Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

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

For the fiscal year ended December 31, 2019

☐ **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	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.001 Par Value Per Share	PODD	The NASDAQ Stock Market, LLC

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

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

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

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

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

Indicate by check mark 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," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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, 2019 was approximately $7.2 billion.

The number of shares of common stock outstanding as of February 20, 2020 was 62,863,402.

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, 2019. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

PART I

Item 1. Business

Overview

Insulet Corporation ("we" or the "Company") is primarily engaged in the development, manufacture and sale of its proprietary Omnipod® System, an innovative, discreet and easy-to-use continuous insulin delivery system for people with insulin-dependent diabetes, which we have been selling since 2005. The Omnipod System consists of the following: the Omnipod Insulin Management System ("Omnipod") and the Omnipod DASH™ Insulin Management System ("Omnipod DASH" or "DASH"), our next generation digital mobile Omnipod platform.

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 even less of the Type 1 diabetes population outside the United States use insulin pump therapy. An even smaller portion of the Type 2 diabetes population in and outside of the United States who are insulin-dependent use insulin pump therapy. We believe these factors present a significant available market for the Omnipod System globally. The Omnipod System features two discreet and easy-to-use devices: a small, lightweight, self-adhesive disposable tubeless Omnipod device ("Pod") that is worn on the body for up to three days at a time, and its wireless companion, the 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. Omnipod DASH, launched in 2019, features a secure Bluetooth enabled Pod and PDM with a color touch screen user interface supported by smartphone connectivity.

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. Most of our drug delivery revenue consists of sales of Pods to Amgen for use in the Neulasta® Onpro® kit, an innovative delivery system for Amgen's white blood cell booster to help reduce the risk of infection after intense chemotherapy.

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. We estimate that three to four million people have Type 1 diabetes in the countries we currently serve.
- 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 individuals progress to multiple drug therapies, which often include insulin therapy. We estimate that approximately five to six million people have Type 2 diabetes in the countries we currently serve.

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 people 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. Individuals with diabetes 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 people 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 for individuals with diabetes 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.

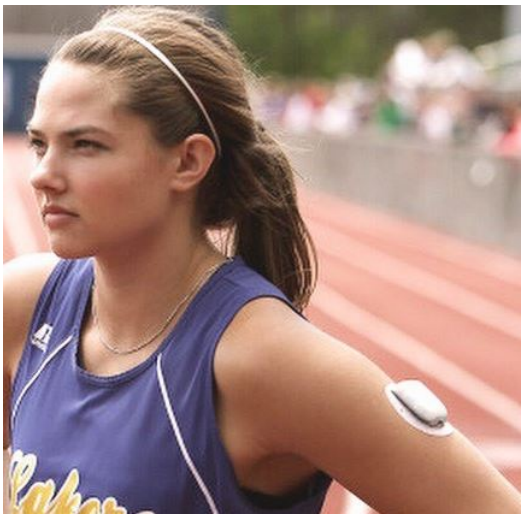
MDI therapy involves the administration of fast-acting insulin before meals (bolus) to lower blood glucose levels to a healthy range. MDI therapy may also require a separate injection of a long-acting (basal) insulin, to control glucose levels between meals; typically, once or twice per day. By comparison, 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.

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.

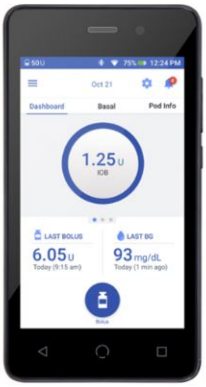
Our Solution: The Omnipod System

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 user 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 needed 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 users. 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 to use, which 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 helps redefine persons for whom insulin pump therapy is appropriate, allowing healthcare professionals to prescribe pump therapy to a broader group of people with diabetes.

The Omnipod System's unique patented design and proprietary manufacturing process allow us to provide pump therapy at a relatively low or no up-front investment compared to conventional tubed insulin pumps. 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.

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 and reduced frequency and severity of hypoglycemic episodes. These results are consistent with other published literature of other continuous subcutaneous insulin infusion devices like 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 users accessible through a kiosk, home computer or a mobile application on the user's smartphone that provides users 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 sold directly to wholesalers, private healthcare organizations, healthcare facilities, mail order pharmacies and independent retailers. These entities, and the Company in some cases, seek reimbursement from health insurance companies and/or government administrative payors. The Omnipod System is also marketed and sold through distributors, as well as marketed to physicians and consumers. Our products are subject to regulatory changes and competition in technological innovation, price, convenience of use, service and product performance. Consumers generally have commercial insurance, Medicare or Medicaid coverage that pays for the product.

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

Markets and Distribution Methods

The Omnipod System is currently available in the United States, Canada and in certain countries in Europe and the Middle East. We sell the Omnipod System directly to consumers, through distribution partners and most recently in the U.S. through the pharmacy channel. For the year ended December 31, 2019, approximately 65% of our Omnipod System sales were through intermediaries.

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

	Years Ended December 31,		
	2019	2018	2017
Amgen, Inc.	*	12%	15%
Ypsomed Distribution AG and affiliates	*	*	22%
Cardinal Health Inc. and affiliates	11%	12%	11%

* Represents less than 10% of revenue for the period.

Our sales and marketing efforts are focused on customer retention and growing user, clinician and payor demand for the Omnipod System. We have a uniform sales and marketing approach, aligned across users, physicians and providers, to capitalize on the unique benefits of our Omnipod System technology. We have three areas of focus:

- Build consumer awareness about the features and benefits that the Omnipod System provides.
- Build physician support by increasing the clinical evidence that demonstrates the benefits that the Omnipod System provides and improving the monitoring data available to physicians providing diabetes care.
- Provide payors with the clinical and economic justification for why the Omnipod System provides a unique value to the people whom they insure.

Training

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

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 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 consumers in the insulin delivery market. Because most 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 products and supplies for 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 Diabetes Care Inc. (“Tandem”). In addition, we compete with Roche Holdings Ltd. (“Roche”) and The Ypsomed Group (“Ypsomed”) outside the United States. 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. In addition to the established insulin pump competitors, several companies are working to develop and market new insulin 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 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 users, and improving our supply chain operations. These efforts include:

Omnipod Horizon™ Automated Insulin Delivery System (“Omnipod Horizon”)

We are developing an automated insulin delivery system that utilizes the DASH mobile platform to allow the Pod, our automated insulin delivery algorithm located on the Pod and the glucose sensor values obtained directly from a third party’s continuous glucose monitor to predict glucose levels into the future and automatically adjust the insulin dose required to help reduce the occurrence of blood glucose highs and lows. We plan to launch Omnipod Horizon with a continuous glucose monitor manufactured by Dexcom, Inc.; however, we have signed a development agreement to integrate Abbott Diabetes Care, Inc.’s continuous glucose monitor in the future. Omnipod Horizon 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 Omnipod Horizon performed well and was safe for over five days of use in adults, adolescents and children with Type 1 diabetes and in December 2019, we began patient enrollment in our pivotal trial. Omnipod Horizon was granted designation in the U.S. Food and Drug Administration's ("FDA") breakthrough device program, which is a program intended to help people 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 technology and Automated Insulin Delivery 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 existing MDI therapy.

Paramount to our ability to deliver phone control is our commitment to cyber and information security. Omnipod DASH is the first FDA-cleared insulin pump certified under the Diabetes Technology Society's "Standard for Wireless Diabetes Device Security" cybersecurity assurance standard and program, known as DTSec. This certification is a cybersecurity standard intended to raise confidence in the security of network connected medical devices through independent expert evaluation. In addition, Omnipod DASH is International Standards Organization ("ISO") 27001 certified, 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 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.

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.

During 2019, we began producing product from our new highly automated manufacturing facility in Acton, Massachusetts. 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 North American customer base and support growth. To date, we have invested approximately $320 million in property, equipment and infrastructure related to the new facility. We expect to continue to expand our investment in this facility in 2020 to support the growth of our business.

We also continue to 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 continue to invest in improvements and efficiencies to our entire supply chain, including improvements in automation at our suppliers and contract manufacturer.

Raw Materials

We use a diverse and broad range of raw materials in the assembly and manufacturing of the Omnipod System. We purchase all our raw materials and select components used in the manufacturing of our products from external suppliers. In addition, we purchase some supplies from a single or limited number of sources for reasons of proprietary know-how, quality assurance, cost-effectiveness, or constraints resulting from regulatory requirements. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability.

We rely on a limited number of suppliers for certain of the components and sub-assemblies used in the manufacture of the Omnipod System, including with respect to application-specific integrated circuit chips, bluetooth low-energy chips and other specialized parts. The design of certain of these components and sub-assemblies (including, in some instances, the raw materials used to manufacture the same) is proprietary and the intellectual property rights with respect thereto may be owned exclusively by one party. Where such ownership exists, we are sole sourced with the supplier controlling such intellectual property rights. These sole sourced components are critical to the design and functionality of the Omnipod System. In the case of sole sourced parts, we manage risk through holding inventory ourselves and at the supplier to ensure continuity of supply and low risk of disruption. We purchase other components and sub-assemblies from manufacturers with whom we are at least dual sourced.

Quality Assurance

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 ISO. 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. 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, 2019, we had over 200 patents in the United States and in certain other countries, with expiration dates ranging from 2021 through 2042, and had over 100 patent applications pending. The issued patents and pending patent applications cover, among other things:

- the basic architecture of the Omnipod System, including the pump and the PDM;
- the Omnipod shape memory alloy drive system;
- the Omnipod System cannula insertion system;
- communication features between system components for the Omnipod System and next generation products;
- software, 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®, DASH™, Omnipod CONTROL™, Omnipod DISPLAY™, Omnipod VIEW™, 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, product storage, pre-market clearance or approval, advertising and promotion, sales and distribution, post-market adverse event reporting, post-market surveillance, complaint handling, repair or recall of products and record keeping.

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 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 pre-market

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 PMA is obtained. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite 510(k) or PMA application(s).

PMA. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, and 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 information 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 conducts a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulations ("QSR"), 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 people 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 pre-market approval, a new pre-market approval application or application supplement may be required in the event of modifications to the device, its labeling, intended use or indication or its manufacturing process. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials. Clinical trials are almost always required to support a PMA application and may also be required to support 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 people, unless the product is deemed a "non-significant risk" device, in which case IDE approval from the FDA would not be required, although the clinical trial would need to meet other requirements including Institutional Review Board ("IRB") approval. Clinical trials for a significant risk device may begin once an IDE is approved by the FDA and the appropriate IRB at each 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 the FDA. 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;
- QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during 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, the 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 efficacy 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 of new products or modified products, rescinding previously granted 510(k) clearances or withdrawing previously granted PMAs, 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

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”) and the Medical Device Regulation (“MDR”), which will replace MDD in May 2020. 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 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 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. We have been distributing the Omnipod in certain countries in Europe through intermediaries or directly to end-users since 2010 and have been distributing Omnipod throughout Canada since receiving Health Canada approval in 2009.

Other Regulations

Licensure. Several states require that durable medical equipment (“DME”) providers be licensed in order to sell products 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 in the United States, we are required to work with intermediaries who have the appropriate pharmacy license for the applicable market in which we provide consumers 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, 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 users 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 as providing reimbursement assistance, coding and billing information or other customer 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 could be subject to significant criminal, civil and administrative penalties, including imprisonment, fines, damages, and exclusion from Medicare, Medicaid or other governmental programs, any of which could have a material 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. 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 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 monetary 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. In some cases, these state laws apply regardless of the payor, 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 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.

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 imposes 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.

California Consumer Privacy Act. The California Consumer Privacy Act ("CCPA") is a consumer privacy law, which provides certain privacy rights and consumer protection for residents of the state of California that became effective in January 2020. These consumer rights include the right to know what personal information is collected, the right to know whether the data is sold or disclosed and to whom, the right to request a company to the delete personal information collected, the right to opt-out of the sale of personal information and the right to non-discrimination in terms of price or service when a consumer exercises a privacy right. If we fail to comply with these regulations, we could be subject to civil sanctions, including fines and penalties for noncompliance.

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 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 the Centers for Medicare & Medicaid Services ("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.

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 user training. We cannot predict the final form of these federal and state regulations or the effect their application 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. Additionally, in 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, customers 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 these 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.

U.S. Foreign Corrupt Practices Act ("FCPA"). We are also subject to FCPA and similar anti-bribery laws in non-U.S. jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, our customer relationships outside of the United States may be with governmental entities and therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents.

Employees

As of December 31, 2019, we had 1,350 full-time employees.

Company Information

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 our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the U.S. Securities and Exchange Commission ("SEC"). We have also posted the charters for our Audit Committee, Compensation Committee and Nominating, Governance and Risk Committee, as well as our Code of Business Conduct and Ethics, under the heading "Corporate Governance" in the Investors section of our website. The information on our website is not incorporated in this report by reference. In addition, the SEC maintains a website (http//www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors

Risks Relating to Our Business

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

Prior to 2018 and since our inception in 2000, we incurred significant losses. Our losses from continuing operations for the years ended December 31, 2017, 2016 and 2015 were $26.8 million, $27.2 million and $61.6 million, respectively. The extent of any future losses and the timing of profitability are uncertain, and we may not sustain profitability. As of December 31, 2019, we had an accumulated deficit of $672.0 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. 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.

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 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 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 consumers 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 referrals to actual sales of the Omnipod System;
- the inability of users to continue paying for our products;
- attrition rates of consumers 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. consumers who have lost their jobs or healthcare coverage may no longer be covered by an employer-

sponsored health insurance plan and consumers reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the Omnipod System to a new user is generally dependent on the availability of third-party reimbursement and may require the user to make a significant co-payment, an economic downturn could reduce the referrals generated by our sales force and thereby reduce our sales orders. Similarly, existing users could cease purchasing the Omnipod System and return to MDI or other less-costly therapies, which would cause our consumer attrition rate to increase. Any decline in new orders or increase in our consumer attrition rate would reduce our revenue, which in turn would make it more difficult to achieve our per-unit cost-savings goals, which we are attempting to attain in part through increases in our manufacturing volume.

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

During the past several years, the U.S. healthcare industry has been subject to an increase in governmental regulation at both the federal and state levels. Efforts to control healthcare costs, including limiting access to care, alternative delivery models and changes in the methods used to determine reimbursement scenarios and rates, are ongoing at the federal and state government levels. There are 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, including establishing a research project agenda and contracting with entities to conduct the research. 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.

The ACA 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 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 that was signed into law 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.

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 capital expenditures, including adding further manufacturing capacity;
- costs associated with expanding our sales and marketing efforts globally;
- expenses we incur in manufacturing and selling our products;
- costs of developing new products or technologies and enhancements to our products;
- costs associated with any expansion;
- costs of complying with regulatory requirements, including obtaining and maintaining FDA approval or clearance of our current or future products;
- 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 $376.1 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 2020.

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 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. As a result of these and other factors, we do not know whether additional capital will be available when needed, or 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, including potentially curtailing planned product development activities. In addition, we may not be able to 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, 2019, we had outstanding principal amounts due of $1.2 billion on our Convertible Senior Notes, which mature between 2024 and 2026. 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 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 cash from 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 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 a significant portion of all finished Omnipod Systems. We do not have long-term supply agreements with all our suppliers, and, in many cases, we, or Flex on our behalf, make purchases based on 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 safety or efficacy 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.

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 System in Europe, Canada and the Middle East. Our operations outside of the United States are subject to risks that are inherent in conducting business under non-U.S. laws, regulations and customs. Sales outside the United States made up 34% of our revenues in 2019 and we expect non-U.S. sales to contribute significantly to our future growth. If the U.S. dollar strengthens in relation to the currencies of other countries where we sell our products, such as the euro, our U.S. dollar reported revenue and income will decrease. Changes in the relative values of currencies occur regularly and, in some instances, may have a significant effect on our operating results. We also rely on third-party suppliers located outside the United States. For example, a significant portion of our Omnipod Systems are manufactured at a facility in China operated by Flex.

