UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

oxtimes ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2020

 $\hfill\Box$ 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

IN	SULET CORP	ORATION
(Exact name of Registrant as spe	cified in its charter)
Delaware (State or Other Jurisdic Incorporation or Organ		04-3523891 (I.R.S. Employer Identification No.)
100 Nagog Park Acton (Address of Principal Execu	Massachusetts ative Offices)	01720 (Zip Code)
Regis	trant's telephone number, including	area code: (978) 600-7000
	Securities registered pursuant to Sec	ction 12(b) of the Act:
<u>Title of Each Class</u> Common Stock, \$0.001 Par Value Per S	Trading Symbol(s) Share PODD	Name of Each Exchange on Which Registered The NASDAQ Stock Market, LLC
Sec	curities registered pursuant to Sectio	on 12(g) of the Act: None
ndicate by check mark if the registrant is a well-known sea	soned issuer, as defined in Rule 405 or	f the Securities Act. Yes x No □
ndicate by check mark if the registrant is not required to fil	e reports pursuant to Section 13 or Sec	ction 15(d) of the Act. Yes \square No \mathbf{x}
ndicate by check mark whether the registrant (1) has filed a 2 months (or for such shorter period that the Registrant wa 0 days. Yes \times No \square		on 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding has been subject to such filing requirements for the past
		File required to be submitted pursuant to Rule 405 of Regulation S-T istrant was required to submit and post such files). Yes x No □
ndicate by check mark whether the registrant is a large accelerated filer," "accelerated filer," "smaller report		n-accelerated filer, or a smaller reporting company. See the definitions of company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer x		Non-accelerated filer \square
Accelerated filer \square		Smaller reporting company \square
		Emerging growth company \square
f an emerging growth company, indicate by check mark if t inancial accounting standards provided pursuant to Section		e extended transition period for complying with any new or revised
,		ent's assessment of the effectiveness of its internal control over financial public accounting firm that prepared or issued its audit report.
ndicate by check mark whether the Registrant is a shell cor	mpany (as defined in Rule 12b-2 of the	e Exchange Act). Yes □ No ⊠
The aggregate market value of the common stock held by neeported on The NASDAQ Global Market on June 30, 2020	C I	d by reference to the last reported sale price of the Common Stock as
The number of shares of common stock outstanding as of Fo	ebruary 18, 2021 was 66,080,324.	
	DOCUMENTS INCORPORATED	D BY REFERENCE
The registrant intends to file a proxy statement pursuant to I tatement are incorporated by reference into Part III of this a		e end of the fiscal year ended December 31, 2020. Portions of such proxy

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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, a continuous insulin delivery system for people with insulin-dependent diabetes, which we have been selling since 2005. The Omnipod System includes: the Omnipod Insulin Management System ("Omnipod") and the Omnipod DASHTM Insulin Management System ("Omnipod DASH"), our digital mobile Omnipod platform. 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, a 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 four to four and a half 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 seven to seven and a half million people have Type 2 diabetes in the countries we currently serve.

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 insulindependent use insulin pump therapy. We believe these factors present a significant available market for the Omnipod System globally.

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. There are two

primary types of insulin therapy practiced today: multiple daily injections ("MDI") therapy using syringes or insulin pens and pump therapy using insulin pumps.

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 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 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 advantages, along with technological advancements and increased awareness of insulin pump therapy will continue to generate demand for insulin pump devices.

Our Solution: The Omnipod System

The Omnipod System is a continuous insulin delivery system that provides all the benefits of insulin pump therapy in a unique way. We believe the Omnipod System's innovative proprietary 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 features two discreet and easy-to-use devices that eliminates the need for the external tubing required with conventional pumps:

- a small, lightweight, self-adhesive disposable tubeless Omnipod device ("Pod") that the user fills with insulin and wears directly on the body. It can be worn in multiple locations, including the abdomen, hip, back of upper arm, upper thigh or lower back. The Pod delivers precise, personalized doses of insulin into the body through a small flexible tube (called a cannula); and
- the Personal Diabetes Manager ("PDM"), a wireless, handheld device that programs the Pod with the user's personalized insulin-delivery instructions and, wirelessly monitors the Pod's operation.

Omnipod DASH, launched in the United States in 2019 and in 2020 in our international markets, features a secure Bluetooth enabled Pod and PDM with a color touch screen user interface supported by smartphone connectivity. In addition, the updated release launched in June 2020 features an option to choose Spanish language, nightly automatic data uploads providing users and their clinicians with cloud access to data, and the ability for us to push software updates wirelessly to users.

The Omnipod System provides continuous insulin delivery at preset rates, eliminating the need for individual insulin injections. 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 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 snack or meal to correct high blood glucose.

We have designed the Omnipod System to fit within the normal daily routines of users. 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. It can be worn for up to three days at a time and, because it is waterproof, there is no need to remove it when showering, swimming or performing other activities. 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 allows 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, which reduces the risk to third-party payors in the U.S., compared to conventional tubed insulin pumps.

Several publications over the past decade have found that compared to MDI 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 published literature of other continuous subcutaneous insulin infusion devices. 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. In the United States, consumers generally have commercial insurance, Medicare or Medicaid coverage that pays for the product. 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 in the U.S. also through the pharmacy channel. For the year ended December 31, 2020, approximately 70% of our Omnipod System sales were through intermediaries.

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

		Years Ended December 31,	
	2020	2019	2018
la, Inc.	11%	*	*
nal Health Inc. and affiliates	10%	11%	12%
en, Inc.	*	*	12%

^{*} 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. With the launch of Omnipod DASH, we created an online training program for Omnipod DASH customers transitioning from Omnipod. In addition, due to the challenges COVID-19 has presented, we have also been using virtual training to onboard new Omnipod customers transitioning from MDI. Our virtual capabilities have allowed us to continue to onboard new customers despite COVID-19 and in a cost-effective manner. Our distributors and intermediaries have also implemented virtual training programs.

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 lesser 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 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.

Omnipod 5, powered by HorizonTM Automated Insulin Delivery System ("Omnipod 5")

We are developing an automated insulin delivery ("AID") 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 ("CGM") 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 5 with a CGM manufactured by Dexcom, Inc. and compatibility with the Android platform. In addition, we have signed a development agreement to integrate Abbott Diabetes Care, Inc.'s CGM in the future and are also working on developing compatibility with iOS. Omnipod 5 is intended to be controllable through a secure mobile app on the user's smartphone (i.e. "phone control"). We completed the first phase of our Omnipod 5 pivotal trial in October 2020. We also recently completed our Omnipod 5 clinical study of pediatric users ages two to six years old and are planning for an expanded indication by the end of 2021. In addition, we have begun enrolling individuals with Type 2 diabetes in an Omnipod 5 feasibility study. Based on the results of the feasibility work, we plan to conduct additional studies with the goal of expanding Omnipod 5's indications. Omnipod 5 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 CGM technology and AID algorithms in conjunction with insulin pump therapy will continue to provide people with insulin-dependent diabetes benefits that will make insulin pump therapy an even more attractive treatment alternative to 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.

In addition to our focus on Omnipod 5, we are also working on innovation programs designed to drive:

- simplicity of user interaction with our systems;
- improved outcomes through algorithm advancements;
- insights and value from our growing datasets and analytics; and
- user choice of sensor and smartphone integrations.

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.

In 2019, we began producing product at our highly automated manufacturing facility in Acton, Massachusetts and in 2020, we began producing on our second line in this facility. We completed the installation our third U.S. manufacturing line and expect to produce sellable product on this line in 2021. Our Acton facility has the capacity to house up to four lines. In addition to increasing supply redundancy and adding capacity closer to our North American customer base to support the growth of our business, we expect that once the Acton facility is fully utilized, the highly automated assembly process will be able to produce a globally cost competitive product.

In addition, we continue to produce our devices on varying degrees of semi-automated manufacturing lines at a facility in China operated by a contract manufacturer. In 2020, we invested in another contract manufacturer in China allowing us to leverage our local supplier base. These contract manufacturing agreements expire in December 2022 and October 2021, respectively, and are subject to automatic renewal, unless canceled by the parties under the terms of the contracts.

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

Raw Materials

We use a 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. 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 rely on a limited number of suppliers for certain of the components and sub-assemblies used in the manufacture of the Omnipod System, including 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 them) is proprietary and the intellectual property rights

may be owned exclusively by one party. In such cases, we are sole sourced with the supplier controlling the 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. We work closely with all suppliers to ensure continuity of supply while maintaining high quality and reliability.

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 BSI Group, an accredited Notified Body for CE Marking, and from 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, certain corresponding state agencies, and other regulatory bodies.

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 measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of the Omnipod System or obtain and use information that we regard as proprietary.

Patents

As of December 31, 2020, we had over 250 patents in the United States and in certain other countries, with expiration dates ranging from 2021 through 2042, and had over 130 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 INSULETTM, OMNIPOD®, OMNIPOD® 5 Automated Insulin Delivery System, SIMPLIFY LIFETM, Omnipod DASH®, Omnipod CONTROLTM, Omnipod DISPLAY®, Omnipod VIEW®, OMNIPOD U-200TM, OMNIPOD U-500TM, Pod Pals® and PodderTM.

