrovic
Shacey Petrovic
Chief Executive Officer
(Principal Executive Officer)

February 25, 2019 /s/ Michael L. Levitz
Michael L. Levitz
Chief Financial Officer
(Principal Financial and Accounting Officer)

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POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Insulet Corporation, hereby severally constitute and appoint Shacey Petrovic 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 25, 2019.

Signature	Title
/s/ Shacey Petrovic Shacey Petrovic	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/ Michael R. Minogue Michael R. Minogue	Director
/s/ Corinne H. Nevinny Corinne H. Nevinny	Director

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EXHIBIT INDEX

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

Number	Description
3.1	Eighth Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 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 Exhibit 3.1 to our Current Report on Form 8-K, filed February 26, 2016)
4.1	Specimen Stock Certificate (Incorporated by reference to Exhibit 4.1 to Amendment No.2 to our Registration Statement on Form S-1 (File No. 333-140694) filed April 25, 2007)
4.2	Indenture, dated as of November 10, 2017, between Insulet Corporation and Wells Fargo Bank, National Association, as Trustee (Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K, filed on November 13, 2017)
4.3	Form of 1.375% Convertible Senior Notes due 2024 (included in Exhibit 4.2)
4.4	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 to our Current Report on Form 8-K filed September 13, 2016)
4.5	Form of 1.25% Convertible Senior Notes due 2021 (included in Exhibit 4.4)
10.1	Insulet Corporation 2017 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 19, 2017)
10.2	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Incentive Stock Option Agreement for Employees (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.3	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement for Employees (Incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.4	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Restricted Stock Unit Agreement for Employees (Incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.5	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Performance Vesting Restricted Stock Unit Agreement for Officers (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2017, filed November 3, 2017)
10.6	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Non-Qualified Stock Option Agreement for Directors (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)

10.7	Form of Insulet Corporation 2017 Stock Option and Incentive Plan Restricted Stock Unit Agreement for Directors (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, filed August 4, 2017)
10.8	Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A filed on April 2, 2015)
10.9	Form of Vice President Restricted Stock Unit Agreement with Performance Component under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)
10.10	Form of Employee Restricted Stock Unit Agreement with Performance Component under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)

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10.11	Form of Executive Officer 3 Year Performance Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)
10.12	Form of Vice President 3 Year Performance Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)
10.13	Form of Executive Officer Cliff Vesting Performance Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)
10.14	Form of International 3 Year Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.6 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)
10.15	Form of Executive Officer 3 Year Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, filed May 9, 2017)
10.16	Form of International Non-Qualified Stock Option Agreement under the Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed August 4, 2016)
10.17	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 Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed August 4, 2016)
10.18	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 Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed August 4, 2016)
10.19	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 Exhibit 10.59 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016)
10.20	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 Exhibit 10.60 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016)
10.21	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 Exhibit 10.61 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016)

10.22	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 Exhibit 10.62 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016)
10.23	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 Exhibit 10.63 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016)
10.24	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 Exhibit 10.64 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed February 29, 2016)
10.25	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 Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, filed August 12, 2015)
10.26	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 Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, filed August 12, 2015)
10.27	Form of Incentive Stock Option Agreement under the Insulet Corporation Third Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2015, filed August 12, 2015)

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10.28	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 Exhibit 10.51 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed February 26, 2015)
10.29	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 Exhibit 10.53 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed February 26, 2015)
10.30	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 Exhibit 10.56 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed February 26, 2015)
10.31	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 Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014)
10.32	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 Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014)
10.33	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 Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014)
10.34	Form of Incentive Stock Option Agreement under the Second Amended and Restated 2007 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.7 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, 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 Exhibit 10.10 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, 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 Exhibit 10.11 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014)
10.37	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 Exhibit 10.15 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014, filed November 5, 2014)
10.38	Form of Non-Qualified Stock Option Agreement for Michael Levitz, David Colleran and Michael Spears (Incorporated by reference to Exhibit 10.1 to our Registration Statement on Form S-8 (No. 333-208387) filed December 8, 2015)

10.39	Amended and Restated Executive Severance Plan, effective as of January 1, 2019 (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed October 22, 2018)
10.40	Insulet Corporation Fourth Amended and Restated 2007 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed August 4, 2016)
10.41	Form of Employee Non-Competition and Non-Solicitation Agreement by and between Insulet Corporation and each of its executive officers (Incorporated by reference to Exhibit 10.17 to Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-140694), filed April 25, 2007)
10.42	Offer Letter between Shacey Petrovic and Insulet Corporation, dated September 10, 2018 (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed September 14, 2018)
10.43	Offer Letter between Wayde D. McMillan and Insulet Corporation, dated January 3, 2019 (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on January 7, 2019)
10.44	Employment Agreement by and between Insulet Corporation and Patrick J. Sullivan dated September 16, 2014 (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed September 16, 2014)
10.45	Retirement Agreement between Patrick J. Sullivan and Insulet Corporation, dated September 10, 2018 (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed September 14, 2018)
10.46	Letter Agreement between Brad Thomas and Insulet Corporation, dated April 27, 2018 (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 1, 2018)
10.47+	Materials Supplier Agreement between Insulet Corporation and Flextronics Medical Sales and Marketing, Ltd, dated September 1, 2016 (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, filed November 4, 2016)

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10.48+	First Amendment to Materials Supplier Agreement between Insulet Corporation and Flextronics Medical Sales and Marketing, Ltd, entered into on June 29, 2018 and made effective as of January 1, 2018 (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018, filed August 2, 2018)
10.49+	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 Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2013, filed November 7, 2013)
10.50+	Master Equipment and Services Agreement between Insulet Corporation and ATS Automated Tooling Systems Inc., dated August 31, 2016 (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, filed November 4, 2016)
10.51	Purchase and Sale Agreement by and between 100 Nagog Park Limited Partnership and Insulet Corporation, dated December 16, 2016 (Incorporated by reference to Exhibit 1.1 to our Current Report on Form 8-K filed December 20, 2016 (Items 1.01 and 9.01)
10.52+	Supply Agreement, dated November 21, 2013, between Amgen and Insulet Corporation, as amended by Amendment No. 1 through Amendment No. 14 (Incorporated by reference to Exhibit 10.18 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed February 28, 2017)
10.53+	Amendment No. 16, entered into effective as of August 15, 2018, to Supply Agreement, dated November 21, 2013, between Amgen Inc. and Insulet Corporation (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018, filed November 1, 2018)
21.1	Subsidiaries of the Registrant
23.1	Consent of Independent Registered Public Accounting Firm (Grant Thornton LLP)
24.1	Power of Attorney (included on signature page)
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Chief Executive Officer and Chief Financial Officer
101	The following materials from Insulet Corporation's Annual Report on Form 10-K for the year ended December 31, 2018 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Operations; (iii) the Consolidated Statements of Comprehensive Income (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.