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.

In addition to the risks discussed elsewhere in the risk factors included in this Item 1A, other risks associated with doing business internationally, include:

- political instability and actual or anticipated military or political conflicts;
- economic instability and inflation or recession;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- negative consequences from changes in or interpretations of tax laws;
- difficulty in establishing, staffing and managing non-U.S. operations;
- difficulties associated with foreign legal systems, including increased costs associated with enforcing contractual obligations in foreign jurisdictions;
- changes in foreign currency exchange rates;
- minimal or diminished protection of intellectual property in some countries;
- changes in regulatory requirements;
- failure to fulfill foreign regulatory requirements on a timely basis or at all in order 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 consumer 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.

Most of our customer relationships outside of the United States are with governmental entities and we could be materially and adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions.

The FCPA and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of anti-bribery laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our results of operations, financial condition and cash flows.

The long-term impacts on our business of the United Kingdom's recent withdrawal from the European Union are unknown.

On January 31, 2020, the U.K. left the European Union. This withdrawal, commonly referred to as "Brexit" 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 in all 50 states. While we anticipate entering into additional contracts with other third-party payors, we cannot assure you 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 consumers to obtain coverage for the use of the Omnipod System. Coverage decisions and rates of reimbursement increasingly require clinical evidence showing an improvement in user 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 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 in the United States 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 consumers 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.

We expect to sell Omnipod DASH primarily through the pharmacy channel in the United States, which 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 that 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 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 in the United States and Roche and Ypsomed outside the United States.

Many of our competitors are large, well-capitalized companies with more market share and resources than we have. As a result, they can 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 involves a user injecting themselves with both long-acting and short-acting insulin with a syringe or insulin pen. 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 changes 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, our results of operations could be materially adversely impacted.

We rely on the proper function, availability and security of our product and information technology systems and a cyber-attack or other breach or disruption of our product or 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 customers. We use our information technology systems to manage or support a variety of business processes and activities, including sales, shipping, billing, customer service, procurement and supply chain, manufacturing and accounts payable. In addition, we use enterprise information technology systems to record, process, and summarize transactions and other financial information and results of operations for internal reporting purposes and to comply with financial reporting, legal, and tax regulatory 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 customer 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. Additionally, the FDA has warned that insulin pumps may have cybersecurity vulnerabilities and could be manipulated by hackers, causing danger to diabetes patients. If our product is breached or 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, 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 customer 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, 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 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 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 user direction could have a material adverse effect on our revenue and future profitability. Medtronic commercially launched a “hybrid closed-loop” system in 2017, and in January 2020 Tandem announced the commercial launch of an automated insulin delivery system, 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 and Type 2 diabetes. We may be unable to effectively introduce and market new products or may fail to keep pace with advances in technology. The healthcare industry is characterized by continuous technological change, resulting in changing consumer preferences and requirements. The success of our business depends on our ability to introduce new products and adapt to these changing technologies and consumer demands. To compete in the marketplace, we must make substantial investments in new product development whether internally or externally through licensing or acquisitions. Even if we can develop, manufacture and obtain regulatory and reimbursement approvals for our new products, the success of those products depends on market acceptance. Market acceptance for our new products could be affected by several factors, including:

- the availability of alternative products from our competitors;
- the price of our products;
- the timing of our market entry; and
- our ability to market and distribute our products effectively.

Our failure to introduce new and innovative products in a timely manner could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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 current and potential users, 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 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 consumers. 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 users for the purchase of FreeStyle test strips to the same extent as they reimburse users 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 current and potential users.

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, manufacture and sale of a modified Omnipod System for delivery of a specific drug other than insulin. Most 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 users 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 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;
- demand of non-insulin drugs, including the impact of generics and biosimilars;
- 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;

- 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, such as China, where we rely on a third-party contract manufacturer to produce our product. Additionally, for a variety of reasons, we may decide not to file for patent protection. Our patent rights underlying our products may not be adequate, and our competitors or users 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 sign 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 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 being issued. 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 users, cause product shipment delays, limit or prohibit us from manufacturing, marketing or selling our current or future products, require

us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue could decrease substantially, and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities.

We are subject to extensive government regulation, 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;
- regulatory clearances and approvals including premarket clearance and approval;
- product safety;
- advertising and promotion;
- marketing, sales and distribution;
- conformity assessment procedures;
- product traceability and record keeping procedures;
- 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 PMA from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. In December 2012, we received 501(k) clearance for our Omnipod. We have since obtained clearance for modified versions of this device, including Omnipod DASH, which was recently cleared by the FDA to be used as an integrated insulin pump in an interoperable automated insulin delivery system. We may be required to obtain a new 510(k) clearance or PMA for significant further post-market modifications to the Omnipod System. Obtaining 510(k) clearance or PMA 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 PMA 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 PMAs for new products or for modifications to, or additional indications for, the Omnipod System in a timely fashion or at all. Delays in obtaining future clearances could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could harm our revenue and future profitability.

We also are subject to numerous post-marketing regulatory requirements, which include quality system regulations related to the manufacture 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;
- operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to the Omnipod System;
- rescinding 510(k) clearance or suspending or withdrawing PMAs 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 Cures Act enacted in December 2016 and 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 the 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- 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 Canada and certain countries in Europe and the Middle East. As a result, we are required to comply with additional foreign regulatory requirements. 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 refuse our requests for 510(k) clearance or premarket approval of new products or may not clear or approve these products for the indications that are necessary or desirable for successful commercialization. Even early stage review may result in issues. For example, the FDA has issued guidance intended to explain the procedures and criteria used in assessing whether 510(k) and PMA submissions should be accepted for substantive review. Under the “Refuse to Accept” guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) and PMA submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information. If the information is not provided within a defined time, the submission will not be accepted for FDA review. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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

We, our contract manufacturer and our component suppliers are required to comply with the FDA’s 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 manufacturers’ or component suppliers’ facilities would pass

any future quality system inspection. If our or any of our contract manufacturers 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 manufacturers, 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 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 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 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. If a change 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 and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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, or at all, and our business and operating results 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 consumers in that state.

Several states require that DME providers be licensed in order to sell products to customers 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 consumers 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 payors 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 customer and product support programs, we may have with hospitals, physicians, customers 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 "Item 1—Business—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 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 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 health information and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated 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 of personal data. In the state of California, the CCPA, which provides certain privacy rights and consumer protection for residents of the state became effective January 2020. These consumer rights include the right to know what personal information is collected, the right to know whether the data is sold or disclosed and to whom, the right to request a company to the delete personal information collected, the right to opt-out of the sale of personal information and the right to non-discrimination in terms of price or service when a consumer exercises a privacy right. If we fail to comply with these regulations, we could be subject to civil sanctions, including fines and penalties for noncompliance.

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 users, 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 GDPR imposes requirements in the European Economic Area 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 and amounts could be significant.

Product liability suits and other litigation, whether or not meritorious, could be brought against us. 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 users, including death. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we believe that we are reasonably insured against these risks, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

Our ability to grow our revenue depends in part on our retaining a high percentage of our 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 consumers, which include appeals assistance, ongoing customer communications, newsletters, support, training and an automatic re-order program for certain customers. 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.

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 and maintained in a limited number of locations.

Our manufacturing of the Omnipod System is conducted in two locations, at our U.S. manufacturing facility in Massachusetts and on manufacturing lines owned by us at a facility located in China, operated by a subsidiary of Flex. Political or financial instability, currency fluctuations, the outbreak of pandemics such as the Coronavirus, labor unrest, transport capacity and costs, port security, weather conditions, natural disasters or other events that could slow or disrupt port activities and affect foreign trade are beyond our control and could materially disrupt our supply of product from China, increase our costs, and/or adversely affect our results of operation. In addition, substantially all our U.S. Omnipod System inventory is held at a single location in Massachusetts and our European Omnipod System inventory is maintained by a third-party logistics entity primarily in a single location in the Netherlands. We take precautions to ensure that Flex and the third-party logistics entity safeguard our assets, including insurance and 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 manufacturing equipment and/or 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, manufacturing equipment, inventory or other property or to any of our suppliers, may have a material adverse effect on our business, financial condition and results of operations.

If we are unable to obtain sufficient components or raw materials on a timely basis or if we experience other manufacturing difficulties, including not effectively managing the start-up and commissioning of new manufacturing lines, our business may be adversely affected.

The manufacture of our product requires the timely delivery of sufficient amounts of quality components and materials. We manufacture our products in two locations, at our U.S. manufacturing facility in Massachusetts and on manufacturing lines owned by us at a facility located in China, operated by a subsidiary of Flex. We acquire our components and materials from many suppliers in various countries. We work closely with our suppliers to ensure the continuity of supply, but we cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of components and materials, in certain instances we acquire components and materials from a sole supplier. In addition, due to the stringent regulations and requirements of the FDA and other similar non-U.S. regulatory agencies regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for some components or materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our products in a timely or cost-effective manner, and our ability to make product sales.

The manufacture of our product is highly exacting and complex, due in part to strict regulatory requirements. Problems in the manufacturing process, including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors, could lead to launch delays, product shortage, unanticipated costs, lost revenues and damage to our reputation. A failure to identify and address manufacturing problems prior to the release of products to our customers may also result in a quality or safety issue. Significant manufacturing problems or inability to obtain key components and materials could have a material adverse effect on our business, results of operations, financial condition and cash flows. In addition, as we commence operation of new manufacturing lines, we could experience quality issues and unexpected operational delays that 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. 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 employees, including managing geographically dispersed teams. 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.

As we continue to expand our sales internationally, we will need to obtain regulatory approvals and reimbursement agreements with government agencies or private third-party payors in those countries. Failure to obtain such agreements would limit our ability to successfully penetrate those foreign markets. In addition, the geographic expansion of our business will require additional manufacturing capacity to supply those markets as well as additional sales and marketing resources.

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

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

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

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

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

- dilutive issuances of equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;

- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which in future periods may result in significant charges to earnings.

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

We need to expand our distribution network to maintain and grow our business and revenue. If we fail to expand and maintain an effective sales force or successfully develop our relationships with 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.

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 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;
- 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 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.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our owned global headquarters, which encompasses our U.S. manufacturing and office facility in Acton, Massachusetts is approximately 300,000 square feet. We also lease a total of approximately 200,000 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 13 to the consolidated financial statements included under Item 8 of this Form 10-K and is incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

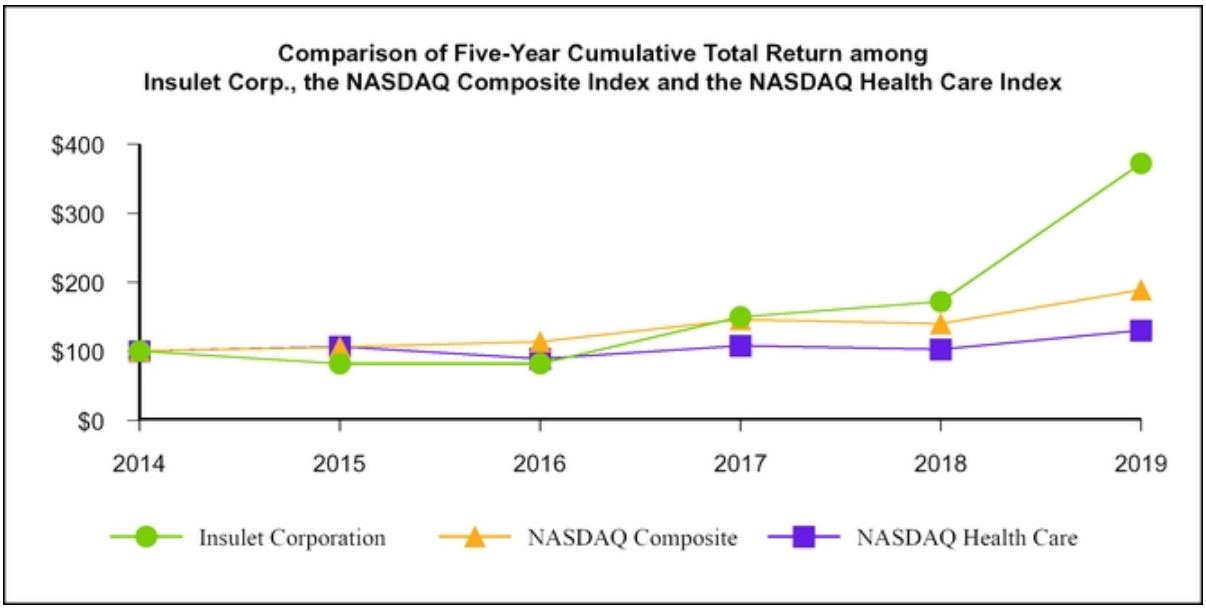
MARKET FOR REGISTRANT'S COMMON EQUITY

Our common stock is listed on The NASDAQ Global Market ("NASDAQ") under the trading symbol PODD.

As of February 20, 2020, there were 9 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 following graph shows the cumulative total return on $100 invested in each of our common stock, the NASDAQ Composite Index and the NASDAQ Health Care Index for the five-year period beginning on December 31, 2014, and ending on December 31, 2019, assuming reinvestment of all dividends. The historical stock price performance on the graph below is not necessarily indicative of future stock price performance.



	2014	2015	2016	2017	2018	2019
Insulet Corporation	$ 100	$ 82	$ 82	$ 150	$ 172	$ 372
NASDAQ Composite	$ 100	$ 106	$ 114	$ 146	$ 140	$ 189
NASDAQ Health Care	$ 100	$ 107	$ 89	$ 108	$ 103	$ 130

The material in this performance graph is not soliciting material, is not deemed filed with the SEC and is not incorporated by reference in any filing of Insulet Corporation under the Securities Act of 1933, as amended or the Securities 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.

Dividends

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

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data

The following table presents selected financial and other data for Insulet Corporation. The consolidated statement of operations data set forth below for 2019, 2018 and 2017, and the consolidated balance sheet data as of December 31, 2019 and December 31, 2018, are derived from our audited consolidated financial statements included elsewhere in this annual report. The consolidated statement of operations data for 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, December 31, 2016 and December 31, 2015 are derived from our audited consolidated financial statements that are not included in this annual report.

The selected historical financial data presented below should be read in conjunction with our consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this annual report.

	Years Ended December 31,				
(in millions, except per share data)	**2019**	**2018**	**2017**	**2016**	**2015**
Consolidated Statement of Operations Data:					
Revenue	**$ 738.2**	$ 563.8	$ 463.8	$ 367.0	$ 263.9
Gross profit	**$ 480.3**	$ 370.2	$ 277.2	$ 211.1	$ 133.3
Operating income (loss) [1]	**$ 50.0**	$ 27.4	$ (7.4)	$ (10.7)	$ (48.7)
Income (loss) from continuing operations [2]	**$ 11.6**	$ 3.3	$ (26.8)	$ (27.2)	$ (61.6)
Income (loss) from continuing operations per share:					
Basic	**$ 0.19**	$ 0.06	$ (0.46)	$ (0.48)	$ (1.08)
Diluted	**$ 0.19**	$ 0.05	$ (0.46)	$ (0.48)	$ (1.08)
Weighted-average number of shares:					
Basic	**60.6**	58.9	58.0	57.3	56.8
Diluted	**62.3**	61.0	58.0	57.3	56.8
Consolidated Balance Sheet Data:					
Total assets	**$ 1,142.9**	$ 928.7	$ 816.7	$ 456.6	$ 275.1
Convertible debt, net	**$ 887.9**	$ 592.0	$ 566.2	$ 332.8	$ 172.0
Shareholders' equity	**$ 75.9**	$ 212.1	$ 158.5	$ 63.2	$ 34.1

[1] 2018 includes a charge of $12.6 million for severance costs associated with the retirement of the Company's former CEO, of which $8.2 million represented stock-based compensation expense resulting from the accelerated vesting of equity awards.