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, pre-market clearance or approval, manufacturing, labeling, product storage, advertising and promotion, sales and distribution, post-market adverse event reporting, post-market surveillance, complaint handling, repair or recall of products, and record keeping.

Unless an exemption applies, each medical device we seek to commercially distribute in the United States will require either prior 510(k) clearance or premarket approval ("PMA") from the FDA. Both the 510(k) clearance and PMA processes can be expensive and lengthy and entail significant user fees. We have obtained 510(k) clearance for the Omnipod and Omnipod DASH Systems and expect that regulatory approval will be needed for some of our future products. In addition, we may be required to obtain a new 510(k) clearance or pre-market approval for significant post-market modifications to our products.

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. A 510(k) application must be supported by extensive data, including technical information, labeling, and potentially clinical data to meet any Special Controls and to demonstrate the safety and effectiveness of the device to the FDA's satisfaction. 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") and obtain IDE approval prior to commencing 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. Clinical trials for a significant risk device may begin once an IDE is approved by the FDA and the appropriate Institutional Review Board ("IRB") at each clinical trial site. If the product is deemed a "non-significant risk" device, IDE approval from the FDA would not be required, but the clinical trial would need to meet other requirements including IRB approval. Clinical trials for a significant risk device may begin once an IDE is approved by the FDA and the appropriate 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. After a device is placed on the market, numerous regulatory requirements apply, including:

- 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 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 product recall 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 facilities on multiple occasions.

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 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 statutes that, among other things, impose 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 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.

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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. HIPAA regulations have been amended under the Health Information Technology for Economic and Clinical Health Act of 2009. If we are found to be in violation of HIPAA, we could be subject to civil or criminal penalties.

California Consumer Privacy Act and California Privacy Rights 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. The California Privacy Rights Act ("CPRA") amends and expands the CCPA and is to take effect in January 2023 with respect to personal data collected beginning in January 2022. 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. Failure to disclose reportable payments could subject us to penalties and materially adversely impact our business and financial results. Certain states' laws require additional reporting of payments and transfers of value to health care providers.

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 late 2020, the United States Department of Health and Human Services' Office of the Inspector General ("OIG") finalized a rule that will 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"), effective January 2022. The rule also includes 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. The rule was finalized consistent with an Executive Order issued by the President in 2020; with the change in Administrations, it is possible that the rule may be revised before it is fully effective. If it takes effect as written, 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 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.

International 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, clinical trials, manufacture, 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 2021. Devices that comply with the requirements of the relevant directive will be entitled to bear the CE conformity marking and, accordingly, can be commercially distributed. The method of assessing conformity with the applicable directive 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". The latter is required in order for a manufacturer to commercially distribute the product throughout the European Union. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. 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, which allows us to distribute these products throughout the European Union and in other countries that recognize the CE Mark. In addition, we have Health Canada approval to sell these products in Canada.

Outside the United States a range of anti-bribery and anti-corruption laws, as well as industry specific laws and codes of conduct, apply to the medical device industry and interactions with government officials and entities and healthcare professionals. These laws include the U.K. Bribery Act and similar antibribery laws in other jurisdictions in which we operate. Such laws generally prohibit U.S.-based companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business to non-U.S. officials, or in the case of the U.K. Bribery Act, to any person.

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.

Human Capital Resources

Employees

Our people are our most valuable asset and are the source of our innovation and our success. We strive to attract and retain the best talent with competitive compensation and benefits, opportunities for growth and development, and a culture that emphasizes fair and equitable treatment. As of December 31, 2020, we had approximately 1,900 full-time employees,

representing a 41% increase over the prior year. Approximately 84% of our employees are located in the United States and the remainder are located in 12 other countries.

To assess and improve employee retention and engagement, we survey employees annually with the assistance of third party consultants, and take timely action to address key areas of employee concern. In 2020, 90% of our employees responded to the survey. We supplement this anonymous survey with additional surveys throughout the year. Our senior leadership team assesses engagement to understand and identify potential opportunities for improvement.

Our executive leadership team conducts quarterly Town Hall meetings to ensure our global employees are highly engaged and receive timely business updates. To help our employees feel socially connected to their colleagues while working remotely due to COVID-19, we created our "Stay Connected" initiative, which includes weekly video updates from leaders around the world. This initiative also includes virtual meetings with our executive team members. These virtual meetings are designed as casual conversations with our executives so employees can talk about what is on their minds, get to know the executive leaders, and connect with colleagues from across the organization. We have also implemented new technology platforms, including a social networking tool, to ensure our global employees are engaged, motivated, and collaborating with one another.

Diversity, Equity and Inclusion

Our success thrives on the diversity of perspective, thought, experience, and background within our workforce. Our goal is to create an inclusive global culture that reflects the diversity of the customers we serve and fosters an environment where all employees feel welcomed, respected, and valued. Accordingly, we are committed to providing equal opportunity in all aspects of employment. Our annual three-day leadership program includes instruction in unconscious bias and hiring behaviors that support diversity. We have targeted recruitment programs for veterans and university students, including those of diverse backgrounds.

Our Employee Resource Groups ("ERG") serve as a source of inclusion across seven categories: African Descent, LGBTQ+, Sustainability, Veterans and First Responders, Women, Working Parents, and Young Professionals. These ERG support the acquisition of diverse talent and are sponsored by senior leaders across our organization.

Training and Development

We are committed to fostering an environment in which our employees continuously learn and develop. We offer both leadership and professional skills development programs. All employees who join Insulet undergo a robust onboarding program called RITE Start that introduces our core values of respect, integrity, teamwork and excellence, and educates new employees about diabetes, our Omnipod products, our business strategy, and other business topics designed to engage and connect employees to each other and our mission. Employees have access to monthly learning programs and virtual and online learning programs. On June 1, 2020, we launched a new learning platform to all worldwide employees, which provides a daily professional development topic and includes a library of topics for our busy workforce. Since the launch, through December 31, 2020, over 45,000 lessons have been consumed by employees across the globe. Additionally, during our annual Compliance Week, employees logged over 4,300 training hours. We offer leadership development programs to support the growth of our future leaders. We also offer training for new managers and resources for experienced leaders. Additionally, we offer professional certification course reimbursement of up to \$3,000 annually and tuition reimbursement of up to \$5,250 annually for courses taken in pursuit of an undergraduate degree and up to \$10,000 annually for courses taken in pursuit of a graduate degree. Finally, in response to COVID-19, we launched a series of virtual training programs and employee communications designed to support employees and leaders during a stressful transition to work at home, including programs on leading effective remote meetings, managing remotely and how to leverage collaborative learning tools.

Competitive Pay and Benefits

Our compensation program is designed to align employee compensation with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation program balances incentive earnings for both short-term and long-term performance. Specifically,

- We provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location.
- We engage internationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking.
- We align our executives' long-term equity compensation with our shareholders' interests.

Annual increases and incentive compensation are based on our performance as well as each individual's contribution to the results achieved and
are documented through our talent management process as part of our annual review process.

We are committed to providing comprehensive benefit options that allow our employees and their families to live healthier and more secure lives. Our wide-ranging benefits include: health insurance, telehealth, prescription drug benefits, dental insurance, vision insurance, accident insurance, critical illness insurance, life insurance, disability insurance, health savings accounts, flexible savings accounts, retirement plans, legal services, identity theft protection, maternity/paternity leave, and employee assistance program. In addition, we offer a free online wellness program; subsidized child, senior care or pet services and access to personal services; free virtual babysitting and tutoring services; Pod perks, which provides a free Omnipod System, including PDM and Pods to benefit eligible employees, interns or dependents; summer hours; and a flexible work policy. In addition, our employee stock purchase plan is available to all full-time employees and has a participation rate of over 50%.

Health and Safety

The health and safety of our employees is a top priority. Our safety focus is evident in our response to the COVID-19 pandemic around the globe, which includes the following:

- Creating a COVID-19 task force guided by several core principles, including protecting the health and safety of our employees and a COVID-19
 response plan designed and guided by the World Health Organization, the Centers for Disease Control and Prevention, local governments, and
 health authorities and professionals;
- Adopting virtual on-boarding program for new employees and virtual customer training;
- Revising our flexible work policy to allow for greater work from home flexibility and providing equipment and tools to support remote work;
- Implementing health screening at our manufacturing facilities and corporate headquarters and enhanced cleaning procedures at all facilities;
- Providing meals for manufacturing employees to limit exposure and requiring manufacturing employees to quarantine for a period of time and
 produce two negative COVID-19 tests, if they travel to a "hotspot" location or attend a gathering where social distancing is not possible, before
 returning to the plant
- Providing 80 hours of COVID-19 paid sick time to all employees to use if they contract the virus or to care for family members and offering athome COVID-19 testing to all U.S. full-time, part-time, and temporary employees and contractors;
- Requiring health and safety protocols training and site specific training for all employees before being allowed to return to the office;
- Installing signage at all facilities to remind employees to wear a mask, wash hands, and social distance;
- Installing cubicle panel extensions at our corporate headquarters to further protect employees within their designated workstations and plexiglass in the cafeteria to allow for safe food delivery and dining;
- Providing personal protective equipment and cleaning supplies to each employee at all facilities, globally and to all field personnel.

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 Related to Our Business and Industry

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.

Our main product is the Omnipod System, from which we expect to continue to derive nearly all our revenue. 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 intellectual property rights of others;
- 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;
- the inability of users to continue paying for our products;
- attrition rates of consumers who cease using the Omnipod System;
- competitive pricing; 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, which would adversely affect our business, financial condition and results of operations.

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.

In addition to promoting, marketing and selling the Omnipod System through our own direct sales force, we also utilize domestic and international intermediaries to distribute our product to end-users. We need to expand our distribution network to maintain and grow our business and revenue. 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, which would adversely affect our business, financial condition and 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.

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, we expect to continue to increase our manufacturing capacity, our personnel and the scope of our 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 continued development of our manufacturing and our relationships with our contract manufacturers and other suppliers. We may also need to partner with additional third-party suppliers to manufacture certain components of the Omnipod System and install additional manufacturing lines. 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.

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. In the United States, 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 our efforts will be successful. 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 CMS has issued guidance clarifying that Medicare Part D Plan Sponsors may provide coverage for products such as the Omnipod System under the Medicare Part D prescription drug program. 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.

In the United States, we began selling Omnipod DASH in 2019, primarily through the pharmacy channel, which required negotiation of new or amended agreements with our intermediaries and payors. The availability of Omnipod DASH may be limited or restricted if we are unable to maintain these agreements and sustain an adequate level of reimbursement under these agreements. As we expand our Omnipod System 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.

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.

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, commonly referred to as the "individual mandate". Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute 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 and on our ability to maintain or increase sales of any of our products.

Risks Related to Product Development, Market Access and Competition

We face competition from numerous competitors, many of whom have far greater resources than we have, and, as a result, we may not be able to compete effectively.

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 in the United States. Other suppliers we compete with include Tandem in the United States and Roche and Ypsomed outside the United States. 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.

Many of our competitors are large, well-capitalized companies with more resources than we have. These companies may have competitive advantages over us, including:

- 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, clinical trials, manufacturing, marketing and obtaining regulatory approval; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we may not be able to compete effectively against these companies or their products, which may adversely impact our business.

We also compete with MDI therapy, including smart pens, which is substantially less expensive than pump therapy. 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.

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, we could experience pricing pressure. If prices were to fall, our results of operations could be materially adversely impacted.

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 2020 Tandem launched an AID 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 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 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.

Future market or clinical studies may be unfavorable to the Omnipod System and its efficacy, which could hinder our sales efforts and have a material adverse effect on our business, results of operations, financial condition and cash flows.

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.

In addition, 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.

We may be unable to adequately protect our intellectual property rights.

Our success depends in part on our ability to maintain the proprietary nature of our technologies. We rely on a combination of patents, 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.

Our ability to compete depends in part on our continued ability to develop or acquire commercially valuable patent rights and to protect those rights adequately. We may not be able to develop additional proprietary technologies that are patentable. Further, we cannot ensure that our pending patent applications will result in the issuance of patents to us, that patents issued to or licensed by us in the past or in the future will not be challenged or circumvented by competitors or that these patents will be found to be valid or sufficiently broad to preclude our competitors from introducing technologies similar to those covered by our patents and patent applications. In addition, our ability to enforce and protect our intellectual property rights may be limited in certain circumstances outside the United States. For example, we may not be able to protect our intellectual property rights effectively in China, where we rely on third-party contract manufacturers to produce our product. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

Our efforts to safeguard our unpatented and unregistered intellectual property rights, including requiring employees, consultants and other third parties to sign confidentiality, non-disclosure or assignment of invention agreements, may not be successful. The agreements may be breached and trade secrets and other proprietary information could be disclosed to our competitors. Further, we may have inadequate remedies for any breach. In addition, others may independently develop substantially equivalent or superior proprietary information and techniques or gain access to our trade secrets or disclose such technologies. If we are unable to sufficiently protect our intellectual property rights and our intellectual property is disclosed or misappropriated, our competitiveness could be impaired, which would limit our growth and future revenue.

To protect our intellectual property, we may need to assert claims of infringement against third parties. Any lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. The outcome of litigation to enforce our intellectual property rights is highly unpredictable. A court could determine that some or all of our asserted intellectual property rights are not infringed, or are invalid or unenforceable. 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. We have settled infringement suits in the past and as disclosed in Note 13 to the consolidated financial statements included in Item 8, we are currently subject to patent infringement litigation with Roche Diabetes Care, Inc. In addition, 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

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 our customers from using our products or us from manufacturing, selling, or importing our products, or could enter an order mandating that we undertake certain remedial activities.

Risks Related to Economic Conditions and Operating Internationally

Our financial condition and results of operations have been and may to continue to be adversely affected by the COVID-19 pandemic.

The COVID-19 pandemic has created significant volatility, uncertainty and economic disruption in the markets we sell our products into and operate in and negatively impacted business and healthcare activity globally. The pandemic and preventative measures taken to contain or mitigate the outbreak, have caused, and are continuing to cause, business slowdown or shutdown in affected areas and disruption in the financial markets globally. This has led to a significant increase in unemployment and a loss of employee-sponsored insurance coverage for many people in the United States. As a result, consumers may reduce their spending, new orders for our Omnipod System may decline and our customer attrition rate may increase, which could have a material adverse effect on our business, sales, financial condition and results of operations.

The COVID-19 pandemic also has the potential to significantly impact our supply chain if the manufacturing plants that produce our products or product components, the distribution centers where we manage our inventory, or the operations of our logistics and other service providers, including third parties that sterilize our products, are disrupted, temporarily closed or experience worker shortages for a sustained period of time. Although China, where we manufacture a significant portion of our product, has experienced a recovery and we are currently producing at pre-COVID-19 levels, should China suffer a COVID-19 relapse, it could hinder our ability to produce product and have a material adverse effect on our business and results of operations.

As a result of the COVID-19 pandemic, we have transitioned to a remote work environment for those employees who can perform their job function outside of our facilities. The remote work environment has increased risks associated with our information technology systems and networks, including cyber-attacks, computer viruses, disruptions, or shutdowns that could result in a failure to protect our information technology systems and data integrity.

The further spread of COVID-19, and the requirements to take action to help limit the spread of the illness, may impact our ability to carry out our business as usual. For example, the COVID-19 pandemic may divert healthcare resources away from the conduct of clinical trials and interrupt the operations of the FDA and comparable foreign regulatory agencies, which could delay product approval timelines, including for our Omnipod 5.

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 approximately one third of our revenues in 2020 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 third-party contract manufacturer facilities in China

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 this Item 1A, other risks associated with doing business internationally, include:

- political instability and actual or anticipated military or political conflicts;
- 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 regulatory requirements;
- 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, in January 2020, the U.K. withdrew from the European Union, commonly referred to as "Brexit". The effects of Brexit will depend on the terms of the U.K.'s future relationship with the European Union. Although it is unknown what those terms will be, it is possible that there could be greater restrictions on imports and exports and on the movement of people between the U.K. and European Union countries, and increased regulatory complexities.

Failure to comply with the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws could materially adversely affect our business and result in civil and/or criminal sanctions.

The FCPA, the U.K. Bribery Act and similar anti-bribery laws enacted in other 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. Because we do business in the U.K., the U.K. Bribery Act also extends to our interaction with public and private sector entities and persons outside the U.K., including in the U.S. 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 have a material adverse effect on our results of operations, financial condition and cash flows.

Risks Related to Supply Chain, Operations and Third-Party Arrangements

Our Omnipod System inventory is produced and maintained in a limited number of locations.

Our manufacturing of the Omnipod System is conducted in three locations, at our U.S. manufacturing facility in Massachusetts and on manufacturing lines owned by us at two facilities located in China, which are operated by third-party contract manufacturers. Political or financial instability, currency fluctuations, the outbreak of pandemics such as the COVID-19, 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 operations. Further, following the COVID-19 pandemic there may be increased pressure for U.S. medical device companies to reduce dependency on China for their supply chain. 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 our third-party contract manufacturers and logistics entity safeguard our assets, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural or other disaster, such as a fire or flood, could cause substantial delays in our operations, damage or destroy our 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 manufacturing difficulties, including not effectively managing the start-up of new manufacturing lines, our business may be harmed.

The manufacture of our product requires the timely delivery of sufficient amounts of quality components and materials. 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 hinder our ability to manufacture our products in a timely or cost-effective manner, and have a material adverse effect on our business and results of operations.

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.

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, two third-party contract manufacturers in China perform assembly and supply 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 our contract manufacturers, 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;
- our suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements, and
- our suppliers may fail to comply with conflict minerals, anti-slavery or other applicable laws, thus impairing our ability to source materials.

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. An 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.

We rely on agreements or licenses to intellectual property or other rights in order to sell our current product and commercialize new products.