[2] 2019 includes an $8.7 million loss on extinguishment of debt.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our selected financial data and our consolidated financial statements and the accompanying notes included in this annual report. The following discussion may contain forward-looking statements that reflect our plans, estimates and beliefs, which are subject to risks, uncertainties and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed under the headings "Risk Factors" and "Forward-Looking Statements."

Overview

We are primarily engaged in the development, manufacture and sale of our proprietary Omnipod System, an innovative, 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 a person's body. Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod device that is worn on the body for up to three days at a time and its wireless companion, the handheld PDM. The Omnipod System, which features two discreet and 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.

The Omnipod is currently available in the United States, Canada and certain countries in Europe and the Middle East. We sell the Omnipod through direct sales to consumers or through our distribution partners and most recently in the U.S. through the pharmacy channel.

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. Most of our drug delivery revenue currently consists of sales of Pods to Amgen for use in the Neulasta Onpro kit, an innovative delivery system for Amgen's white blood cell booster to help reduce the risk of infection after intense chemotherapy.

Our mission is to improve the lives of people with diabetes. To assist in achieving this mission, we are focused on the following strategic objectives:

- delivering consumer-focused innovation;
- ensuring the best customer experience globally;
- expanding our global footprint; and
- driving operational excellence.

In the first half of 2019, we began production at our new highly automated manufacturing facility in Acton, Massachusetts, which also serves as our new 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. As of December 31, 2019, we had made cumulative investments of approximately $320 million in property, plant and infrastructure related to the new facility. We expect to continue to expand our investment in this facility in 2020 to support the growth of our business.

Additionally, in the first half of 2019, we completed a full market launch of Omnipod DASH in the United States. Omnipod DASH is our next-generation digital mobile Omnipod platform, featuring a secure Bluetooth enabled Pod and PDM with a color touch screen user interface supported by smartphone connectivity. In December of 2019, we introduced DASH to select European markets.

In late 2019, we completed our pre-pivotal trial for Omnipod Horizon, a closed loop control system that utilizes the DASH mobile platform to allow the Pod to communicate with a continuous glucose monitor and help control insulin delivery utilizing an algorithm located on the Pod. In December 2019, we began patient enrollment in our pivotal trial. We expect to launch Omnipod Horizon in the second half of 2020. While we expect Horizon to contribute to our long-term revenue growth, we do not expect it to meaningfully contribute to growth in 2020.

Our long-term financial objective is to sustain profitable growth. To achieve this goal, we expect our efforts in 2020 to focus primarily on the launch of Omnipod Horizon in the United States. In order to support our continued growth and the expected launch of Omnipod Horizon, in 2020 we also plan to focus on the startup of our second manufacturing line in our Acton facility and the installation of a third U.S. manufacturing line, which we expect to begin production on in 2021. Additionally, in 2020, we

expect to enter five new countries in Western Europe and the Middle East and further roll out DASH in Europe and Canada to expand the commercial sale of Omnipod and our global footprint. While we expect these new countries to contribute to our long-term revenue growth, we do not expect them to have a meaningful contribution in 2020. Finally, we plan to continue our product development efforts and expand awareness of and access to our products. 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.

Results of Operations

	Years Ended December 31,				Years Ended December 31,			
(In millions)	**2019**	**2018**	**Change $**	**Change %**	**2018**	**2017**	**Change $**	**Change %**
Revenue								
U.S. Omnipod	**$ 420.4**	$ 323.5	$ 96.9	30 %	$ 323.5	$ 271.6	$ 51.9	19 %
International Omnipod	**253.1**	172.0	81.1	47 %	172.0	120.0	52.0	43 %
Total Omnipod	**673.5**	495.5	178.0	36 %	495.5	391.6	103.9	27 %
Drug Delivery	**64.7**	68.3	(3.6)	(5)%	68.3	72.2	(3.9)	(5)%
Total revenue	**738.2**	563.8	174.4	31 %	563.8	463.8	100.0	22 %
Cost of revenue	**257.9**	193.6	64.3	33 %	193.6	186.6	7.0	4 %
Gross profit	**480.3**	370.2	110.1	30 %	370.2	277.2	93.0	34 %
Gross margin	**65.1%**	65.7%			65.7%	59.8%		
Operating expenses:								
Research and development	**129.7**	90.5	39.2	43 %	90.5	75.7	14.8	20 %
Sales and marketing	**185.1**	146.2	38.9	27 %	146.2	124.2	22.0	18 %
General and administrative	**115.5**	106.1	9.4	9 %	106.1	84.7	21.4	25 %
Total operating expenses	**430.3**	342.8	87.5	26 %	342.8	284.6	58.2	20 %
Operating income (loss)	**50.0**	27.4	22.6	82 %	27.4	(7.4)	34.8	470 %
Interest expense, net of portion capitalized	**(34.6)**	(28.9)	(5.7)	20 %	(28.9)	(21.2)	(7.7)	36 %
Loss on extinguishment of debt	(8.7)	—	(8.7)	NM	—	(0.6)	0.6	NM
Interest and other income, net	7.8	6.7	1.1	16 %	6.7	2.6	4.1	158 %
Income (loss) before income taxes	**14.5**	5.2	9.3	179 %	5.2	(26.6)	31.8	120 %
Income tax expense	**(2.9)**	(1.9)	(1.0)	53 %	(1.9)	(0.2)	(1.7)	850 %
Net income (loss)	**$ 11.6**	$ 3.3	$ 8.3	252 %	$ 3.3	$ (26.8)	$ 30.1	112 %

NM = Not meaningful

Comparison of the Years Ended December 31, 2019 and December 31, 2018

Revenue

Total revenue for 2019 increased $174.4 million, or 31%, to $738.2 million, compared with $563.8 million in 2018 due to strong growth in our U.S. and International Omnipod revenue. U.S. Omnipod revenue increased $96.9 million, or 30%, to $420.4 million, primarily due to higher volumes as we continue to expand awareness of and access to the Omnipod, and increased sales through the pharmacy channel, which has higher average selling prices due in part to the fact that we offer the PDM for no charge. International Omnipod revenue increased $81.1 million, or 47%, to $253.1 million, primarily due to the continued adoption of our product and more favorable pricing as a result of our shift to direct sales of the Omnipod in Europe in July 2018. Drug Delivery revenue decreased $3.6 million, or 5%, to $64.7 million, compared with 2018.

For 2020, we expect strong Omnipod revenue growth driven by continued market penetration and continued volume growth of Omnipod DASH, primarily in the U.S. pharmacy channel, partially offset by lower Drug Delivery revenue, due to a lower demand forecast. Internationally, we expect higher revenues primarily due to increasing sales volume as a result of greater awareness and availability of the Omnipod and further roll out of Omnipod DASH in Europe and Canada. In the U.S., we expect higher revenues primarily due to an increase in sales volume as a result of expanded payor coverage, greater awareness and availability of the Omnipod, commercial expansion strategies and the move into the pharmacy channel.

Gross Margin

Gross margin was 65.1% of revenue in 2019, compared with 65.7% in 2018. The decrease in gross margin was primarily due to start-up costs and inefficiencies related to our new U.S. manufacturing operations and product mix, which more than offset favorable distribution channel mix, favorable pricing following the expiration of our former distribution agreement in Europe and favorable geographic mix. We expect full year 2020 gross margin to be relatively consistent with 2019, which reflects the benefits of continued

improvements in manufacturing and supply chain operations and the move into the pharmacy channel in the U.S., offset by start-up costs and inefficiencies as we continue to ramp up our U.S. manufacturing operations.

Research and Development

Research and development expenses for 2019 increased $39.2 million, or 43%, to $129.7 million, compared with $90.5 million in 2018. This increase was primarily due to an increase in research and development expenses related to 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. We expect research and development spending for the full year 2020 to increase compared with 2019.

Sales and Marketing

Sales and marketing expenses for 2019 increased $38.9 million, or 27%, to $185.1 million, compared with $146.2 million in 2018. This increase was primarily attributable to investments to support our mid-2018 transition to direct sales of Omnipod in Europe, the expansion of our U.S. sales force and investments in customer support. We expect sales and marketing expenses for the full year 2020 to increase compared with 2019 due to additional expansion of our U.S. sales force and customer support personnel to facilitate our continued growth and expected entry into five new countries.

General and Administrative

General and administrative expenses for 2019 increased $9.4 million, or 9%, to $115.5 million, compared with $106.1 million in 2018. This increase was primarily attributable to increased personnel-related costs related to 2018 hires to support the establishment of our direct operations in Europe and increased depreciation related to our new headquarters facility, partially offset by $12.6 million of severance charges in 2018 related to the retirement of our former CEO, including stock-based compensation expense for the accelerated vesting of equity awards. We expect general and administrative expenses for 2020 to increase compared with 2019 as we continue to grow our business and make investments in our operating structure to support growth.

Interest Expense, Net of Portion Capitalized

Interest expense, net for 2019 increased $5.7 million, or 20%, to $34.6 million, compared with 2018. Interest expense, net for 2019 includes $9.5 million of cash interest expense and $35.6 million of non-cash interest expense associated with our convertible debt, partially offset by $10.5 million of interest capitalized as part of the cost of our U.S. manufacturing facility. The increase in interest expense, net primarily resulted from a $6.3 million increase in non-cash interest expense resulting from net impact of the issuance of $800.0 million of 0.375% convertible notes and the repayment of $402.5 million principal amount of 1.25% convertible notes. We expect interest expense for 2020 to increase compared with 2019 due to the annualized impact of the higher non-cash interest expense associated with the 0.375% convertible notes, compared with the 1.25% convertible notes.

Loss on Extinguishment of Debt

During 2019, we incurred an $8.7 million loss on extinguishment of debt related to the repurchase of our 1.25% Notes.

Interest and Other Income, Net

Other income, net for 2019 increased $1.1 million, to $7.8 million, compared with $6.7 million in 2018. This increase was primarily due to a $1.8 million insurance settlement received, partially offset by a decrease in interest income on our investment portfolio.

Income Tax Expense

Income tax expense was $2.9 million and $1.9 million on pre-tax income of $14.5 million and $5.2 million for 2019 and 2018, respectively. Our effective tax rate was 19.8% and 37.0% for 2019 and 2018, respectively. The decrease in our effective tax rate primarily resulted from an increase in earnings in the U.S., which has a full valuation allowance. See Note 18 to the consolidated financial statements for additional information on our income tax expense.

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

Revenue

Total revenue for 2018 increased $100.0 million, or 22%, to $563.8 million, compared with $463.8 million in 2017, primarily due to continued growth in our International and U.S. Omnipod revenue. International Omnipod revenue increased $52.0 million, or 43%, to $172.0 million, primarily due to both higher volumes and pricing as a result of our shift to direct sales of the Omnipod in Europe in July 2018. U.S. Omnipod revenue increased $51.9 million, or 19%, to $323.5 million due to expanded access to and awareness of the Omnipod System. Our Drug Delivery revenue decreased $3.9 million, or 5%, to $68.3 million, primarily reflecting a lower number of shipments during the year, partially offset by the favorable impact of adoption of new accounting guidance that requires 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.

Gross Margin

Cost of revenue was 65.7% of revenue in 2018, compared with 59.8% in 2017. The significant increase in gross margin was primarily due to favorable pricing resulting from our shift to direct sales in Europe following the expiration of our former distributor agreement and lower product cost as a result of continued improvements in manufacturing and supply chain operations.

Research and Development

Research and development expenses for 2018 increased $14.8 million, or 20%, to $90.5 million, compared with $75.7 million in 2017. This increase in research and development expenses was primarily due to an increase in expenses related to 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 at which production began in 2019.

Sales and Marketing

Sales and marketing expenses for 2018 increased $22.0 million, or 18% to $146.2 million in 2018, compared with $124.2 million in 2017. This increase in sales and marketing expenses was primarily due to investments to support our mid-2018 transition to direct sales of Omnipod 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 in connection with the adoption of new revenue recognition guidance described in Note 2 to the consolidated financial statements.

General and Administrative

General and administrative expenses for 2018 increased $21.4 million, or 25%, to $106.1 million, compared with $84.7 million in 2017. This increase in general and administrative expenses was primarily due to $12.6 million of severance charges associated with the retirement of our former CEO, of which $8.2 million related to stock-based compensation expense for the accelerated vesting of equity awards. General and administrative expenses also increased due to personnel costs to support the establishment of our direct commercial operations in Europe.

Interest Expense, Net of Portion Capitalized

Interest expense, net for 2018 increased $7.7 million, or 36%, to $28.9 million, compared with to 2017. Interest expense, net for 2018 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. The increase in interest expense, net 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 a $7.1 million increase in capitalized interest.

Interest and Other Income, Net

Interest and other income, net increased $4.1 million, to $6.7 million for 2018, compared with 2017. This increase was primarily due to an increase in interest income on our investment portfolio.

Income Tax Expense

Income tax expense was $1.9 million in 2018, compared with $0.2 million in 2017. The increase of $1.7 million in income tax expense was primarily due to growth in our international operations where we do not have net operating loss carryforwards. See Note 18 to the consolidated financial statements for additional information on our income tax expense.

Liquidity and Capital Resources

As of December 31, 2019, we had $213.7 million in cash and cash equivalents and $220.8 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.

Convertible Debt

To finance our operations and global expansion, we have periodically issued convertible senior notes, which are convertible into our common stock. In September 2019, we issued $800.0 million aggregate principal amount of 0.375% Convertible Senior Notes due September 2026. The net proceeds of $780.2 million were used to partially fund the redemption of our 1.25% Convertible Senior Notes due September 2021 and for the purchase of capped call options (“Capped Calls”) on our common stock. By entering into the Capped Calls, we expect to reduce the potential dilution to our common stock (or, in the event the conversion is settled in cash, to provide a source of cash to settle a portion of our cash payment obligation) in the event that at the time of conversion our stock price exceeds the conversion price under the Convertible Senior Notes. The Capped Calls have an initial strike price of $335.90 per share and cover 3.5 million shares of our common stock.

As of December 31, 2019, the following notes were outstanding:

Issuance Date	Coupon	Principal Outstanding (in millions)	Due Date	Initial Conversion Rate per Share of Common Stock	Conversion Price per Share of Common Stock
November 2017	1.375%	$ 402.5	November 2024	10.7315	$93.18
September 2019	0.375%	800.0	September 2026	4.4105	$226.73
Total		$ 1,202.5			

Additional information regarding our debt issuances is provided in Note 12 to the consolidated financial statements.

Summary of Cash Flows

	Years Ended December 31,	
(in millions)	2019	2018
Cash provided by (used in):		
Operating activities	**$ 98.4**	$ 35.9
Investing activities	**(73.6)**	(184.5)
Financing activities	**73.5**	(8.7)
Effect of exchange rate changes on cash	**1.5**	(1.4)
Net increase (decrease) in cash and cash equivalents	**$ 99.8**	$ (158.7)

The discussion of our operating, financing and investing activities for 2017 has been omitted from this Form 10-K but can be found in Item 7. Management's Discussion and Analysis and Results of Operations in our Form 10-K/A for the fiscal year ended December 31, 2018 filed with the Securities and Exchange Commission on February 28, 2019.