We rely on agreements or licenses to intellectual property or other rights in order to sell our current product and commercialize new products. If we cannot retain or obtain these agreements, licenses, or other rights, we may not be able to sell, develop or commercialize our products. For example, our rights to incorporate the FreeStyle blood glucose meter into the Omnipod are governed by a license agreement with Abbott. In addition, we have a commercial agreement with Dexcom that allows us to launch Omnipod 5 with integration to Dexcom's CGM and have a development agreement with Abbott to integrate Abbott's CGM into Omnipod 5. The loss of any of these rights could impair the functionality of the Omnipod or prevent us from selling our products without significant development and regulatory activities that may not be completed in time to prevent an interruption in the availability of the Omnipod to consumers. This could result in a material adverse effect on our business, financial condition and results of operations.

We also have a partnership with Glooko that allows the Omnipod System to connect with Glooko's cloud-based diabetes data management system so that users and healthcare providers can monitor user data, including insulin delivery trends and blood glucose levels. Our agreement with Glooko expires in December 2025. If this agreement is not renewed in the future, our business could be materially adversely impacted.

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 System as appropriate delivery device;
- 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;
- demand for 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.

Risks Related to Government Regulation and Litigation

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.

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 December 2012, we received 510(k) clearance for our Omnipod. We have since obtained clearance for modified versions of this device, including Omnipod DASH, which was cleared by the FDA in 2018 to be used as an integrated insulin pump in an interoperable AID 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. 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. The FDA is in the process of reviewing the 510(k) approval process and criteria and has announced initiatives to improve the current preand 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. Failure to fulfill foreign regulatory requirements on a timely basis or at all could adversely affect our ability to grow our business.

If we, our contract manufacturers 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 sales and operating results could suffer.

We, our contract manufacturers 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, sterilization, labeling, packaging, 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.

Malfunction of our products could lead to recalls or safety alerts and have a significant adverse impact on us.

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 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, such as our voluntary Medical Device Correction issued in February 2020, may require the dedication of our time and capital, could distract management from operating our business and potentially harm our reputation and financial results.

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. 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.

Recalls of any of our products would divert managerial and financial resources and could have an adverse effect on our reputation, results of operations and financial condition, and 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. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

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 prescribe 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 with our characterization of certain statements 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 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.

The medical device industry is heavily regulated. If we fail to comply with all applicable laws and government regulations, we could be subject to substantial penalties and/or be excluded from participation in government programs.

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.

Risks Related to Privacy and Security

We are subject to complex and evolving laws and regulations regarding privacy and data protection, many of which are subject to change and uncertain interpretation, which 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 relating to privacy and data protection, data security, data retention and deletion, personal information, electronic contracts and other communications. The introduction of new products or expansion of our activities in certain jurisdictions may subject us to additional laws and regulations. For example, data privacy laws at the federal and state levels protect the confidentiality of certain health information and restrict the use and disclosure of that protected information. In particular, the U.S. privacy rules under HIPAA 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. In the state of California, the CCPA, which provides certain privacy rights and consumer protection for residents of the state became effective in 2020, and the CPRA, which amends and expands the CCPA, will take effect in 2023. 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 delete the 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. California and other states' laws apply more broadly and now or in the future may reach data we hold that relates to employees and health care providers, not just customers. In addition, data security protection laws passed by the federal government and many states require notification to data subjects, including customers and others, when there is a security breach of personal data. If we fail to comply with these regulations, we could be subject to civil sanct

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 significant fines and penalties.

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 res

Failure to maintain the privacy and security of our customer, third-party payor, employee, supplier or Company information could result in substantial costs and/or subject us 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 and device security. The methods used to obtain unauthorized access, disable or degrade service or sabotage systems are also constantly changing and evolving, and may be difficult to anticipate or detect for long periods of time. We have implemented and regularly review and update processes and procedures to protect against unauthorized access to or use of secured data and to prevent data loss. However, the ever-evolving threats mean we must continually evaluate and adapt our systems and processes, and our efforts may not be adequate to safeguard against all data security breaches, misuse of data or sabotage of our systems. Any future significant compromise or breach of our data security, whether external or internal, or misuse of customer, third-party payor, employee, supplier or Company data, could result in 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.

Risks Related to Our Debt

We may not be able to generate sufficient cash flow from operations to service our debt, which is substantial.

As of December 31, 2020, we had debt of \$1.3 billion, including \$1.2 billion aggregate principal amount of 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 guarantee that we will maintain a level of cash flows from operating activities sufficient to permit us to repay the principal or service our interest. If our cash flows and capital resources are insufficient to fund these 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.

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 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

General Risks

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 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.

Acquisitions or investments in new businesses, products or technologies could disrupt our business.

If we are presented with appropriate opportunities, we may pursue acquisitions or investments in complementary businesses, products or technologies. We may not complete the transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition or investment. Even if we are successful in making an acquisition, the products and technologies that we acquire may not be successful or may require significantly greater resources and investments than we originally anticipated. We could also experience negative effects on our results of operations and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges if the acquisitions are not as successful as we originally anticipate. We will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations of any acquired company, integration of acquired technology with our products, and the potential loss of key employees, customers, distributors or suppliers of the acquired businesses. Integration of an acquired business also may require management resources that otherwise would be available for development of our existing business. If an acquired business fails to operate as anticipated or cannot be successfully integrated into our existing business, our stock price, business, financial condition and results of operations could be materially and adversely affected. Furthermore, we may have to incur debt or issue equity to pay for any future acquisitions or investments, the issuance of which could be dilutive to our existing stockholders

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 additional manufacturing capacity;
- costs associated with any expansion, including 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 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 may in the future seek additional funds from public and private stock offerings, borrowings under credit lines or other sources, and 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 any sustained disruption to the credit and financial markets from the COVID-19 pandemic. If the macro-economic disruption continues for pro-longed periods, we may need to raise additional capital and capital may not be available on acceptable terms, or at all. We cannot predict when the macro-economic disruption stemming from COVID-19 will ebb or when the economy will return to pre-COVID-19 levels, if at all.

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.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We own a 350,000 square foot facility in Acton, MA, which houses both our headquarters and our U.S. manufacturing. As of December 31, 2020, we leased a total of 15 facilities in 7 countries consisting of approximately 225,000 square feet of office, research and development and warehousing space and other related facilities, primarily in North America and Europe.

Item 3. Legal Proceedings

The information required by this Item is provided under "Legal Proceedings" in Note 13 to the consolidated financial statements included in 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

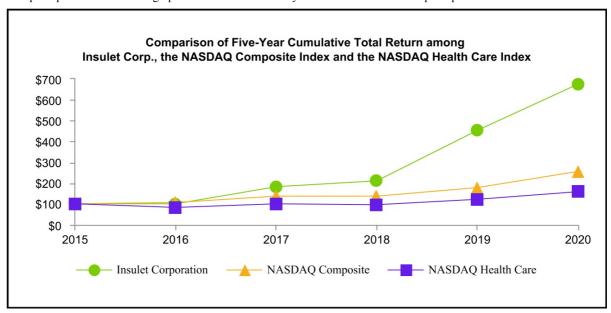
MARKET FOR REGISTRANT'S COMMON EQUITY

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

As of February 18, 2021, there were 8 registered holders of record of our common stock.

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, 2015, and ending on December 31, 2020, assuming reinvestment of all dividends. The historical stock price performance on the graph below is not necessarily indicative of future stock price performance.



	2	015	2016	2017	201	8	2019	2020
Insulet Corporation	\$	100 \$	100 5	\$ 182	\$ 2	10 \$	453 \$	676
NASDAQ Composite	\$	100 \$	108 5	138	\$ 1.	38 \$	179 \$	257
NASDAQ Health Care	\$	100 \$	83 5	\$ 101	\$	97 \$	122 \$	158

The material in this performance graph shall not be deemed to be 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

Consistent with the amendments to Regulation S-K, we are not required to disclose information previously required by this item.

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 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, a 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; and its wireless companion, the handheld PDM. The Omnipod System, which features 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.

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, a 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 key strategic imperatives:

- · driving access and awareness;
- delivering consumer-focused innovation;
- · expanding our global addressable market; and
- driving operational excellence.

Our long-term financial objective is to sustain profitable growth. To achieve this goal, our efforts are focused on the launch of Omnipod 5, powered by HorizonTM ("Omnipod 5"), our AID system. We completed the first phase of our Omnipod 5 pivotal trial in October. We also recently completed our Omnipod 5 clinical study of pediatric users ages two to six years old and are planning for an expanded indication by the end of 2021. In addition, we have begun enrolling individuals with Type 2 diabetes in an Omnipod 5 feasibility study. Based on the results of the feasibility work, we plan to conduct additional studies with the goal to further expand Omnipod 5's indications.

During 2020, we began producing salable product on our second highly automated manufacturing line in the U.S. and secured a second contract manufacturer in China, which increased our capacity and redundancy. Additionally, in order to support our continued growth and the expected launch of Omnipod 5 in the first half of 2021, we recently installed a third highly automated manufacturing line in the U.S. on which salable product is expected in 2021.

In 2020, we completed the roll out of Omnipod DASH, our digital mobile Omnipod platform, in the countries we serve in Europe. In January 2021, we completed our full commercial launch of Omnipod DASH internationally with our roll out in Canada. The majority of our global customers start on Omnipod DASH. We expect the introduction of Omnipod DASH throughout our international markets to be a growth driver as we increase our presence within our existing markets and enter into new countries over the long term.

In 2020, we entered five new countries in Western Europe and the Middle East to expand the commercial sale of Omnipod and our global footprint. While this expansion into additional countries did not have a material impact on our 2020 revenues, it is expected to contribute to our long-term growth.

We are continuing to expand internationally in a targeted and strategic manner. In the first quarter of 2021, we expanded into Turkey and we expect to launch Omnipod DASH in Australia in 2021. Additionally, we are working on our strategy to enter larger markets, such as Asia Pacific and Latin America.

Finally, we plan to continue our product development efforts and expand awareness of and access to our products. Achieving the above strategic imperatives 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

The discussion of our results of operations for 2018 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 for the fiscal year ended December 31, 2019 filed with the Securities and Exchange Commission on February 26, 2020.

Comparison of the Years Ended December 31, 2020 and December 31, 2019

Revenue

	Years Ended	December 31	,			
(In millions)	 2020	20	19	% Change	Currency Impact	Constant Currency(1)
U.S. Omnipod	\$ 526.9	\$	420.4	25.3 %	— %	25.3 %
International Omnipod	 308.0		253.1	21.7 %	1.8 %	19.9 %
Total Omnipod	 834.9		673.5	24.0 %	0.7 %	23.3 %
Drug Delivery	69.5		64.7	7.4 %	— %	7.4 %
Total	\$ 904.4	\$	738.2	22.5 %	0.6 %	21.9 %

⁽¹⁾ Constant currency revenue growth is a non-GAAP financial measure which should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. See "Management's Use of Non-GAAP Measures."

Total revenue for 2020 increased \$166.2 million, or 22.5%, to \$904.4 million, compared with \$738.2 million in 2019. Constant currency revenue growth of 21.9% was primarily driven by higher volume and, to a lesser extent, favorable sales channel mix. The COVID-19 pandemic negatively impacted global new customer starts throughout 2020, largely beginning in the second quarter. We expect our revenues in 2021 to continue to be impacted by the global pandemic's effect on both 2020 and 2021 new customer starts, particularly in our international markets.

U.S. Omnipod

U.S. Omnipod revenue for 2020 increased \$106.5 million, or 25.3%, to \$526.9 million, compared with \$420.4 million in 2019. This increase was primarily due to higher volumes driven by growing our customer base and, to a lesser extent, an increase due to growth through the pharmacy channel, where Pods have a higher average selling price due in part to the fact that we offer the PDM for no charge. In 2021, we expect strong Omnipod revenue growth driven by continued market penetration and volume growth of Omnipod DASH, primarily in the pharmacy channel. We expect this revenue growth to be partially offset by the impact of lower new customer starts in 2020 stemming from COVID-19.

International Omnipod

International Omnipod revenue for 2020 increased \$54.9 million, or 21.7%, to \$308.0 million, compared with \$253.1 million in 2019. Excluding the 1.8% favorable impact of currency exchange, the remaining 19.9% increase was primarily due to higher volumes as we continue to expand awareness and access to the Omnipod. Similar to in the U.S., in 2021, we expect higher International Omnipod revenue due to continued volume growth and market penetration aided by the full launch of Omnipod DASH throughout our international markets and our virtual training capabilities. We expect this revenue growth to be partially offset by the impact of lower new customer starts in 2020 stemming from COVID-19 and continued lockdowns in Europe.

Drug Delivery

Drug Delivery revenue for 2020 increased \$4.8 million, or 7.4%, to \$69.5 million, compared with \$64.7 million in 2019. This increase was primarily due to increased demand for Amgen's Neulasta® Onpro® kit which includes our pods. In 2021, we expect Drug Delivery revenue to decline or grow slightly dependent upon forecasted demand.

Operating Expenses

	Years Ended December 31,								
		20	20	2019					
(In millions)		Amount	Percent of Revenue	Amount	Percent of Revenue				
Cost of revenue	\$	322.1	35.6 %	\$ 257.9	34.9 %				
Research and development expenses	\$	146.8	16.2 %	\$ 132.3	17.9 %				
Selling, general and administrative expenses	\$	384.0	42.5 %	\$ 298.0	40.4 %				

Cost of Revenue

Cost of revenue for 2020 increased \$64.2 million, or 24.9%, to \$322.1 million, compared with \$257.9 million in 2019. Gross margin was 64.4% in 2020, compared with 65.1% in 2019. The 70 basis point decrease in gross margin was primarily due to start-up costs and inefficiencies driven by the addition of the second line at our U.S. manufacturing facility, as well as two months of higher depreciation expense for under-utilized plant capacity, recruiting and screening expenses, expedited shipping costs and manufacturing incentives totaling \$8.5 million, primarily associated with our contract manufacturer in China as a result of COVID-19. This decrease was partially offset by higher average selling price due to growth in the U.S. pharmacy channel. We expect gross margin for 2021 to increase to 67% to 70%, which reflects expected revenue growth both in the U.S. and internationally, including in the pharmacy channel, and the benefits of continued improvements in manufacturing and supply chain operations.

Research and Development

Research and development expenses for 2020 increased \$14.5 million, or 11.0%, to \$146.8 million, compared with \$132.3 million in 2019. This increase was primarily due to year-over-year headcount additions as we focus on driving innovation, particularly Omnipod 5, partially offset by reduced spend on Omnipod DASH, which was launched in the prior year period. We expect research and development spending in 2021 to increase compared with 2020 as we continue to invest in advancing our innovation and clinical pipeline.

Selling, General and Administrative

Selling, general and administrative expenses for 2020 increased \$86.0 million, or 28.9%, to \$384.0 million, compared with \$298.0 million in 2019. This increase was primarily attributable to investments in customer support and other initiatives to support our growth, including year-over-year headcount additions, mainly sales and customer service personnel, \$18.8 million increase in advertising expense driven by the pilot of our direct-to-consumer advertising campaign and online advertising, \$14.6 million of cumulative amortization expense related to the resolution of a purchase price contingency associated with the acquisition of customer relationships from a former European distributor on July 1, 2018, as well as \$4.8 million of stock-based compensation expense from a company-wide 20th anniversary equity grant, a significant portion of which vested immediately. These increases were partially offset by a \$9.7 million decrease in travel and entertainment expenses due to reduced activity resulting from COVID-19. We expect selling, general and administrative expenses to increase in 2021 compared with 2020 due to expansion of our U.S. sales force and customer support personnel, investments to expand market acceptance and access for Omnipod 5, including direct-to-consumer advertising, and investments in our operating structure to facilitate operational efficiencies and continued growth.

Non-Operating Items

Interest Expense, Net

Interest expense, net for 2020 increased \$17.4 million, or 62.8%, to \$45.1 million, compared with \$27.7 million in 2019. This increase was primarily due to a \$9.6 million increase in non-cash interest expense resulting from the 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, a \$3.9 million decrease in capitalized interest, primarily due to U.S. manufacturing line 2 being placed in service in the first quarter of 2020, and a \$3.9 million decrease in interest income due to lower market rates and a shift in a portion of our investment portfolio to more liquid investments.

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.

Other Income, Net

Other income, net for 2020 increased \$2.4 million, to \$3.3 million, compared with \$0.9 million in 2019. This increase was primarily driven by unrealized foreign currency gains due to the change in exchange rates, partially offset by a \$1.8 million insurance recovery for damaged inventory in excess of our cost received during the year ended December 31, 2019.

Income Tax Expense

Income tax expense was \$2.9 million on pre-tax income of \$9.7 million and \$14.5 million for both 2020 and 2019, respectively. Our effective tax rate was 29.6% and 19.8% for 2020 and 2019, respectively. The increase in our effective tax rate primarily resulted from a decrease to pre-tax income in the U.S., which has a valuation allowance. See Note 18 to the consolidated financial statements for additional information on our income tax expense.

Adjusted EBITDA

The table below presents reconciliations of Adjusted EBITDA, a non-GAAP financial measure, to net income, the most directly comparable financial measure prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"):

	Years Ended December 31,					
(in millions)	2020			2019		
Net income	\$	6.8	\$	11.6		
Interest expense, net		45.1		27.7		
Income tax expense		2.9		2.9		
Depreciation and amortization ⁽¹⁾		55.4		27.9		
Stock-based compensation ⁽²⁾		35.9		28.7		
Loss on extinguishment of debt		_		8.7		
Adjusted EBITDA	\$	146.1	\$	107.5		

⁽¹⁾ The year ended December 31, 2020 includes \$14.6 million of cumulative amortization expense associated with customer relationships that were acquired on July 1, 2018. For more information see Note 13 to the consolidated financial statements.