Operating Activities

Net cash provided by operating activities of $98.4 million in 2019 was primarily attributable to net income, as adjusted for non-cash interest, stock-based compensation, depreciation and amortization, partially offset by a $19.7 million working capital cash outflow. The working capital outflow was driven by a $30.2 million increase in inventories and a $21.9 million increase in prepaid expenses and other assets, partially offset by a $36.2 million increase in accounts payable, accrued expenses and other current liabilities, primarily driven by timing of payments. The increase in inventories was primarily due to an increase in raw materials and finished goods related to the startup of our U.S. manufacturing plant and an increase in work-in-process to support demand for our product. The increase in prepaid expenses and other assets was primarily driven by an increase in operating lease assets resulting from new leases entered into during the year and an increase in deferred commissions.

Net cash provided by operating activities of $35.9 million in 2018 was primarily attributable to net income, as adjusted for stock-based compensation, non-cash interest, depreciation and amortization, partially offset by a $52.8 million working capital cash outflow. The working capital outflow was driven by a $38.8 million increase in inventories to support higher demand for our product and a $22.9 million increase in accounts and unbilled receivables driven by our shift to direct sales of the Omnipod in Europe and the adoption of new revenue guidance on January 1, 2018, which resulted in recording $13.4 million of unbilled revenue at December 31, 2018.

Investing Activities

Net cash used in investing activities was $73.6 million and $184.5 million in 2019 and 2018, respectively.

Capital Spending—Capital expenditures were $163.7 million and $157.4 million for 2019 and 2018, respectively, primarily associated with the construction of our manufacturing and corporate headquarters facility in Acton, Massachusetts. We expect capital expenditures for 2020 to be relatively consistent with 2019 as we continue to expand manufacturing capacity to support our growth and the launch of Omnipod Horizon. We expect to fund our capital expenditures using a combination of existing cash and investments as well as cash generated from operations.

Purchases and Sales of Investments—During 2019, net sales of marketable securities were $97.3 million, compared with net purchases of marketable securities of $22.1 million for 2018. The increase in net sales of marketable securities was driven by a shift in a portion of our investment portfolio to investments that are classified as cash equivalents in order to satisfy future cash needs.

Financing Activities

Net cash provided by financing activities was $73.5 million in 2019, compared with net cash used in financing activities of $8.7 million in 2018.

Debt Issuance and Repayment—As previously discussed under "Convertible Debt" during 2019, we received net proceeds of $780.2 million from the issuance of our 0.375% Notes. We used $663.6 million of the proceeds to partially fund the redemption of our 1.25% Notes and $85.4 million to purchase Capped Calls. During 2018, we paid $6.7 million to settle all our outstanding 2% Notes.

Option Exercises and Issuance of Shares Under Employee Stock Purchase Plan ("ESPP")—Total proceeds from option exercises and the issuance of common stock under our ESPP increased $35.1 million to $50.9 million in 2019, compared with $15.8 million in 2018. This increase was primarily driven by option exercises stemming from the retirement of our former CEO and the departure of other executives, partially offset by a $9.2 million decrease in payments of withholding taxes related to net restricted share settlements. The decrease in tax payments was driven by a reduction in the vesting of restricted shares in 2019, compared with 2018, which was also due to the retirement of our former CEO and departure of other executives in 2018 and 2019, respectively.

Commitments and Contingencies

Contractual Obligations—A summary of our contractual obligations and commitments for debt, operating lease obligations and other obligations at December 31, 2019 is presented in the following table:

(in millions)	Total	2020	2021	2022	2023	2024	Thereafter
Operating lease obligations	$ 20.6	$ 4.7	$ 5.0	$ 4.7	$ 2.3	$ 2.4	$ 1.5
Debt obligations	1,202.5	—	—	—	—	402.5	800.0
Interest payments	46.9	8.5	8.5	8.5	8.5	7.8	5.1
Purchase obligations (1)	158.7	115.8	40.9	2.0	—	—	—
Total contractual obligations	$ 1,428.7	$ 129.0	$ 54.4	$ 15.2	$ 10.8	$ 412.7	$ 806.6

(1) Purchase obligations include commitments for the purchase of Omnipod System components, commitments related to establishing additional manufacturing capabilities and other commitments for purchases of goods or services in the normal course of business. These commitments are derived from purchase orders, supplier contracts and open orders based on projected demand information.

Following the expiration of an agreement with a former European distributor on June 30, 2018, we were required to pay a quarterly per-unit fee for Omnipod sales to certain customers of the former European distributor for a one-year period through June 30, 2019. The methodology applicable for determining the total fee under the distribution agreement is subject to an active arbitration proceeding in Switzerland. The final amount of the fee could vary significantly depending on the number of customers who count for purposes of calculating the fee under the terms of the agreement; accordingly, this fee has been excluded from the contractual obligations table above. We estimate that the final aggregate fee for the applicable twelve-month period could be in the range of $5 million to $55 million. We paid $3.8 million and $1.3 million of this fee during 2019 and 2018, respectively.

Off-Balance Sheet Arrangements

As of December 31, 2019, we had various outstanding letters of credit and bank guarantees totaling $2.9 million, none of which are individually significant. The Company has restricted cash that serves as collateral for these outstanding letters of credit and bank guarantees that is included in cash and cash equivalents on the consolidated balance sheet.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. The following accounting policies are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. Management's estimates are based on the relevant information available at the end of each period.

Revenue Recognition

We recognize revenue when a customer obtains control of the promised products in an amount that reflects the net consideration to which we expect to be entitled. We sell products both direct to consumers and through distributors who resell the products to consumers. Transaction price is typically based on contracted rates less any estimates of claim denials and historical reimbursement experience, guidelines and payor mix, and less estimated variable consideration adjustments including rebates. Recognizing revenue requires us to exercise judgment and use estimates that can have a significant impact on the amount and timing of revenue we report. We exercise significant judgment when we determine the transaction price, including variable consideration adjustments. The amount of variable consideration that is included in the transaction price is included in revenue only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We estimate reductions to our revenues for rebates paid to distributors in the United States and Canada and pharmacy benefit managers ("PBM") in the United States. Rebates are based on contractual arrangements, which may vary. Our estimates are based on products

sold, historical experience, trends and, as available, channel inventory data. Rebates charged against gross sales amounted to $59.1 million, $34.1 million and $16.1 million in 2019, 2018 and 2017, respectively. Provisions for rebates, sales discounts and returns, are accounted for as a reduction of sales when revenue is recognized and are included within accounts receivable trade or accrued expenses and other current liabilities on our consolidated balance sheets, based upon the recipient of the rebate. If the actual amounts of consideration that we receive differ from our estimates, we would adjust our estimates and that would affect reported revenue in the period that such variances become known.

Our drug delivery product line includes sales of a modified version of the Omnipod to pharmaceutical and biotechnology companies who use our technology as a delivery method for their drugs. Revenue from the drug delivery product was $64.7 million for 2019. Revenue for this product line is recognized as the product is produced. Accounting for drug delivery revenue requires us to select a method to measure progress towards the satisfaction of the performance obligation. This election of the most meaningful measure of progress by which to recognize drug delivery revenue requires the application of judgment. We elected the input method and selected a blend of cost and time to produce as the measure of progress. Accordingly, revenue is recognized 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 our performance obligations. We believe 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.

Product Warranty

We provide a four-year warranty on our PDMs sold in the United States and Europe and a five-year warranty on PDMs sold in Canada and may replace Pods that do not function in accordance with product specifications. We estimate our 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 in the consolidated statements of operations. Costs to service the claims reflect the current product cost. Since we continue to introduce new products and versions, the anticipated performance of the product over the warranty period is also considered in estimating warranty reserves. Changes to the actual replacement rates, which are evaluated quarterly, could have a material impact on our estimated warranty reserve.

Accounts Receivable and Allowance for Doubtful Accounts

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We evaluate the collectability of our accounts receivable based on a combination of factors. We regularly analyze customer accounts, review the length of time receivables are outstanding, review historical loss rates and assess current economic trends that may impact the level of credit losses in the future. Our allowance for doubtful accounts has generally been adequate to cover our actual credit losses. However, since we cannot reliably predict future changes in the financial stability of our customers, we may need to increase our reserves if the financial conditions of our customers deteriorate.

Contingencies

We are involved in various legal proceedings that arise in the ordinary course of business as further discussed in Note 13 to our consolidated financial statements, including an ongoing arbitration proceeding with a former European distributor. Accruals recorded for various contingencies including legal proceedings, self-insurance and other claims, are based on judgment, both regarding the probability of losses and range of loss, and, where applicable, include the consideration of opinions of internal and/or external legal counsel. When a range is established but a best estimate cannot be made, we record the minimum loss contingency amount, which could be zero. An estimate is often initially developed substantially earlier than the ultimate loss is known and is reevaluated each accounting period. As information becomes known, additional loss provision is recorded when either a best estimate can be made, or the minimum loss amount is increased. When events result in an expectation of a more favorable outcome than previously expected, our best estimate is changed to a lower amount. We record receivables from third-party insurers up to the amount of the related liability when we have determined that existing insurance policies will provide reimbursement. In making this determination, we consider applicable deductibles, policy limits and the historical payment experience of the insurance carriers.

Accounting Standards Issued and Not Yet Adopted as of December 31, 2019

In December 2019, the Financial Accounting Standards Board (“FASB”) issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. ASU 2019-12 eliminates certain exceptions in the current guidance regarding the approach for intraperiod tax allocations, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. This new guidance also simplifies the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies such things as the accounting for transactions that result in a step up in the tax basis of goodwill. The guidance is effective for us beginning in the first quarter of 2021 with early adoption permitted. We are currently evaluating the impact of this guidance on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"). ASU 2017-04 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 us beginning in the first quarter of 2020. Early adoption is permitted. We do not expect the adoption of this guidance to impact our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Credit Losses (Topic 326)* ("ASU 2016-13"). ASU 2016-13 requires financial assets measured at amortized cost, such as our trade receivables and contract assets, to 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 assets. The new guidance also requires enhanced disclosures related to trade receivables and associated credit losses. The guidance is effective for us beginning in the first quarter of 2020. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

Forward-Looking Statements

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

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not put undue reliance on any forward-looking statements.

The risk factors discussed in "Risk Factors" could cause our results to differ materially from those expressed in forward-looking statements. In addition, there may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

The primary objectives of our investment strategy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. To minimize our exposure to an adverse shift in interest rates, we invest mainly in cash equivalents and short-term investments in a variety of securities, including money market funds, U.S. Treasury debt and corporate debt securities. Due to the short-term nature of our investments, we believe that we have no material exposure to interest rate risk.

Market Price Sensitive Instruments

As of December 31, 2019, we had outstanding debt related to our convertible senior notes recorded on our consolidated balance sheet of $887.9 million, net of unamortized discount and issuance costs totaling $314.6 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 was $1.35 billion as of December 31, 2019, is also impacted by changes in our stock price.

In order to reduce potential equity dilution, in connection with the issuance of $800.0 million aggregate principal amount of 0.375% Notes, we entered into capped call options "Capped Calls". We expect the Capped Calls to reduce the potential dilution to our common stock (or, in the event the conversion is settled in cash, to provide a source of cash to settle a portion of our cash payment obligation) in the event that at the time of conversion our stock price exceeds the conversion price under the 0.375% Notes. The Capped Calls have an initial strike price of $335.90 per share and cover 3.5 million shares of common stock.

Foreign Currency Exchange Risk

Foreign currency risk arises from our investments in subsidiaries owned and operated in non-U.S. countries. Such risk is also a result of transactions with customers in countries outside the United States. Approximately 34% of our revenue was denominated in foreign currencies for the year ended December 31, 2019. As our business in regions outside of the United States continues to increase, we will be increasingly exposed to foreign currency exchange risk related to our foreign operations. The cost of revenue related to revenue generated outside of the United States is primarily denominated in U.S. dollars; however, operating costs related to these revenues are largely denominated in the same respective currencies, thereby partially limiting our transaction risk exposure. Fluctuations in the rate of exchange between the United States dollar and foreign currencies, primarily the Euro, British Pound and Canadian Dollar, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities.

We have intercompany receivables and payables from our foreign subsidiaries that are denominated in foreign currencies, principally the Euro, the British pound and the Canadian dollar. Fluctuations from the beginning to the end of a reporting period result in the revaluation of our foreign currency-denominated intercompany receivables and payables, generating currency translation gains or losses. Net realized and unrealized gains (losses) from foreign currency transactions are included in interest and other income, net in the consolidated statement of operations and amounted to $0.6 million for the year ended December 31, 2019.

Item 8. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2019 and 2018 and for each of the three years in the period ended December 31, 2019, and the Report of the Registered Independent Public Accounting Firm are included in this report as listed in the index.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Insulet Corporation

Opinions on the financial statements and internal control over financial reporting
We have audited the accompanying consolidated balance sheets of Insulet Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and schedule (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, 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 financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in the 2013 Internal Control-Integrated Framework issued by COSO.

Basis for opinions
The Company's management is responsible for these financial statements, 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 financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements 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 regarding 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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.

Critical audit matters
The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and

we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition - Drug Delivery
As described in Note 4 to the consolidated financial statements, the Company's revenue from drug delivery was $64.7 million for the year ended December 31, 2019. Drug delivery revenue is recognized over time based on the Company's determination of the pattern over which control transfers to the customer. This transfer of control begins during the manufacturing process and continues through the final quality control inspection process until there is complete satisfaction of the performance obligation. We identified drug delivery revenue recognition and the associated unbilled receivable as a critical audit matter.

The principal considerations for our determination that this matter is a critical audit matter are as follows:

Accounting for drug delivery revenue requires the Company to select a method to measure progress towards the satisfaction of the performance obligation. This election of the most meaningful measure of progress by which to recognize drug delivery revenue requires the application of significant Management judgment. The Company elected the input method and selected a blend of cost and time to produce for measure of progress. Given the nature of the revenue being recognized, additional audit effort including modification of the nature and extent of our procedures beyond that of the Company's other revenue streams was required.

Our audit procedures included, but were not limited to, the following:

- We tested the design and operating effectiveness of controls relating to Management's estimate of the measure of progress.
- For the measure of progress, we inspected evidence related to the cost and length of the production cycle.
- For revenue recognized on in-process or finished goods inventory not yet shipped to the customer (and the related unbilled receivable), we inspected customer orders, binding customer forecasts, inventory records, and confirmed inventory quantities directly with third parties when applicable.

Convertible Debt Offering and Note Repurchase
As described in Note 12 to the consolidated financial statements, the Company completed a private placement offering of $800 million in 0.375% Convertible Senior Notes (the "New Notes"), with the proceeds partially used to repurchase the previously outstanding 1.25% Convertible Senior Notes (the "Existing Notes"). We identified these transactions as a critical audit matter.

The principal considerations for our determination that this matter is a critical audit matter are as follows.

Accounting for the convertible debt offering and the repurchase of the Existing Notes was a significant unusual transaction that required extensive audit effort. This included the involvement of technical accounting specialists to evaluate Management's conclusions surrounding the bifurcation of the notes between debt and equity and the extinguishment conclusion for the repurchase of the Existing Notes. Additionally, valuation specialists were included to determine the fair value of the equity component of the New Notes and the fair value of the Existing Notes utilized in the determination of the loss on extinguishment. This included the evaluation of the market yield input, which was derived using a Binomial Option Pricing Model.