Non-GAAP Financial Measures

Management uses the following non-GAAP financial measures:

Constant currency revenue growth represents the change in revenue between current and prior year periods using a constant currency, the exchange rate in effect during the applicable prior year period. We present constant currency revenue growth because we believe it provides meaningful information regarding our results on a consistent and comparable basis. Management uses this non-GAAP financial measure, in addition to financial measures in accordance with GAAP, to evaluate our operating results. It is also one of the performance metrics that determines management incentive compensation.

Adjusted EBITDA represents net income (loss) plus net interest expense, income tax expense (benefit), depreciation and amortization, stock-based compensation and other significant unusual items, as applicable. We present Adjusted EBITDA because management uses it as a supplemental measure in assessing our operating performance, and we believe that it is helpful to investors, and other interested parties as a measure of our comparative operating performance from period to period. Adjusted EBITDA is a commonly used measure in determining business value and we use it internally to report results.

These non-GAAP financial measures should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. In addition, the above definitions may differ from similarly titled measures used by others. Non-GAAP financial measures exclude the effect of items that increase or decrease our reported results of operations; accordingly, we strongly encourage investors to review our consolidated financial statements in their entirety.

Liquidity and Capital Resources

As of December 31, 2020, we had \$907.2 million in cash and cash equivalents and \$40.4 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. As of December 31, 2020, the following notes were outstanding:

Issuance Date	Coupon	pal Outstanding in millions)	Due Date	Conversion Rate (1)	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			

⁽¹⁾ Per \$1,000 face value of notes.

In connection with the issuance of the 0.375% Convertible Senior Notes, we purchased 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

⁽²⁾ The year ended December 31, 2020 includes \$7.3 million of stock-based compensation expense related to a company-wide 20th anniversary equity grant, a significant portion of which immediately vested.

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.

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

Summary of Cash Flows

	Years Ended December 31,					
(in millions)	2020		2019			
Cash provided by (used in):						
Operating activities	\$	84.0	\$	98.4		
Investing activities		14.0		(73.6)		
Financing activities		605.5		73.5		
Effect of exchange rate changes on cash		4.8		1.5		
Net increase in cash and cash equivalents	\$	708.3	\$	99.8		

Operating Activities

Net cash provided by operating activities of \$84.0 million in 2020 was primarily attributable to net income, as adjusted for depreciation and amortization, non-cash interest, and stock-based compensation, and a \$63.4 million working capital cash outflow. The working capital outflow was driven by a \$50.5 million increase in inventories, a \$32.2 million increase in prepaid expenses and other assets and a \$15.6 million increase in accounts receivable, partially offset by a \$27.8 million increase in account expenses and other liabilities, primarily driven by manufacturing operations costs associated with the addition of our new contract manufacturer, as well as an increase in pharmacy rebates due to growth in the pharmacy channel. The increase in inventories was primarily driven by a planned inventory build associated with the further roll out of Omnipod DASH and an increase in work in progress inventory due to additional capacity from our new contract manufacturer. The increase in prepaid expenses and other assets was primarily driven by an increase in software licenses due to head count additions, and an increase in software-as-a-service to support our strategic initiatives. The increase in accounts receivable was primarily driven by revenue growth.

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 \$22.0 million increase in prepaid expenses and other assets, offset by a \$25.6 million increase in accounts payable and a \$17.7 million increase in accrued expenses and other 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.

Investing Activities

Net cash provided by investing activities was \$14.0 million in 2020, compared with net cash used in investing activities of \$73.6 million in 2019.

Capital Spending—Capital expenditures were \$129.0 million in 2020 and primarily related to equipment to increase our manufacturing capacity. Capital expenditures were \$163.7 million in 2019 and primarily related to the construction of our manufacturing and corporate headquarters facility in Acton, Massachusetts. We expect capital expenditures for 2021 to increase compared with 2020 as we continue to expand manufacturing capacity to support our growth and the launch of Omnipod 5. 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 2020, net sales of marketable securities were \$180.5 million, compared with net purchases of marketable securities of \$97.3 million for 2019. 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.

Acquisition of Intangible Assets—In 2020, following the resolution of a purchase price contingency associated with our 2018 acquisition of customer relationships from a former European distributor, we paid the distributor an additional \$36.2 million for a total purchase price of \$41.2 million. We had previously paid the distributor \$3.8 million in 2019 and the remainder in 2018.

Financing Activities

Net cash provided by financing activities was \$605.5 million in 2020, compared with \$73.5 million in 2019.

Issuance of Common Stock—In 2020, we sold 2.4 million common shares for \$478.7 million in an underwritten registered offering. Net proceeds from the offering were \$477.5 million. The proceeds provide us with additional liquidity to mitigate risk and allow us to continue investing in the growth of our business and our strategic initiatives.

Debt Issuance and Repayment—In 2020, we received proceeds of \$70.0 million upon entering into a mortgage of our Acton facility. Additionally, we received proceeds of \$60.0 million upon entering into two equipment financing transactions. Refer to Note 12 to our consolidated financial statements for additional information regarding these transactions.

Option Exercises and Payment of Taxes for Restricted Stock Net Settlements—Total proceeds from option exercises decreased 20.9 million to \$25.7 million in 2020, compared with \$46.6 million in 2019. This decrease was primarily driven by less option exercises in 2020 from the retirement of our former CEO in the prior year period. Payments for taxes related to net restricted and performance stock unit settlements increased \$21.2 million to \$29.8 million in 2020, compared with \$8.6 million in 2019. The increase in payments for taxes related to restricted stock net settlements was driven by increased vesting of restricted shares in 2020, compared with 2019, including the immediate vesting of a significant portion of a company-wide 20th anniversary equity grant in the fourth quarter 2020.

Revision to Nine Months Ended September 30, 2020 Condensed Consolidated Cash Flow Statement

In February 2021, we identified an error in the presentation of certain cash flow activity that impacted several line items within the previously issued Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2020. While these items affected cash flows from operating and investing activities, they had no impact on the net increase (decrease) in cash and cash equivalents or net income. We have assessed the materiality of the misstatement in accordance with ASC 250-10, *Accounting Changes and Error Corrections*, and concluded that this misstatement was not material to our previously issued consolidated financial statements. Accordingly, our Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2020 will be corrected prospectively in our Form 10-Q for the quarterly period ended September 30, 2021 as shown below.

(in millions)	Previo	ısly Reported	Adjustment			As Adjusted
Prepaid and other assets	\$	(16.8)	\$	4.1	\$	(12.7)
Accounts payable, accrued expenses and other current liabilities	\$	36.1	\$	(22.1)	\$	14.0
Net cash provided by operating activities	\$	85.0	\$	(18.0)	\$	67.0
Capital expenditures	\$	(88.5)	\$	10.3	\$	(78.2)
Acquisition of intangible assets	\$	(8.3)	\$	7.7	\$	(0.6)
Net cash provided by investing activities	\$	65.3	\$	18.0	\$	83.3

Commitments and Contingencies

Contractual Obligations—A summary of our contractual obligations and commitments for debt, operating lease obligations and other obligations at December 31, 2020 is presented in the following table:

(in millions)	Short Term			Long Term	Total
Operating lease obligations	\$	5.6	\$	13.1	\$ 18.7
Debt obligations		15.6		1,315.1	1,330.7
Interest payments		14.7		45.8	60.5
Purchase obligations (1)		257.3		36.7	294.0
Total contractual obligations	\$	293.2	\$	1,410.7	\$ 1,703.9

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.

Legal Proceedings—Roche Diabetes Care, Inc. ("Roche") filed a patent infringement lawsuit against us and is seeking monetary damages and attorneys' fees and costs. Since the patent expired in 2019, Roche is not seeking injunctive relief and the lawsuit will have no impact on ongoing sales of our products. We believe that we have meritorious defenses to Roche's claims and intend to vigorously defend against them. At this time, based on available information regarding this litigation, we are unable to reasonably assess the ultimate outcome of this case or determine an estimate, or range of estimates, of potential losses, which could be material; accordingly, we have excluded this exposure from the contractual obligations table above. Refer to Note 13 to our consolidated financial statements for additional information regarding this matter.

Off-Balance Sheet Arrangements

As of December 31, 2020, we had various outstanding letters of credit and bank guarantees totaling \$2.8 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 \$82.5 million, \$59.1 million and \$34.1 million in 2020, 2019 and 2018, 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 \$69.5 million for 2020. 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.

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 a patent infringement case with Roche. 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, 2020

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. The adoption of this guidance is not expected to have a significant impact on our consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Debt Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments by eliminating certain separation models. Under ASU 2020-06, a convertible debt instrument will generally be reported as a single liability at its amortized cost with no separate accounting for embedded conversion features. Consequently, the interest rate of convertible debt instruments will be closer to the coupon interest rate. In addition, ASU 2020-06 eliminates the treasury stock method to calculate diluted earnings per share for convertible instruments and requires the use of the if-converted method. The guidance is effective for us beginning in the first quarter of 2022 with early adoption permitted. Early adoption of ASU 2020-06 as of January 1, 2021, would result in an approximate \$330 million decrease in additional paid in capital from the derecognition of the bifurcated equity component, \$250 million increase in debt from the derecognition of the discount associated with the bifurcated equity component and \$80 million decrease to the opening balance of accumulated deficit, representing the cumulative interest expense recognized related to the amortization of the bifurcated conversion option. Additionally, we expect to write-off the related deferred tax liabilities with a corresponding adjustment to the valuation allowance, resulting in no net impact to the cumulative adjustment to retained earnings. Adoption of this standard will have no impact on our diluted earnings per share as we calculate earnings per share using the if-converted method. We are still evaluating whether we will early adopt this guidance.