Our audit procedures included, but were not limited to, the following:

- We tested the control design and operating effectiveness related to the accounting for the transaction including Management's evaluation of the qualifications of specialists and review of the work performed by the specialists.
- We traced all key terms, and amounts to source documents, including the related offering memorandums and purchase agreements.
- We supplemented the engagement team with technical accounting specialists to confirm Management's accounting conclusions including the determination that the New Notes be bifurcated between debt and equity as well as the determination that the repurchase of a portion of the Existing Notes be accounted for as an extinguishment of debt.
- With the assistance of valuation professionals with specialized skills and knowledge, we tested Management's valuation of both the New Notes and the Existing Notes which included a recalculation of the related amounts and an assessment of the appropriateness of the methodology, inputs, and assumptions used.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2016.

Boston, Massachusetts
February 25, 2020

INSULET CORPORATION

CONSOLIDATED BALANCE SHEETS

(in millions, except share and per share data)	As of December 31, 2019	2018
ASSETS		
Current Assets		
Cash and cash equivalents	**$ 213.7**	$ 113.9
Short-term investments	**162.4**	175.0
Accounts receivable trade, less allowance for doubtful accounts of $3.8 and $3.6	**69.3**	63.3
Unbilled receivable	**13.5**	13.4
Inventories	**101.0**	71.4
Prepaid expenses and other current assets	**31.1**	24.3
Total current assets	**591.0**	461.3
Long-term investments	**58.4**	140.8
Property, plant and equipment, net	**399.4**	258.4
Other intangible assets, net	**13.2**	10.4
Goodwill	**39.8**	39.6
Other assets	**41.1**	18.2
Total assets	**$ 1,142.9**	$ 928.7
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	**$ 54.5**	$ 25.5
Accrued expenses and other current liabilities	**103.2**	90.2
Total current liabilities	**157.7**	115.7
Convertible debt, net	**887.9**	592.0
Other liabilities	**21.4**	8.9
Total liabilities	**1,067.0**	716.6
Commitment and Contingencies (Note 13)		
Stockholders' Equity		
Preferred stock, $.001 par value:		
Authorized: 5,000,000 shares at December 31, 2019 and 2018. Issued and outstanding: zero shares at December 31, 2019 and 2018.	**—**	—
Common stock, $.001 par value:		
Authorized: 100,000,000 shares at December 31, 2019 and 2018. Issued and outstanding: 62,685,492 and 59,188,758 shares at December 31, 2019 and 2018, respectively.	**0.1**	0.1
Additional paid-in capital	**749.0**	898.5
Accumulated deficit	**(672.0)**	(683.6)
Accumulated other comprehensive loss	**(1.2)**	(2.9)
Total stockholders' equity	**75.9**	212.1
Total liabilities and stockholders' equity	**$ 1,142.9**	$ 928.7

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

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except share and per share data)	Years Ended December 31, 2019	2018	2017
Revenue	**$ 738.2**	$ 563.8	$ 463.8
Cost of revenue	**257.9**	193.6	186.6
Gross profit	**480.3**	370.2	277.2
Operating expenses:			
Research and development	**129.7**	90.5	75.7
Sales and marketing	**185.1**	146.2	124.2
General and administrative	**115.5**	106.1	84.7
Total operating expenses	**430.3**	342.8	284.6
Operating income (loss)	**50.0**	27.4	(7.4)
Interest expense, net of portion capitalized	**(34.6)**	(28.9)	(21.2)
Loss on extinguishment of debt	**(8.7)**	—	(0.6)
Interest and other income, net	**7.8**	6.7	2.6
Income (loss) before income taxes	**14.5**	5.2	(26.6)
Income tax expense	**(2.9)**	(1.9)	(0.2)
Net income (loss)	**$ 11.6**	$ 3.3	$ (26.8)
Net income (loss) per share:			
Basic	**$ 0.19**	$ 0.06	$ (0.46)
Diluted	**$ 0.19**	$ 0.05	$ (0.46)
Weighted-average number of common shares outstanding:			
Basic	**60,593,846**	58,859,574	58,003,434
Diluted	**62,304,348**	61,008,024	58,003,434

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

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Years Ended December 31,		
(in millions)	**2019**	**2018**	**2017**
Net income (loss)	**$ 11.6**	$ 3.3	$ (26.8)
Other comprehensive income (loss), net of tax			
Foreign currency translation adjustment, net of tax	**0.6**	(2.2)	0.5
Unrealized gain (loss) on available-for-sale securities, net of tax	**1.1**	(0.2)	(0.3)
Total other comprehensive income (loss), net of tax	**1.7**	(2.4)	0.2
Total comprehensive income (loss)	**$ 13.3**	$ 0.9	$ (26.6)

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

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in millions, except share data)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance, December 31, 2016	57,457,967	$ 0.1	$ 744.2	$ (680.5)	$ (0.7)	$ 63.1
Exercise of options to purchase common stock	505,207	—	14.0	—	—	14.0
Issuance of shares for employee stock purchase plan	59,134	—	1.8	—	—	1.8
Stock-based compensation expense	—	—	31.9	—	—	31.9
Restricted stock units vested, net of shares withheld for taxes	297,040	—	(4.0)	—	—	(4.0)
Allocation to equity for conversion feature on 1.375% Notes, net of issuance costs	—	—	117.5	—	—	117.5
Extinguishment of conversion feature on 2% Notes, net of issuance costs	—	—	(39.2)	—	—	(39.2)
Net loss	—	—	—	(26.8)	—	(26.8)
Other comprehensive income	—	—	—	—	0.2	0.2
Balance, December 31, 2017	58,319,348	0.1	866.2	(707.3)	(0.5)	158.5
Exercise of options to purchase common stock	409,428	—	12.8	—	—	12.8
Issuance of shares for employee stock purchase plan	46,343	—	3.0	—	—	3.0
Stock-based compensation expense			37.5	—	—	37.5
Restricted stock units vested, net of shares withheld for taxes	413,639	—	(17.8)	—	—	(17.8)
Extinguishment of conversion feature on 2% Notes, net of issuance costs	—	—	(3.2)	—	—	(3.2)
Adoption of ASC 606 (Note 2)	—	—	—	20.4	—	20.4
Net income	—	—	—	3.3	—	3.3
Other comprehensive loss	—	—	—	—	(2.4)	(2.4)
Balance, December 31, 2018	59,188,758	0.1	898.5	(683.6)	(2.9)	212.1
Exercise of options to purchase common stock	**1,340,297**	**—**	**46.6**	**—**	**—**	**46.6**
Issuance of shares for employee stock purchase plan	**51,502**	**—**	**4.3**	**—**	—	**4.3**
Stock-based compensation expense	**—**	**—**	**28.7**	**—**	—	**28.7**
Restricted stock units vested, net of shares withheld for taxes	**229,770**	**—**	**(8.6)**	**—**	—	**(8.6)**
Conversion feature of 0.375% Notes, net of issuance costs	**—**	**—**	**207.8**	**—**	—	**207.8**
Extinguishment of conversion feature on 1.25% Notes, net of issuance costs	**—**	**—**	**(642.3)**	**—**	—	**(642.3)**
Issuance of shares for debt repayment	**1,875,165**	**—**	**299.4**	—	—	**299.4**
Purchase of capped call options	**—**	**—**	**(85.4)**	**—**	**—**	**(85.4)**
Net income	**—**	**—**	**—**	**11.6**	**—**	**11.6**
Other comprehensive income	**—**	**—**	**—**	**—**	**1.7**	**1.7**
Balance, December 31, 2019	**62,685,492**	**$ 0.1**	**$ 749.0**	**$ (672.0)**	**$ (1.2)**	**$ 75.9**

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

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)	Years Ended December 31, 2019	2018	2017
Cash flows from operating activities			
Net income (loss)	**$ 11.6**	$ 3.3	$ (26.8)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	**27.9**	15.6	13.9
Non-cash interest expense	**35.6**	29.3	18.0
Stock-based compensation expense	**28.7**	37.5	31.9
Loss on extinguishment of convertible debt	**8.7**	—	0.6
Provision for bad debts	**4.5**	3.4	1.9
Other	**1.1**	(0.4)	0.1
Changes in operating assets and liabilities:			
Accounts and unbilled receivable	**(10.9)**	(22.9)	(26.3)
Inventories	**(30.2)**	(38.8)	1.7
Deferred revenue	**2.0**	(3.8)	1.1
Prepaid expenses and other assets	**(21.9)**	(11.6)	(3.3)
Accounts payable, accrued expenses and other current liabilities	**36.2**	21.2	27.3
Other long-term liabilities	**5.1**	3.1	1.2
Net cash provided by operating activities	**98.4**	35.9	41.3
Cash flows from investing activities			
Capital expenditures	**(163.7)**	(157.4)	(73.8)
Acquisition of intangible assets	**(7.2)**	(5.0)	(3.4)
Purchases of investments	**(150.6)**	(191.4)	(298.0)
Receipts from the maturity or sale of investments	**247.9**	169.3	164.4
Net cash used in investing activities	**(73.6)**	(184.5)	(210.8)
Cash flows from financing activities			
Principal payments of capital lease obligations	**—**	—	(0.3)
Proceeds from issuance of convertible debt, net of issuance costs	**780.2**	—	391.6
Purchase of capped call options	**(85.4)**	—	—
Repayment of convertible debt	**(663.6)**	(6.7)	(98.5)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	**50.9**	15.8	15.8
Payment of withholding taxes in connection with vesting of restricted stock units	**(8.6)**	(17.8)	(4.1)
Net cash provided by (used in) financing activities	**73.5**	(8.7)	304.5
Effect of exchange rate changes on cash	**1.5**	(1.4)	0.4
Net increase (decrease) in cash and cash equivalents	**99.8**	(158.7)	135.4
Cash and cash equivalents, beginning of year	**113.9**	272.6	137.2
Cash and cash equivalents, end of year	**$ 213.7**	$ 113.9	$ 272.6
Supplemental cash flow information			
Cash paid for interest, net of amount capitalized	**$ —**	$ —	$ 2.5
Cash paid for taxes	**$ 2.5**	$ 0.8	$ 0.5
Purchases of property, plant and equipment included in accounts payable and accrued expenses	**$ 13.3**	$ 11.4	$ 3.8

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

Note 1. Nature of the Business

Insulet Corporation (the "Company") is primarily engaged in the development, manufacture and sale of its proprietary Omnipod System, an innovative, continuous insulin delivery system for people with insulin-dependent diabetes. The Omnipod System features a small, lightweight, self-adhesive disposable tubeless Omnipod device that is worn on the body for up to 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 multiple daily injections using syringes or insulin pens or the use of traditional pump and tubing. The Omnipod System consists of two product lines: the Omnipod Insulin Management System ("Omnipod") and its next generation Omnipod DASH™ Insulin Management System ("Omnipod DASH" or "DASH"). Omnipod DASH features a secure Bluetooth enabled Pod and PDM with a color touch screen user interface supported by smartphone connectivity.

The Company generates most of its revenue from sales of the Omnipod System, which is sold in the U.S., Europe, Canada and the Middle East. The Omnipod System is sold either directly to end-users or indirectly through intermediaries. Intermediaries 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 in the United States.

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

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements reflect the consolidated operations of Insulet Corporation and its subsidiaries. The consolidated financial statements have been prepared in United States dollars, in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of the consolidated financial statements in conformity with GAAP requires management to make use of estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses. Actual results may differ from those estimates.

Principles of Consolidation

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

Reclassification of Prior Period Amounts

Certain reclassifications have been made to prior period amounts to conform to the current period financial statement presentation. Software license costs have been reallocated from general and administrative expenses to research and development and sales and marketing expenses based on license usage. These reclassifications have no effect on previously reported net income.

Foreign Currency Translation

For the foreign subsidiaries of the Company, assets and liabilities are translated into U.S. dollars using exchange rates as of the balance sheet date, and income and expenses are translated using the average exchange rates in effect for the related month. The net effect of these translation adjustments is reported in accumulated other comprehensive loss within stockholders' equity on the consolidated balance sheet. Net realized and unrealized gains (losses) from foreign currency transactions are included in interest and other income, net in the consolidated statement of operations and were $0.6 million and $1.0 million for the years ended December 31, 2019 and 2018, respectively. The amount for 2017 was insignificant.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents include money market mutual funds, commercial paper and U.S. government and agency bonds that are carried at cost, which approximates their fair value. Restricted cash that serves as collateral for outstanding letters of credit are included in cash and cash equivalents on the consolidated balance sheet.

Investments in Marketable Securities

Short-term and long-term investment securities consist of certificates of deposit, commercial paper, U.S. government and agency bonds and corporate bonds. Theses available-for-sale marketable securities are carried at fair value and unrealized gains and losses

are included as a component of other comprehensive loss in stockholders' equity on the consolidated balance sheet. 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 on the consolidated balance sheet. 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 included in other income, net in the consolidated statement of operations.

Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable consist of amounts due from third-party payors, customers and intermediaries and are presented net of an allowance for doubtful accounts. The allowance for doubtful accounts reflects an estimate of losses inherent in the Company's accounts receivable portfolio determined based on historical experience, specific allowances for known troubled accounts and other available evidence. Accounts receivable are written off when management determines they are uncollectible.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined under the first-in, first-out method. The Company reduces the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors in order to state inventories at net realizable value. Factors influencing these adjustments include inventories on hand compared to estimated future usage and sales. Work in process is calculated based upon a buildup of cost based on the stage of production. Manufacturing variances attributable to abnormally low production are expensed in the period incurred.

Contract Acquisition Costs

The Company incurs commission costs to obtain a contract related to new customer starts. These costs are capitalized as contract assets 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 costs are periodically reviewed for impairment.

Fair Value Measurements

Fair value is defined as the price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. When estimating fair value, the Company may use one or all 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, the Company uses the following fair value hierarchy based on three levels of inputs:

Level 1 — observable inputs, such as quoted prices in active markets for identical assets or liabilities;

Level 2 — significant other observable inputs that are observable either directly or indirectly;

Level 3 — significant unobservable inputs for which there is little or no market data, which require the Company to develop its own assumptions.

Certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and other liabilities are carried at cost, which approximates their fair value because of their short-term maturity. See Notes 5 and 12 for financial assets and liabilities held at carrying amount on the consolidated balance sheet and Note 6 for investments measured at fair value on a recurring basis.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Major improvements are capitalized, while routine repairs and maintenance are expensed as incurred. Depreciation for property, plant and equipment, other than land and construction in progress, is based upon the following estimated useful lives using the straight-line method:

Building and building improvements	20 to 39 years
Leasehold improvements	Lesser of lease term or useful life of asset
Machinery and equipment	2 to 15 years
Furniture and fixtures	3 to 5 years

The Company assesses the recoverability of assets whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company recognizes an impairment loss if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows. The 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 based on their estimated fair values at the date of acquisition. The Company allocates the purchase price in excess of net tangible assets acquired to identifiable intangible assets. 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. 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.

Goodwill and Other Intangible Assets

Goodwill represents the excess of the purchase price of an acquired entity over the amounts assigned to assets and liabilities assumed in a business combination. 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 may assess its goodwill for impairment initially using a qualitative approach to determine whether conditions exist that indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. If management concludes, based on its assessment of relevant events, facts and circumstances that it is more likely that not that a reporting unit's carrying value is greater than its fair value, then a quantitative analysis will be performed to determine if there is any impairment. Alternatively, the Company may elect to initially perform a quantitative analysis instead of starting with a qualitative analysis. In performing the quantitative 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.

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in other transactions are recorded at cost and are stated at cost less accumulated amortization. Intangible assets with finite useful lives are amortized using the straight-line method over the following estimated useful lives of the assets:

Customer relationships	5 - 10 years
Internal-use software	3 - 10 years
Intellectual property	15 years

Amortization expense is included in operating expenses in the consolidated statement of operations. The Company reviews intangible assets for impairment by comparing the fair value of the assets, estimated using an income approach, with their carrying value. If the carrying value exceeds the fair value of the intangible asset, the Company recognizes an impairment equal to the difference between the carrying value of the asset and the present value of future cash flows. The Company assesses the remaining useful life and the recoverability of intangible assets whenever events or circumstances indicate that the carrying value of an asset may not be recoverable using undiscounted cash flows.

Leases

The Company determines if an arrangement includes a lease at inception. Lease agreements generally have lease and non-lease components, which are accounted for separately. At lease commencement, the Company recognizes operating lease liabilities equal to the present value of the lease payments and operating lease assets representing the right to use the underlying asset for the lease term. The Company assesses if it is reasonably certain to exercise lease options to extend or terminate the lease for inclusion or exclusion in the lease term when the Company measures the lease liability. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at lease commencement in determining the present value of lease payments. The Company's incremental borrowing rate estimates a secured rate that reflects the term of the lease, the nature of the underlying asset and the economic environment. The Company excludes leases with an expected term of one year or less from recognition on the consolidated balance sheet. Operating lease assets includes lease payments made prior to lease commencement and excludes lease incentives and initial direct costs incurred. Lease expense is recognized on a straight-line basis over the lease term and is included in general and administrative expenses in the consolidated statements of operations.

Contingencies

The Company records a liability on the consolidated balance sheet for loss contingencies when a loss is 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.

Product Warranty

The Company provides a four-year warranty on its PDMs sold in the United States and Europe and a five-year warranty on PDMs sold in Canada and may replace Pods that do 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 in the consolidated statements of operations. Costs to service the claims reflect the current product cost. Since the Company continues to introduce new products and versions, the anticipated performance of the product over the warranty period is also considered in estimating warranty reserves.

Revenue Recognition

Effective January 1, 2018, the Company adopted ASU 2014-09, *Revenue from Contracts with Customers*, and its related amendments (collectively referred to as ASC 606) using the modified retrospective method for all contracts not completed as of the date of adoption. The cumulate effect of applying the new revenue standard resulted in a $20.4 million decrease to the opening balance of accumulated deficit upon adoption, primarily related to how revenue is recognized for the Company's drug delivery product line and the capitalization of contract acquisition costs such as commissions. Financial information for 2017 has not been restated and continues to be reported under the guidance in effect prior to the adoption of ASC 606.

Revenue is recognized when a customer obtains control of the promised products. The amount of revenue recognized reflects the consideration 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:

- *Identify Contracts with Customers.* The Company's contracts with its direct customers generally consist of a physician order form, a customer 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.
- *Identify 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 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.
- *Determine 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 it is probable that a significant future reversal of cumulative revenue under the contract will not occur; otherwise, the Company reduces the variable consideration. The variable consideration in the Company's contracts is not typically constrained and the Company's contracts do not contain significant financing components.
- *Allocate Transaction Price to Performance Obligations.* 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.
- *Recognize Revenue as Performance Obligations are Satisfied.* 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 ownership. 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.

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. 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.

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.

Concentrated Insulin Delivery: 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 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 expenses.

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 $9.7 million, $6.6 million and $5.0 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Stock-Based Compensation

The Company measures stock-based compensation expense at the grant date based on the fair value of the award and recognizes the compensation expense over the requisite service period, which is generally the vesting period. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are expected to vest. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated 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. A valuation allowance is provided to reduce the deferred tax assets if, based on the available evidence, it is more likely than not that some or all the deferred tax assets will not be realized. 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.

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 most of its cash, and short-term and long-term investments with a limited number of financial institutions that have a high investment grade credit rating.

In addition to manufacturing the Omnipod System, the Company also purchases Omnipod Systems from Flex Ltd. As of both December 31, 2019 and 2018, liabilities to this vendor represented 10% of the combined balance of accounts payable and accrued expenses and other current liabilities. See Note 4 for customer concentration.

Recently Adopted Accounting Standards

Effective January 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 and its related amendments (collectively referred to as ASC 842). ASC 842 requires lessees to recognize

operating lease liabilities and operating lease assets, representing the right to use the underlying asset for the lease term, on the balance sheet for leases classified as operating leases. The Company adopted ASC 842 on January 1, 2019 using the modified retrospective method, whereby the new guidance is applied prospectively as of the date of adoption and prior periods are not restated. The Company elected the practical expedients that permit the Company to not reassess (1) whether any expired or existing contracts are or contain leases, (2) the lease classification for any expired or existing leases, and (3) any initial direct costs for existing leases as of the effective date. Upon the adoption, the Company recorded operating lease liabilities of $10.8 million and operating lease assets of $8.8 million on its consolidated balance sheet. The difference between the value of the lease obligations and the operating lease assets was primarily attributable to a $1.1 million cease-use liability established in 2018 associated with the Company's former headquarters, which was reclassified to an operating lease liability upon adoption of ASC 842. See Note 11 for additional information regarding leases.

Effective January 1, 2019, the Company early adopted 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 certain costs to implement a cloud computing arrangement that is a service contract to be capitalized consistent with the rules applicable to internal-use software capitalization projects. The Company adopted this new guidance prospectively. The Company defers eligible costs related to the implementation of cloud computing arrangements within other current and non-current assets and amortizes such costs over the expected term of the hosting arrangement to the same income statement line as the associated cloud operating expenses. Adoption of this standard resulted in the Company capitalizing $3.6 million of cloud computing implementation costs for the year ended December 31, 2019.

Note 3. Segment and Geographic Data

The Company operates under one reportable segment. Operating segments are defined as components of an enterprise for 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 ("CEO") is the CODM as the CEO is the ultimate decision maker for key operating decisions, determining the allocation of resources and assessing the financial performance of the Company. These decisions, allocations and assessments are performed by the CODM using consolidated financial information, as the Company's current product offering primarily consists of the Omnipod System and drug delivery devices based on the Omnipod platform.

Geographic information about revenue, based on delivery location, is as follows:

	Years Ended December 31,		
(in millions)	**2019**	**2018**	**2017**
United States	**$ 485.1**	$ 391.8	$ 343.8
All other	**253.1**	172.0	120.0
Total	**$ 738.2**	$ 563.8	$ 463.8

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

	As of December 31,	
(in millions)	**2019**	**2018**
United States	**$ 363.0**	$ 232.3
China	**35.9**	25.6
Other	**0.5**	0.9
Total	**$ 399.4**	$ 258.8

Note 4. Revenue and Contract Acquisition Costs

The following table summarizes the Company's disaggregated revenues:

	Years Ended December 31,		
(in millions)	**2019**	**2018**	**2017**
U.S. Omnipod	**$ 420.4**	$ 323.5	$ 271.6
International Omnipod	**253.1**	172.0	120.0
Total Omnipod	**673.5**	495.5	391.6
Drug Delivery	**64.7**	68.3	72.2
Total revenue	**$ 738.2**	$ 563.8	$ 463.8

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

	Years Ended December 31,		
	2019	**2018**	**2017**
Amgen, Inc.	*****	12%	15%
Ypsomed	*****	*	22%
Cardinal Health Inc. and affiliates	**11%**	12%	11%

* Represents less than 10% of revenue for the period.

Deferred revenue related to unsatisfied performance obligations was included in the following consolidated balance sheet accounts in the amounts shown:

	As of December 31,	
(in millions)	**2019**	**2018**
Accrued expenses and other current liabilities	**$ 3.2**	$ 1.2
Other liabilities	**1.0**	0.9
Total deferred revenue	**$ 4.2**	$ 2.1

Revenue recognized for the year ended December 31, 2019 included in deferred revenue at the beginning of 2019 was $1.2 million. Revenue recognized during the 2018 included in deferred revenue at the beginning of 2018 was $2.4 million. No revenue was recognized for the years ended December 31, 2019 and 2018 from performance obligations satisfied or partially satisfied in previous periods.

Contract acquisition costs, representing capitalized commission costs related to new customers, net of amortization, were included in the following consolidated balance sheet accounts in the amounts shown:

	As of December 31,	
(in millions)	**2019**	**2018**
Prepaid expenses and other current assets	**$ 9.5**	$ 7.3
Other assets	**19.9**	16.0
Total capitalized contract acquisition costs, net	**$ 29.4**	$ 23.3

The Company recognized $8.8 million and $6.9 million of amortization of capitalized contract acquisition costs for the years ended December 31, 2019 and 2018, respectively.

Note 5. Cash and Cash Equivalents

The following tables provide a summary of cash and cash equivalents as of December 31, 2019 and 2018 and the level in the fair value hierarchy in which those measurements fall:

(in millions)	Fair Value Measurements		
December 31, 2019	**Total**	**Level 1**	**Level 2 [1]**
Cash	**$ 85.3**	**$ 85.3**	**$ —**
Money market mutual funds	**115.5**	**115.5**	**—**
Commercial paper	**10.0**		**10.0**
Restricted cash	**2.9**	**2.9**	
Total cash and cash equivalents	**$ 213.7**	**$ 203.7**	**$ 10.0**
December 31, 2018			
Cash	$ 64.0	$ 64.0	$ —
Money market mutual funds	47.2	47.2	—
Restricted cash	2.7	2.7	
Total cash and cash equivalents	$ 113.9	$ 113.9	$ —

[1] Fair value was determined using market prices obtained from third-party pricing sources.

Note 6. Investments

The Company's short-term and long-term investments in debt securities had maturity dates that range from two months to two years at December 31, 2019. Realized gains or losses in each of the three years ended December 31, 2019, 2018 and 2017 were insignificant.

The following tables provides amortized costs, gross unrealized gains and losses, fair values and the level in the fair value hierarchy for the Company's investments at December 31, 2019 and 2018:

(in millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Level 1	Level 2 [1]
December 31, 2019						
U.S. government and agency bonds	**$ 94.7**	**$ 0.3**	**$ —**	**$ 95.0**	**$ 85.0**	**$ 10.0**
Corporate bonds	**51.0**	**0.1**	**—**	**51.1**	**—**	**51.1**
Certificates of deposit	**6.3**	**—**	**—**	**6.3**	**—**	**6.3**
Commercial paper	**10.0**	**—**	**—**	**10.0**		**10.0**
Total short-term investments	**$ 162.0**	**$ 0.4**	**$ —**	**$ 162.4**	**$ 85.0**	**$ 77.4**
U.S. government and agency bonds	**$ 52.9**	**$ 0.1**	**$ (0.1)**	**$ 52.9**	**$ 42.9**	**$ 10.0**
Corporate bonds	**2.8**	**—**	**—**	**2.8**	**—**	**2.8**
Certificates of deposit	**2.7**	**—**	**—**	**2.7**	**—**	**2.7**
Total long-term investments	**$ 58.4**	**$ 0.1**	**$ (0.1)**	**$ 58.4**	**$ 42.9**	**$ 15.5**
December 31, 2018						
U.S. government and agency bonds	$ 113.0	$ —	$ (0.5)	$ 112.5	$ 69.6	$ 42.9
Corporate bonds	56.2	—	(0.2)	56.0	—	56.0
Certificates of deposit	6.5	—	—	6.5	—	6.5
Total short-term investments	$ 175.7	$ —	$ (0.7)	$ 175.0	$ 69.6	$ 105.4
U.S. government and agency bonds	$ 90.5	$ 0.1	$ (0.2)	$ 90.4	$ 64.1	$ 26.3
Corporate bonds	46.7	—	—	46.7	—	46.7
Certificates of deposit	3.7	—	—	3.7	—	3.7
Total long-term investments	$ 140.9	$ 0.1	$ (0.2)	$ 140.8	$ 64.1	$ 76.7

[1] Fair value was determined using market prices obtained from third-party pricing sources.

Note 7. Inventories

At the end of each period, inventories were comprised of the following:

	As of December 31,	
(in millions)	**2019**	**2018**
Raw materials	**$ 23.3**	$ 10.4
Work-in-process	**40.3**	30.2
Finished goods	**37.4**	30.8
Total inventories	**$ 101.0**	$ 71.4

Note 8. Property, Plant and Equipment, Net

Property, plant and equipment at cost and accumulated depreciation were as follows:

	As of December 31,	
(in millions)	**2019[1]**	**2018**
Land	**$ 2.5**	$ 2.5
Building and building improvements	**116.9**	44.2
Machinery and equipment	**194.8**	93.3
Furniture and fixtures	**12.7**	6.3
Leasehold improvements	**1.6**	1.4
Construction in process	**161.5**	176.1
Total property, plant and equipment	**490.0**	323.8
Less: accumulated depreciation	**(90.6)**	(65.4)
Property, plant and equipment, net	**$ 399.4**	$ 258.4

[1] Reclassification of prior period amounts were made from furniture and fixtures to building and building improvements to conform with current period financial statement presentation.

Depreciation expense related to property and equipment was $25.2 million, $13.8 million and $12.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. Construction in process primarily consists of manufacturing equipment located at the Company's U.S. manufacturing facility in Acton, Massachusetts, which is expected to be placed into service during 2020.

Note 9. Goodwill and Other Intangible Assets, Net

Goodwill

The changes in the carrying amount of goodwill for 2019 and 2018 were as follows:

	Years Ended December 31,	
(in millions)	**2019**	**2018**
Beginning balance	**$ 39.6**	$ 39.8
Foreign currency adjustment	**0.2**	(0.2)
Ending balance	**$ 39.8**	$ 39.6

Intangible Assets, Net

The gross carrying amount, accumulated amortization and net book value of intangible assets at the end of each period were as follows:

	As of December 31,					
	2019			2018		
(in millions)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Customer relationships [1]	**$ 9.9**	**$ (2.8)**	**$ 7.1**	$ 6.1	$ (1.9)	$ 4.2
Internal-use software	**12.0**	**(6.8)**	**5.2**	11.3	(5.1)	6.2
Intellectual property	**1.0**	**(0.1)**	**0.9**	—	—	—
Total intangible assets	**$ 22.9**	**$ (9.7)**	**$ 13.2**	$ 17.4	$ (7.0)	$ 10.4

[1] Includes customer relationships acquired from the Company's former European distributor. See Note 13.

Intangible asset amortization expense was $2.7 million, $1.8 million and $1.2 million for the years ended December 31, 2019, 2018 and 2017, respectively. Amortization expense associated with the intangible assets included on the Company's balance sheet as of December 31, 2019 is expected to be as follows:

Years Ending December 31,	(in millions)
2020	$ 2.9
2021	2.4
2022	1.9
2023	1.3
2024	1.2
Thereafter	3.5
Total	$ 13.2

Note 10. Accrued Expenses and Other Current Liabilities

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

	As of December 31,	
(in millions)	2019	2018
Employee compensation and related costs	**$ 45.8**	$ 37.8
Professional and consulting services	**19.3**	14.9
Accrued rebates	**7.5**	2.8
Supplier purchases	**2.4**	7.7
Value added taxes payable	**1.8**	8.5
Other	**26.4**	18.5
Accrued expenses and other current liabilities	**$ 103.2**	$ 90.2

Reconciliations of the changes in the Company's product warranty liability were as follows:

	Years Ended December 31,	
(in millions)	2019	2018
Product warranty liability at beginning of year	**$ 6.4**	$ 5.3
Warranty expense	**13.4**	7.8
Warranty claims settled	**(11.3)**	(6.7)
Product warranty liability at end of year	**$ 8.5**	$ 6.4

Note 11. Leases

As of December 31, 2019, the Company leased certain office spaces, laboratory space, warehouse space and automobiles, all of which were classified as operating leases. Certain of the Company's operating leases include escalating rental payments, some include the option to extend for up to 5 years, and some include options to terminate the leases at certain times within the lease term. As of December 31, 2019, the Company included options to extend certain leases for 5 years in the measurement of the lease liability.