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, 2020, we had outstanding debt related to our convertible senior notes recorded on our consolidated balance sheet of \$933.1 million, net of unamortized discount and issuance costs totaling \$269.4 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 \$2.0 billion as of December 31, 2020, is also impacted by changes in our stock price.

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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 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, 2020. 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 other income (expense), net in the consolidated statement of income and amounted to a loss of \$3.2 million for the year ended December 31, 2020.

Item 8. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2020 and 2019 and for each of the three years in the period ended December 31, 2020, 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

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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, 2020 and 2019, and the related consolidated statements of income, comprehensive income, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and financial statement schedules included under Item 15(a) (collectively referred to as the "financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 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, 2020, 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 matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that

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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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition - Drug Delivery

As described in Note 4 to the consolidated financial statements, the Company's revenue from drug delivery was \$69.5 million for the year ended December 31, 2020. 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 (and the related unbilled receivable), we inspected customer orders, binding customer forecasts, inventory records, and third party shipping documentation.

/s/ GRANT THORNTON LLP

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

Boston, Massachusetts February 23, 2021

INSULET CORPORATION CONSOLIDATED BALANCE SHEETS

		nber 31,		
(in millions, except share and per share data)		2020	2019	
ASSETS				
Current Assets				
Cash and cash equivalents	\$		\$ 213	3.7
Short-term investments		40.4		2.4
Accounts receivable trade, net		83.8	69	9.3
Inventories		154.3	101	1.0
Prepaid expenses and other current assets		63.0	4	4.6
Total current assets		1,248.7	591	1.0
Long-term investments		_	58	8.4
Property, plant and equipment, net		478.7	399	9.4
Other intangible assets, net		28.7	13	3.2
Goodwill		39.8	39	9.8
Other assets		77.0	41	1.1
Total assets	\$	1,872.9	\$ 1,142	2.9
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities				
Accounts payable	\$	54.1	\$ 54	4.5
Accrued expenses and other current liabilities		138.1	103	3.2
Current portion of long-term debt		15.6		—
Total current liabilities		207.8	157	7.7
Long-term debt, net		1,043.7	887	7.9
Other liabilities		17.8	21	1.4
Total liabilities		1,269.3	1,067	7.0
Commitment and Contingencies (Note 13)				
Stockholders' Equity				
Preferred stock, \$.001 par value:				
Authorized: 5,000,000 shares at December 31, 2020 and 2019. Issued and outstanding: zero shares at December 31, 2020 and 2019.		_		_
Common stock, \$.001 par value:				
Authorized: 100,000,000 shares at December 31, 2020 and 2019. Issued and outstanding: 66,017 and 62,685 shares at December 31, 2020 and 2019		0.1	(0.1
Additional paid-in capital		1,264.3	749	9.0
Accumulated deficit		(666.3)	(672	2.0)
Accumulated other comprehensive income (loss)		5.5	`	1.2)
Total stockholders' equity		603.6	7:	5.9
Total liabilities and stockholders' equity	\$	1,872.9	\$ 1,142	2.9

INSULET CORPORATION CONSOLIDATED STATEMENTS OF INCOME

	Years Ended December 31,								
(in millions, except share and per share data)	·	2020		2019		2018			
Revenue	\$	904.4	\$	738.2	\$	563.8			
Cost of revenue		322.1		257.9		193.6			
Gross profit		582.3		480.3		370.2			
Research and development		146.8		132.3		94.8			
Selling, general and administrative		384.0		298.0		248.0			
Operating income		51.5		50.0		27.4			
Interest expense, net		(45.1)		(27.7)		(21.3)			
Loss on extinguishment of debt		_		(8.7)		_			
Other income (expense), net		3.3		0.9		(0.9)			
Income before income taxes		9.7		14.5		5.2			
Income tax expense		(2.9)		(2.9)		(1.9)			
Net income	\$	6.8	\$	11.6	\$	3.3			
Net income per share:									
Basic	\$	0.11	\$	0.19	\$	0.06			
Diluted	\$	0.10	\$	0.19	\$	0.05			
Weighted-average number of common shares outstanding (in thousands):									
Basic		64,735		60,594		58,860			
Diluted		65,946		62,304		61,008			

INSULET CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Years Ended December 31,					
(in millions)		2020		2019		2018
Net income	\$	6.8	\$	11.6	\$	3.3
Other comprehensive income, net of tax						
Foreign currency translation adjustment		6.8		0.6		(2.2)
Unrealized (loss) gain on available-for-sale securities, net of tax		(0.1)		1.1		(0.2)
Total other comprehensive income (loss), net of tax		6.7		1.7		(2.4)
Total comprehensive income	\$	13.5	\$	13.3	\$	0.9

INSULET CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common	Stock				m
(dollars in millions)	Shares (in thousands)	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss (Income)	Total Stockholders' Equity
Balance, December 31, 2017	58,319	\$ 0.1	\$ 866.2	\$ (707.3)	\$ (0.5)	\$ 158.5
Exercise of options to purchase common stock	410	_	12.8	` <u>_</u>	`	12.8
Issuance of shares for employee stock purchase plan	46	_	3.0	_	_	3.0
Stock-based compensation	_	_	37.5	_	_	37.5
Restricted stock units vested, net of shares withheld for taxes	414	_	(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)	_	_	` <u>_</u>	20.4	_	20.4
Net income	_	_	_	3.3	_	3.3
Other comprehensive loss	_	_	_	_	(2.4)	(2.4)
Balance, December 31, 2018	59,189	0.1	898.5	(683.6)	(2.9)	212.1
Exercise of options to purchase common stock	1,340	_	46.6	` _	` <u>_</u>	46.6
Issuance of shares for employee stock purchase plan	51	_	4.3	_	_	4.3
Stock-based compensation	_	_	28.7	_	_	28.7
Restricted stock units vested, net of shares withheld for taxes	230	_	(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	_	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	0.1	749.0	(672.0)	(1.2)	75.9
Adoption of ASU 2016-13 (Note 1)	_	_	_	(1.1)	_	(1.1)
Issuance of common stock	2,370	_	477.5	_	_	477.5
Exercise of options to purchase common stock	674	_	25.7	_	_	25.7
Issuance of shares for employee stock purchase plan	38	_	6.0	_	_	6.0
Stock-based compensation	_	_	35.9	_	_	35.9
Restricted stock units vested, net of shares withheld for taxes	250	_	(29.8)	_	_	(29.8)
Net income	_	_	_	6.8	_	6.8
Other comprehensive income	_	–			6.7	6.7
Balance, December 31, 2020	66,017	\$ 0.1	\$ 1,264.3	\$ (666.3)	\$ 5.5	\$ 603.6

INSULET CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,				1	
(in millions)		2020		2019		2018
Cash flows from operating activities						
Net income	\$	6.8	\$	11.6	\$	3.3
Adjustments to reconcile net income to net cash provided by operating activities:						
Depreciation and amortization		55.4		27.9		15.6
Non-cash interest		45.2		35.6		29.3
Stock-based compensation		35.9		28.7		37.5
Loss on extinguishment of convertible debt		_		8.7		_
Provision for credit losses		3.3		4.5		3.4
Other		0.8		1.1		(0.4)
Changes in operating assets and liabilities:						
Accounts receivable		(15.6)		(10.8)		(14.6)
Inventories		(50.5)		(30.2)		(38.8)
Prepaid expenses and other assets		(32.2)		(22.0)		(19.9)
Accounts payable		7.1		25.6		(5.4)
Accrued expenses and other liabilities		27.8		17.7		25.9
Net cash provided by operating activities		84.0		98.4		35.9
Cash flows from investing activities						
Capital expenditures		(129.0)		(163.7)		(157.4)
Acquisition of intangible assets		(37.5)		(7.2)		(5.0)
Purchases of investments		(37.9)		(150.6)		(191.4)
Receipts from the maturity or sale of investments		218.4		247.9		169.3
Net cash provided by (used in) investing activities		14.0		(73.6)		(184.5)
Cash flows from financing activities				<u> </u>		
Proceeds from issuance of common stock, net of issuance costs		477.5		_		_
Proceeds from mortgage, net of issuance cost		68.3		_		_
Proceeds from equipment financing		60.0		_		_
Proceeds from issuance of convertible debt, net of issuance cost		_		780.2		_
Purchase of capped call options		_		(85.4)		_
Repayment of convertible debt		_		(663.6)		(6.7)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase						
plan		31.7		50.9		15.8
Payment of withholding taxes in connection with vesting of restricted stock units		(29.8)		(8.6)		(17.8)
Other		(2.2)				
Net cash provided by (used in) financing activities		605.5		73.5		(8.7)
Effect of exchange rate changes on cash		4.8		1.5		(1.4)
Net increase (decrease) in cash, cash equivalents, and restricted cash		708.3		99.8		(158.7)
Cash, cash equivalents, and restricted cash, beginning of year		213.7		113.9		272.6
Cash, cash equivalents, and restricted cash, end of year (Note 5)	\$	922.0	\$	213.7	\$	113.9
Supplemental cash flow information						
Cash paid for interest, net of amount capitalized	\$	2.6	\$	_	\$	_
Cash paid for taxes	\$	3.0	\$	2.5	\$	0.8
Purchases of property, plant and equipment included in accounts payable and accrued expenses	\$	6.7	\$	13.3	\$	11.4

INSULET CORPORATION

NOTES TO 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 ("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 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 DASHTM 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, a 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. A portion of facility costs and certain information technology costs have been allocated from selling, general and administrative to research and development expenses based on square foot and system usage, respectively and certain quality assurance costs were reclassified from research and development expenses to selling, general and administrative expenses. The net impact of these adjustments was a \$2.6 million and \$4.3 million increase to research and development expenses and decrease to selling, general and administrative expenses for the years ended December 31, 2019 and December 31, 2018, respectively. There was no change to previously reported operating or 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 other income (expense), net in the consolidated statement of income and were \$3.2 million, \$0.6 million and \$1.0 million for the years ended December 31, 2020, 2019 and 2018, respectively.