As of December 31, 2019, operating lease assets and operating lease liabilities were included in the following consolidated balance sheet accounts in the amounts shown:

	(in millions)
Operating lease asset:	
Other assets	**$ 16.1**
Operating lease liabilities:	
Accrued expenses and other current liabilities	**$ 3.6**
Other liabilities	**14.4**
Total	**$ 18.0**

The Company's total operating lease cost was $4.3 million for the year ended December 31, 2019. Total rental expense was $3.3 million and $2.8 million for the years ended December 31, 2018 and 2017, respectively. Cash paid for amounts included in the measurement of lease liabilities was $3.6 million for the year ended December 31, 2019. Operating lease liabilities arising from obtaining operating lease assets was $9.8 million for the year ended December 31, 2019.

Maturities of lease liabilities as of December 31, 2019 are as follows:

Years Ending December 31,	(in millions)
2020	$ 4.5
2021	5.0
2022	4.7
2023	2.3
2024	2.4
Thereafter	1.5
Total future minimum lease payments	20.4
Less: imputed interest	(2.4)
Present value of future minimum lease payments	$ 18.0

As of December 31, 2019, the weighted average remaining lease term for operating leases was 4.4 years and the weighted-average discount rate used to determine the operating lease liability was 5.9%.

Note 12. Convertible Debt, Net

The components of outstanding convertible debt consisted of the following:

	As of December 31,	
(in millions)	**2019**	**2018**
1.25% Convertible Senior Notes, due September 2021	**$ —**	$ 345.0
1.375% Convertible Senior Notes, due November 2024	**402.5**	402.5
0.375% Convertible Senior Notes, due September 2026	**800.0**	—
Unamortized debt discount	**(294.8)**	(143.6)
Debt issuance costs	**(19.8)**	(11.9)
Total convertible debt, net	**$ 887.9**	$ 592.0

0.375% Convertible Senior Notes

In September 2019, the Company issued $800.0 million aggregate principal amount of 0.375% Convertible Senior Notes due September 2026 (the "0.375% Notes"). The notes are convertible into the Company's common stock at an initial conversion rate of 4.4105 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of $226.73

per share, subject to adjustment under certain circumstances. The notes will be convertible June 1, 2026 through August 28, 2026 and prior thereto under certain circumstances.

The Company recorded a debt discount of $213.0 million related to the 0.375% 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 5.29% per annum. The Company also incurred debt issuance costs and other expenses of $19.8 million, of which $5.3 million was reclassified as a reduction to the value of the conversion feature allocated to equity. The remaining $14.5 million of debt issuance costs was recorded as a reduction of debt on the consolidated balance sheet. The net proceeds of $780.2 million were used to fund the redemption of the Company's 1.25% Convertible Senior Notes due September 2021 (the "1.25% Notes") and to purchase capped call options ("Capped Calls"), both of which are discussed below.

Additional interest of 0.5% per annum is payable if the Company fails to timely file required documents or reports with the Securities and Exchange Commission ("SEC"). If the Company merges or consolidates with a foreign entity, the Company may be required to pay additional taxes. The Company determined that the higher interest payments and tax payments required in certain circumstances were embedded derivatives that should be bifurcated and accounted for at fair value. The Company assessed the value of the embedded derivatives at December 31, 2019 and determined it had nominal value.

In conjunction with the issuance of the 0.375% Notes, the Company paid $85.4 million to enter into Capped Calls on the Company's common stock with certain counterparties, which was recorded as a reduction to additional paid-in capital on the consolidated balance sheet. By entering into the Capped Calls, the Company expects to reduce the potential dilution to its common stock (or, in the event the conversion is settled in cash, to provide a source of cash to settle a portion of its cash payment obligation) in the event that at the time of conversion its stock price exceeds the conversion price under the 0.375% Notes. The Capped Calls have an initial strike price of $335.90 per share, which represents a premium of 100% over the last reported sale price of the Company's common stock of $167.95 per share on the date of the transaction. The Capped Calls cover 3.5 million shares of common stock.

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 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 notes, which is equivalent to a conversion price of $93.18 per share, subject to adjustment under certain circumstances. The notes will be convertible August 15, 2024 through November 13, 2024 and prior thereto only under certain circumstances.

The Company recorded a debt discount of $120.7 million related to the 1.375% Notes resulting from the allocation of a portion of the proceeds to the fair value of the conversion feature reflecting a nonconvertible debt borrowing rate of 6.8% per annum. The Company also incurred debt issuance costs and other expenses of $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 was presented as a reduction of debt on the consolidated balance sheet.

Additional interest of 0.5% per annum is payable if the Company fails to timely file required documents or reports with the SEC. If the Company merges or consolidates with a foreign entity, the Company may be required to pay additional taxes. The Company determined that the higher interest payments and tax payments required in certain circumstances were embedded derivatives that should be bifurcated and accounted for at fair value. The Company assessed the value of the embedded derivatives at each balance sheet date and determined it had nominal value.

1.25% Convertible Senior Notes

In 2019, the Company repurchased its $345.0 million principal amount ($312.0 million net of discount and issuance costs) 1.25% Notes for total consideration of $963.0 million comprised of $663.6 million in cash and $299.4 million representing the fair value of the 1.87 million shares issued. The Company allocated $642.3 million of the settlement to the fair value of the equity component and $320.7 million to the debt component, which resulted in an $8.7 million loss on extinguishment.

2% Convertible Senior Notes

In 2017, the Company repurchased $63.4 million in principal of its 2% Convertible Senior Notes due June 2019 (the "2% Notes"). The Company called the remaining 2% Notes in 2018 and settled the outstanding principal and conversion feature for $6.7 million in cash. The Company allocated $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.

Fair Value

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, 2019 and 2018 are as follows:

	As of December 31,			
	2019		2,019 2018	
(in millions)	Carrying Value	Estimated Fair Value [1]	Carrying Value	Estimated Fair Value [1]
1.25% Convertible Senior Notes	**—**	**—**	301.0	483.9
1.375% Convertible Senior Notes	**306.9**	**512.8**	291.0	426.0
0.375% Convertible Senior Notes	**581.0**	**840.0**	—	—
Total	**$ 887.9**	**$ 1,352.8**	$ 592.0	$ 909.9

[1] Fair value was determined using market prices obtained from third-party pricing sources.

Note 13. Commitments and Contingencies

Legal Proceedings

Between May 5, 2015 and June 16, 2015, three class action lawsuits were filed by shareholders in the U.S. District Court, for the District of Massachusetts, against the Company and certain individual current and former executives of the Company. Two suits subsequently were voluntarily dismissed. Arkansas Teacher Retirement System v. Insulet, et al., 1:15-cv-12345, ("ATRS") alleged that the Company (and certain executives) committed violations of Sections 10(b) and 20(a) and Rule 10b-5 of the Securities Exchange Act of 1934 by making allegedly false and misleading statements about the Company's business, operations, and prospects. On February 8, 2018, the parties executed a binding stipulation of settlement, under which all claims were released, and a payment was made to the plaintiffs and the class they purport to represent. On August 6, 2018, the Court issued an order approving the settlement, but took the plaintiffs' motion for fees and expenses under advisement, which motion remains pending. 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. The Company does not expect the outcome of these proceedings, either individually or in the aggregate, to have a material adverse effect on its results of operations.

Fees to Former European Distributor

Following the expiration of an agreement with a former European distributor on June 30, 2018, the Company was required to pay a quarterly per-unit fee for Omnipod sales to certain customers of the former European distributor for a one-year period through June 30, 2019. The Company recognized a liability and an associated intangible asset for this fee as qualifying sales occurred. The methodology applicable for determining the total fee under the distribution agreement is subject to an active arbitration proceeding in Switzerland. The final amount of the fee could vary significantly depending on the number of customers who count for purposes of calculating the fee under the terms of the agreement. The Company estimates that the final aggregate fee is in the range of $5 million to $55 million. As of December 31, 2019 and 2018, the Company had accrued $2.7 million and $2.9 million, respectively, for fees related to Omnipod devices sold to qualifying customers. The associated gross intangible asset for the fee was $7.8 million and $4.2 million as of December 31, 2019 and 2018, respectively.

Note 14. Stock-Based Compensation

Equity Award Plan

In May 2017, the Company adopted the 2017 Stock Option and Incentive Plan (the "2017 Plan"), which replaced its previous stock option and incentive plan (the "2007 Plan"). The 2017 Plan provides for a maximum of 5.2 million shares to be issued, in addition to the number of shares related to awards outstanding under the 2007 Plan that are terminated by expiration, forfeiture or cancellation. The shares can be issued as 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. As of December 31, 2019, 3.9 million shares remain available for future issuance under the 2017 Plan.

Stock-Based Compensation

Compensation cost related to stock-based awards recognized for the years ended December 31, 2019, 2018 and 2017 was recorded as follows:

	Year Ended December 31,		
(in millions)	**2019**	**2018**	**2017**
Cost of revenue	**$ 1.0**	$ 0.8	$ 0.5
Research and development	**9.1**	8.2	5.9
Sales and marketing	**7.8**	7.6	8.8
General and administrative	**10.8**	20.9	16.7
Total	**$ 28.7**	$ 37.5	$ 31.9

Stock Options

Options are granted to purchase common shares at prices that are equal to the fair market value of the shares on the date the options are granted. Options generally vest in equal annual installments over a period of four years and expire 10 years after the date of grant. The grant-date fair value of options, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period.

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2018	3,077,624	$ 39.16		
Granted	125,640	93.16		
Exercised	(1,345,386)	35.02		$ 119.2
Forfeited and canceled	(128,366)	51.55		
Outstanding at December 31, 2019	1,729,512	$ 45.39	5.4	$ 217.6
Vested, December 31, 2019	1,361,514	$ 38.71	4.7	$ 180.4
Vested or expected to vest, December 31, 2019	1,689,570	$ 44.59	5.3	$ 213.9

The aggregate intrinsic value of options exercised for the years ended December 31, 2018 and 2017 was $23.5 million and $11.8 million, respectively.

The Company uses the Black-Scholes pricing model to determine the fair value of options granted. 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. The assumptions used in the Black-Scholes pricing model for options granted during each year, along with the weighted-average grant-date fair values, were as follows:

	Years Ended December 31,		
	2019	2018	2017
Risk-free interest rate	**1.8% - 2.6%**	2.2% - 2.9%	1.7% - 1.9%
Expected life of options (in years)	**4.4 - 4.8**	4.5 - 5.4	4.7 - 5.3
Dividend yield	**—%**	—%	—%
Expected stock price volatility	**40.1% - 40.5%**	38.7% - 40.7%	38.5% - 39.1%
Fair value per option	**$ 34.98**	$ 30.34	$ 17.28

As of December 31, 2019, there was $7.6 million of unrecognized compensation cost related to non-vested stock options. This cost is expected to be recognized over a weighted average period of 2.4 years.

Restricted Stock Units

Restricted Stock Units ("RSUs") generally vest in equal annual installments over a three-year period. The grant-date fair value of RSUs, adjusted for estimated forfeitures, is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The Company determines the fair value of restricted stock units based on the closing price of its common stock on the date of grant.

RSU activity is as follows:

	Number of Shares	Weighted Average Fair Value
Outstanding at December 31, 2018	416,811	$ 56.51
Granted	218,810	96.62
Vested	(231,647)	50.13
Forfeited	(51,687)	71.32
Outstanding at December 31, 2019	352,287	$ 83.44

The weighted-average grant-date fair value per share of RSUs granted was $96.62, $76.03 and $46.13 for the years ended December 31, 2019, 2018 and 2017, respectively. The total fair value of RSUs vested was $11.6 million, $14.7 million and $11.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, there was $18.9 million of unrecognized compensation cost related to time-based RSUs, which is expected to be recognized over a weighted-average period of 1.9 years.

Performance Stock Units

Performance stock units ("PSUs") generally vest over a three-year period from the grant date and include both a service and performance component. Stock-based payments that contain performance conditions are recognized when such conditions are probable of being achieved. Certain of these performance stock units could ultimately vest at up to 200% of the target award depending on the achievement of the performance criteria.
PSU activity is as follows:

	Number of Shares	Weighted Average Fair Value
Outstanding at December 31, 2018	335,396	$ 53.17
Granted	81,118	95.91
Vested	(93,088)	34.27
Forfeited	(24,270)	62.32
Outstanding at December 31, 2019 [(1)]	299,156	$ 73.35

[(1)] Based on 200% achievement of the performance metrics, approximately 172,000 shares of Insulet were earned for awards that were granted in 2017 for the performance period ended December 31, 2019. These shares vested in February 2020.

The weighted-average grant-date fair value per share of PSUs granted was $95.91, $75.07 and $50.02 for the years ended December 31, 2019, 2018 and 2017, respectively. The total fair value of PSUs vested was $3.2 million, $7.6 million and $0.9 million for the years ended December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, there was $12.2 million of unrecognized compensation cost related to PSUs, which is expected to be recognized over a weighted-average period of 1.9 years.

Employee Stock Purchase Plan

The Employee Stock Purchase Plan ("ESPP") authorizes the issuance of up to 880,000 shares of common stock to participating employees. Employees that 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 by authorizing payroll deductions of up to 10% of their base salary. The purchase price for each share purchased is 85% of the lower of the fair market value of the common stock on the first or last day of the offering period. The Company issued 51,502, 46,343 and 59,134 shares of common stock for the years ended December 31, 2019, 2018 and 2017, respectively, to employees participating in the ESPP. As of December 31, 2019, 547,075 shares remain available for future issuance under the ESPP Plan.

The Company uses the Black-Scholes pricing model to determine the fair value of shares purchased under the ESPP. The calculation of the fair value of shares purchased is affected by the stock price on the purchase date, the expected volatility of the Company's stock over the expected term, the risk-free interest rate and the dividend yield. The estimated fair value of shares purchased under the ESPP were based on the following assumptions:

	Years Ended December 31,		
	2019	**2018**	**2017**
Risk-free interest rate	**1.6% - 2.3%**	2.1% - 2.5%	1.1% - 1.5%
Expected term (in years)	**0.5**	0.5	0.5
Dividend yield	**—%**	—%	—%
Expected stock price volatility	**27.5% - 31.4%**	23.4% - 27.0%	22.9% - 26.7%

The weighted average grant date fair value of the six-month option inherent in the ESPP was $46.30, $26.01, and $15.18, for the years ended December 31, 2019, 2018 and 2017, respectively.

As of December 31, 2019, there was $1.0 million of unrecognized compensation cost related to the ESPP. This cost is expected to be recognized over a weighted average period of 0.4 years.

Note 15. Accumulated Other Comprehensive Loss

Changes in the components of accumulated other comprehensive loss, net of tax, were as follows:

(in millions)	Foreign Currency Translation Adjustment	Unrealized Losses on Available-for-sale Securities	Accumulated Other Comprehensive Loss
Balance, December 31, 2016	$ (0.5)	$ (0.2)	$ (0.7)
Other comprehensive income (loss)	0.5	(0.3)	0.2
Balance, December 31, 2017	—	(0.5)	(0.5)
Other comprehensive loss	(2.2)	(0.2)	(2.4)
Balance, December 31, 2018	(2.2)	(0.7)	(2.9)
Other comprehensive income	**0.6**	**1.1**	**1.7**
Balance, December 31, 2019	**$ (1.6)**	**$ 0.4**	**$ (1.2)**

Note 16. Defined Contribution Plan

The Company maintains a tax-qualified 401(k) retirement plan in the United States. The Company generally makes a matching contribution equal to 50% of each employee's elective contribution to the plan up to six percent of the employee's eligible pay. In addition, the Company offers defined contribution plans for eligible employees in its foreign subsidiaries. The total amount contributed by the Company to these defined contribution plans was $5.3 million, $3.6 million and $3.0 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Note 17. Interest Expense

Interest expense, net of portion capitalized was follows:

	Years Ended December 31,		
(in millions)	**2019**	**2018**	**2017**
Contractual coupon interest	**$ 9.5**	$ 9.8	$ 6.3
Accretion of debt discount	**32.8**	26.7	15.9
Amortization of debt issuance costs	**2.8**	2.6	2.1
Capitalized interest	**(10.5)**	(10.2)	(3.1)
Interest expense, net of portion capitalized	**$ 34.6**	$ 28.9	$ 21.2

Note 18. Income Taxes

The U.S. and foreign components of income (loss) before income taxes were as follows:

	Years Ended December 31,		
(in millions)	**2019**	**2018**	**2017**
U.S.	**$ 2.5**	$ (3.0)	$ (27.7)
Foreign	**12.0**	8.2	1.1
Income (loss) before income taxes	**$ 14.5**	$ 5.2	$ (26.6)

Income tax expense consists of the following:

	Years Ended December 31,		
(in millions)	**2019**	**2018**	**2017**
Current:			
State	**$ 0.2**	$ 0.2	$ 0.1
Foreign	**3.4**	2.1	0.6
Total current expense	**3.6**	2.3	0.7
Deferred:			
Federal	**(0.1)**	—	(0.3)
Foreign	**(0.6)**	(0.4)	(0.2)
Total deferred expense	**(0.7)**	(0.4)	(0.5)
Income tax expense	**$ 2.9**	$ 1.9	$ 0.2

Reconciliations of the federal statutory income rate to the Company's effective income tax rate are as follows:

	Years Ended December 31,		
	2019	**2018**	**2017**
U.S. statutory rate	**21.0 %**	21.0 %	34.0 %
Foreign rate differential	**4.2**	(2.4)	— 0.3
State taxes, net of federal benefit	**1.3**	2.9	10.2
Tax credits	**(15.4)**	(13.7)	13.3
Stock-based compensation	**(158.7)**	(159.1)	33.6
Loss on extinguishment of debt	**14.8**	—	—
Non-deductible officers' compensation	**1.9**	81.3	(20.2)
Permanent items	**3.0**	16.8	(14.0)
Foreign income taxed in the U.S.	**19.0**	26.1	—
Change in valuation allowance	**130.6**	67.0	(57.9)
Other	**(1.9)**	(2.9)	(0.3)
Effective income tax rate	**19.8 %**	37.0 %	(1.0)%

As of December 31, 2019, 2018 and 2017 the Company had no uncertain tax positions.

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, 2019, the Company has chosen to indefinitely reinvest its earnings of its non-U.S. subsidiaries, except Canada. To the extent the Company repatriates its foreign earnings, certain withholding taxes and state taxes may apply. The Company has recorded a deferred tax liability for tax that could be incurred upon repatriation of the Canada earnings, the amount of which is not significant. A deferred tax liability related to the repatriation of the indefinitely reinvested earnings would not be material to the Company's consolidated financial statements.

The Company files federal, state and foreign tax returns, which are subject to examination by the relevant tax authorities. The tax filings relating to the Company's federal and state tax returns are currently open to examination for tax years 2016 through 2018 and 2015 through 2018, respectively. The Company is currently under exam in Ontario, Canada. In addition, the Company generated tax losses from inception in 2000. These years may be subject to examination if the losses are carried forward and utilized in future years.

The components of the net deferred tax asset at the end of each year are as follows:

	As of December 31,	
(in millions)	**2019**	**2018**
Deferred tax assets:		
Net operating loss carryforwards	**$ 144.6**	$ 124.9
Tax credits	**15.2**	13.0
Provision for bad debts	**1.2**	1.1
Depreciation and amortization	**—**	3.5
Capital loss carryforwards	**12.7**	12.6
Stock-based compensation	**8.9**	9.3
Other	**12.6**	6.4
Total deferred tax assets	**195.2**	170.8
Deferred tax liabilities:		
Prepaid assets	**(2.1)**	(2.0)
Depreciation and amortization	**(2.2)**	—
Amortization of debt discount	**(73.4)**	(35.7)
Capitalized contract acquisition costs	**(7.1)**	(5.8)
Other	**(5.0)**	(0.8)
Total deferred tax liabilities	**(89.8)**	(44.3)
Net deferred tax asset before valuation allowance	105.4	126.5
Valuation allowance	**(104.4)**	(126.3)
Net deferred tax asset	**$ 1.0**	$ 0.2

The valuation allowances for deferred tax assets of $104.4 million and $126.3 million at December 31, 2019 and 2018, respectively, relate primarily to U.S. tax loss carryforwards that management believes are not more likely than not to be utilized. The $21.9 million decrease in the Company's valuation allowance during the year ended December 31, 2019 was primarily due to the issuance of convertible debt discussed in Note 12.

The Company's net operating loss carryforwards consist of the following:

	Years Ended December 31,	
(in millions)	**2019**	**2018**
Gross federal net operating loss carryforwards	**$ 607.4**	$ 528.1
State operating loss carryforwards	**298.8**	246.4
Total	**$ 906.2**	$ 774.5

For U.S. federal tax purposes, $66.8 million of the net operating losses have an indefinite carryforward period. The remaining federal carryforwards, if not utilized, will begin to expire in 2020 and will continue to expire through 2037, and the state carryforwards will continue to expire through 2038. 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. Research and

development and other tax credits were $16.1 million and $13.0 million at December 31, 2019 and 2018, respectively. If not utilized, federal research and development credits will begin to expire in 2022.

Note 19. 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. Diluted net income (loss) per share is computed using the weighted average number of common shares outstanding and, when dilutive, 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 table below sets forth the components used in the computation of basic and diluted net income (loss) per share:

	Years Ended December 31,		
(in millions, except share and per share data)	**2019**	**2018**	**2017**
Numerator:			
Net income (loss)	**$ 11.6**	$ 3.3	$ (26.8)
Denominator:			
Weighted average number of common shares outstanding, basic	**60,593,846**	58,859,574	58,003,434
Effect of dilutive common share equivalents			
Stock options	**1,486,973**	1,678,535	—
Restricted stock units	**223,529**	469,915	—
Weighted average number of common shares outstanding, diluted	**62,304,348**	61,008,024	58,003,434
Net income (loss) per share:			
Basic	$ 0.19	$ 0.06	$ (0.46)
Diluted	$ 0.19	$ 0.05	$ (0.46)

The number of common share equivalents excluded from the computation of diluted net income (loss) per share because either the effect would have been anti-dilutive, or the performance criteria related to the units had not yet been met were as follows:

	Years Ended December 31,		
	2019	**2018**	**2017**
2.00% Convertible Senior Notes	—	—	78,783
1.25% Convertible Senior Notes	—	5,910,954	5,910,954
1.375% Convertible Senior Notes	4,319,429	4,319,429	4,319,429
0.375% Convertible Senior Notes	3,528,400	—	—
Unvested restricted stock units	430,593	289,974	994,364
Outstanding stock options	12,820	236,648	3,377,220
Total common share equivalents excluded from computation of diluted net income (loss) per share	8,291,242	10,757,005	14,680,750

Note 20. Quarterly Data (Unaudited)

(in millions, except per share data)	2019 Quarters Ended			
	March 31	June 30	September 30 [1]	December 31 [2]
Revenue	**$ 159.6**	**$ 177.1**	**$ 192.1**	**$ 209.4**
Gross profit	**$ 106.7**	**$ 116.4**	**$ 123.1**	**$ 134.1**
Net income	**$ 4.4**	**$ 1.4**	**$ 0.8**	**$ 5.0**
Net income per share:				
Basic	**$ 0.07**	**$ 0.02**	**$ 0.01**	**$ 0.08**
Diluted	**$ 0.07**	**$ 0.02**	**$ 0.01**	**$ 0.08**

[1] Net income includes a $6.4 million loss on extinguishment of debt incurred in connection with the repurchase of the Company's 1.25% Convertible Senior Notes.

[2] Net income includes a $2.3 million loss on extinguishment of debt incurred in connection with the repurchase of the Company's 1.25% Convertible Senior Notes.

(in millions, except per share data)	2018 Quarters Ended			
	March 31	June 30	September 30 [3]	December 31
Revenue	$ 123.6	$ 124.2	$ 151.1	$ 164.9
Gross profit	$ 75.8	$ 82.1	$ 102.0	$ 110.3
Net income (loss)	$ (6.6)	$ (1.7)	$ 1.7	$ 9.9
Net income (loss) per share:				
Basic	$ (0.11)	$ (0.03)	$ 0.03	$ 0.17
Diluted	$ (0.11)	$ (0.03)	$ 0.03	$ 0.16

[3] Net income includes a charge of $12.6 million for severance costs associated with the retirement of the Company's former CEO, of which $8.2 million represented stock-based compensation expense for the accelerated vesting of share-based equity awards.

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

The following table sets forth activities in the Company's accounts receivable reserve, reserve for rebates 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 millions)				
Year Ended December 31, 2019				
Allowance for doubtful accounts	$ 3.6	$ 4.5	$ (4.3)	$ 3.8
Reserve for rebates	$ 8.6	$ 59.1	$ (55.6)	$ 12.1
Deferred tax valuation allowance	$ 126.3	$ 43.6	$ (65.5)	$ 104.4
Year Ended December 31, 2018				
Allowance for doubtful accounts	$ 2.5	$ 3.4	$ (2.3)	$ 3.6
Reserve for rebates	$ 6.3	$ 34.1	$ (31.8)	$ 8.6
Deferred tax valuation allowance	$ 127.9	$ 13.9	$ (15.5)	$ 126.3
Year Ended December 31, 2017				
Allowance for doubtful accounts	$ 2.9	$ 1.9	$ (2.3)	$ 2.5
Reserve for rebates	$ 1.4	$ 16.1	$ (11.2)	$ 6.3
Deferred tax valuation allowance	$ 191.9	$ 14.2	$ (78.2)	$ 127.9

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, 2019. 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, 2019, 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, 2019 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. Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. 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 our internal controls over financial reporting were effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Grant Thornton LLP, an independent registered public accounting firm. Their report is included in Item 8 of this Form 10-K.

ITEM 9B. OTHER INFORMATION

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item will be set forth in our definitive proxy statement for our 2020 Annual Meeting of Stockholders (the "Proxy Statement") and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item will be set forth in the Proxy Statement and is incorporated herein by reference.

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

Other than as set forth below, the information required by this Item will be set forth in the Proxy Statement and is incorporated herein by reference.

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, 2019.

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 (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders [1]	1,246,226	$ 49.19	3,936,268 [2]
Equity compensation plans not approved by security holders [3]	483,286	$ 35.59	—
Total	1,729,512	$ 45.39	3,936,268

[1] Includes our 2017 Stock Option and Incentive Plan and our Amended and Restated 2007 Stock Option and Incentive Plan. Outstanding restricted stock units convert to common stock without the payment of consideration. As of December 31, 2019, 651,443 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 $49.19. For more information relating to our equity compensation plans, see Note 14 to our consolidated financial statements.

[2] Includes 3,936,268 shares available for future issuance under our 2017 Stock Option and Incentive Plan.

[3] Consists of the following inducement grants made to certain executive officers upon their initial hire by the Company:

- one inducement grant of 499,468 shares of non-qualified stock option awards made to Patrick J. Sullivan in September 2014 (109,468 of which have been exercised as of December 31, 2019);
- one inducement grant of 79,936 non-qualified stock options made to Shacey Petrovic upon being hired by us in February 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, 2019) 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.

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

The information required by this Item will be set forth in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item will be set forth in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements and Schedules

(1) and (2) The required information is set forth in Item 8—"Financial Statements and Supplementary Data."

(3) Exhibit Index:

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 6, 2019, 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 9, 2019).
4.5	Form of 0.375% Convertible Notes due 2026 (included in Exhibit 4.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019, filed November 5, 2019)
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)

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)

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 Employee Stock Purchase Plan (Amended and Restated February 27, 2019) (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed May 30, 2019)
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)

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)
10.54	Form of Capped Call Transactions Confirmation (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed September 9, 2019).
10.55*	Offer Letter between John W. Kapples and Insulet Corporation, dated January 22, 2019 (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed May 3, 2019).
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, 2019 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

+	Confidential treatment granted as to certain portions of this exhibit.
*	Management contract or compensation plan.
#	Filed herewith.
**	Furnished herewith.

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, 2020

/s/ Shacey Petrovic

Shacey Petrovic

Chief Executive Officer
(Principal Executive Officer)

February 25, 2020

/s/ Wayde McMillan

Wayde McMillan

Chief Financial Officer
(Principal Financial Officer)

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Insulet Corporation, hereby severally constitute and appoint Shacey Petrovic and Wayde McMillan, 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, 2020.

Signature	Title
/s/ Shacey Petrovic Shacey Petrovic	Chief Executive Officer (Principal Executive Officer)
/s/ Wayde McMillan Wayde McMillan	Chief Financial Officer (Principal Financial Officer)
/s/ Lauren Budden Lauren Budden	Chief Accounting Officer and Controller (Principal Accounting Officer)
/s/ Sally Crawford Sally Crawford	Director
/s/ John A. Fallon, M.D. John A. Fallon, M.D.	Director
/s/ James R. Hollingshead James R. Hollingshead	Director
/s/ Jessica Hopfield Jessica Hopfield	Director
/s/ David A. Lemoine David A. Lemoine	Director
/s/ Michael R. Minogue Michael R. Minogue	Director
/s/ Corinne H. Nevinny Corinne H. Nevinny	Director
/s/ Timothy J. Scannell Timothy J. Scannell	Director

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

Name of Entity	**State/Country of Organization**
Sub-Q Solutions, Inc.	Delaware
Insulet MA Securities Corporation	Massachusetts
Insulet Singapore Private Limited	Singapore
Insulet Canada Corporation	Canada
Insulet Consulting (Shenzhen) Co., Ltd.	China
Insulet International Holdings Ltd.	United Kingdom
Insulet International Ltd.	United Kingdom
Insulet Austria GmbH	Austria
Insulet France SAS	France
Insulet Germany GmbH	Germany
Insulet Netherlands B.V.	Netherlands
Insulet Netherlands Holdings B.V.	Netherlands
Insulet Switzerland GmbH	Switzerland
Insulet Mexico, S. de R.L. de C.V.	Mexico

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We have issued our report dated February 25, 2020, with respect to the consolidated financial statements, schedule, and internal control over financial reporting included in the Annual Report of Insulet Corporation on Form 10-K for the year ended December 31, 2019. We consent to the incorporation by reference of said report in the Registration Statements of Insulet Corporation on Forms S-3 (No. 333-158354 and 333-172782) and on Forms S-8 (No. 333-231860, 333-144636, 333-153176, 333-183166, 333-202689, 333-208387 and 333-218125).

/s/ GRANT THORNTON LLP

Boston, Massachusetts

February 25, 2020

EXHIBIT 31.1

CERTIFICATION

I, Shacey Petrovic, certify that:

1. I have reviewed this Annual Report on Form 10-K of Insulet Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Shacey Petrovic

Shacey Petrovic

Chief Executive Officer

Date: February 25, 2020

EXHIBIT 31.2

CERTIFICATION

I, Wayde McMillan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Insulet Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Wayde McMillan

Wayde McMillan

Chief Financial Officer

Date: February 25, 2020

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Insulet Corporation, a Delaware corporation (the "Company"), does hereby certify with respect to the Annual Report of the Company on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "Report") that, to their knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Shacey Petrovic

Shacey Petrovic
Chief Executive Officer

Date: February 25, 2020

/s/ Wayde McMillan

Wayde McMillan
Chief Financial Officer

Date: February 25, 2020