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 required to be set aside in connection with

equipment financings or that serves as collateral for outstanding letters of credit and bank guarantees is included in other assets and 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 accumulated other comprehensive income (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 (expense), net in the consolidated statement of income.

Accounts Receivable and Allowance for Credit Losses

Trade accounts receivable consist of amounts due from third-party payors, customers and intermediaries and are presented at amortized cost. The allowance for credit losses 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.

The allowance for credit losses is measured on a collective (pool) basis when similar risk characteristics exist. The Company has identified the following portfolio segments and measures the allowance for credit losses using the following methods:

Direct Customer Receivables—The Company measures expected credit losses on direct customer receivables using an aging methodology. The risk of loss for direct customer receivables is higher than other portfolios. The Company relies on third-party payors to accept and timely process claims and on direct consumers to have the ability to pay. The estimate of expected credit losses considers historical credit loss information that is adjusted for current conditions and supportable forecasts.

Distributor Receivables—The Company measures expected credit losses on distributor receivables using an individual reserve methodology. The risk of loss in this portfolio is low based on the Company's historical experience. The estimate of expected credit losses considers payment history as well as credit ratings of the distributors, in addition to current conditions and supportable forecasts.

National Healthcare System Receivables—The Company measures expected credit losses on national healthcare system receivables using an individual reserve methodology. The risk of loss in this portfolio is low based on the Company's historical experience. The estimate of expected credit losses considers historical credit loss information that is adjusted for current conditions and supportable forecasts.

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

Leasehold improvements

Machinery and equipment

Euser of lease term or useful life of asset

Lesser of lease term or useful life of asset

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 than 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 based on the pattern in which the economic benefits of the assets are estimated to be consumed over the following estimated useful lives of the assets:

Customer relationships	14 years
Internal-use software	3 to 5 years
Intellectual property	15 years

Amortization expense is included in selling, general and administrative expenses in the consolidated statement of income. 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.

Cloud Computing Arrangements

The Company capitalizes costs incurred to implement cloud computing arrangements that are service contracts 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. As of December 31, 2020 and 2019, the Company had net capitalized implementation costs of \$24.2 million and \$3.5 million, respectively. Amortization expense recorded during the period ended December 31, 2020 was \$1.4 million and was insignificant for the period ended December 31, 2019.

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.

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 revenue in the consolidated statements of income. 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.

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 end-users and certain of our distributors and wholesalers. 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.

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 selling, general and administrative expenses and were \$10.1 million, \$9.7 million and \$6.6 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Advertising Costs

The Company expenses advertising costs as they are incurred. Advertising expenses were \$30.0 million, \$11.2 million and \$10.5 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Stock-Based Compensation

The Company measures stock-based compensation on 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 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 two contract manufacturers. As of December 31, 2020, neither of these vendors represented 10% or more of the combined balance of accounts payable and accrued expenses and other current liabilities. As of December 31, 2019, one of these vendors 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, 2020, the Company adopted Accounting Standards Update ("ASU") 2016-13, *Credit Losses (Topic 326)* ("ASU 2016-13"). ASU 2016-13 requires financial assets measured at amortized cost, such as the Company's 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 Company adopted ASU 2016-13 using the modified retrospective method, whereby the guidance is applied prospectively as of the date of adoption and prior periods are not restated. The cumulative effect of adopting ASU 2016-13 resulted in a \$1.1 million increase to the opening balance of accumulated deficit upon adoption related to an increase in the allowance for credit losses on accounts receivable.

The following table presents the activity in the allowance for credit losses, which is comprised primarily of our direct consumer receivable portfolio. The allowance for credit losses of other portfolios is insignificant.

	Year	r Ended
(in millions)	Decemb	per 31, 2020
Credit losses at the beginning of the year	\$	3.8
Effect of adoption		1.1
Credit losses at the beginning of the year, after adoption		4.9
Provision for expected credit losses		3.3
Write-offs charged against allowance		(5.8)
Recoveries of amounts previously written-off		0.5
Credit losses at the end of the year	\$	2.9

Effective January 1, 2020, the Company adopted 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 units' fair value. The adoption of this guidance had no impact on the consolidated financial statements.

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 customer location, is as follows:

	Years Ended December 31,									
(in millions)	2020			2020 2019		2020		2018		
United States ⁽¹⁾	\$	596.4	\$	485.1	\$	391.8				
International		308.0		253.1		172.0				
Total	\$	904.4	\$	738.2	\$	563.8				

⁽¹⁾ Includes U.S. Omnipod and Drug Delivery revenues.

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

	As of December 31,							
(in millions)		2020		2019				
United States	\$	409.7	\$	363.0				
China		66.2		35.9				
Other		2.8		0.5				
Total	\$	478.7	\$	399.4				

Note 4. Revenue and Contract Acquisition Costs

The following table summarizes the Company's disaggregated revenues:

	Years Ended December 31,										
(in millions)	2020			2019	2018						
U.S. Omnipod	\$ 520	6.9	\$	420.4	\$	323.5					
International Omnipod	30	8.0		253.1		172.0					
Total Omnipod	834	4.9		673.5		495.5					
Drug Delivery	6	9.5		64.7		68.3					
Total revenue	\$ 90	4.4	\$	738.2	\$	563.8					

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

Years Ende	d December 31,

	2020	2019	2018
Anda, Inc.	11%	*	*
Cardinal Health Inc. and affiliates	10%	11%	12%
Amgen, Inc.	*	*	12%

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

At December 31, 2020, the Company had one customer that accounted for 15% of consolidated net accounts receivable. No customer accounted for more than 10% of consolidated net accounts receivable at December 31, 2019.

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)	2020	2019						
Accrued expenses and other current liabilities	\$ 5.	\$ 3.2						
Other liabilities	1.	1.0						
Total deferred revenue	\$ 6.	\$ 4.2						

Revenue recognized from amounts included in deferred revenue at the beginning of each respective period was as follows:

		As of December 31,	
(in millions)	 2020	2019	2018
Deferred revenue recognized	\$ 1.8	1.2	2.4

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			
(in millions)	2020		2	2019
Prepaid expenses and other current assets	\$	11.0	\$	9.5
Other assets	2	21.9		19.9
Total capitalized contract acquisition costs, net	\$	32.9	\$	29.4

The Company recognized \$10.6 million, \$8.8 million, and \$6.9 million of amortization of capitalized contract acquisition costs for the years ended December 31, 2020, 2019, and 2018, respectively.

The Company had unbilled receivables of \$11.6 million and \$13.5 million at December 31, 2020 and 2019, respectively.

Note 5. Cash and Cash Equivalents

The following table provides a summary of cash and cash equivalents as of December 31, 2020 and 2019 and the level in the fair value hierarchy in which those measurements fall:

	As of Dec				
(in millions)		2020		2019	
Cash	\$	164.6	\$	85.3	
Money market mutual funds		739.8		115.5	
Commercial paper		_		10.0	
Restricted cash		2.8		2.9	
Total cash and cash equivalents		907.2		213.7	
Restricted cash included in other assets		14.8		_	
Total cash, cash equivalents, and restricted cash shown in the consolidated statement of cash flows	\$	922.0	\$	213.7	

The restricted cash included in other assets on the consolidated balance sheet is held as a compensating balance against long-term borrowings.

All cash and cash equivalents are level 1, except for commercial paper, which is level 2. The fair value of commercial paper 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 one year at December 31, 2020. Realized gains or losses in each of the three years ended December 31, 2020, 2019 and 2018 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, 2020 and 2019:

(in millions)	Am	ortized Cost	Gro	oss Unrealized Gains	Gr	oss Unrealized Losses	 Fair Value	Level 1	Level 2 (1)
<u>December 31, 2020</u>									
U.S. government and agency bonds	\$	35.1	\$	0.2	\$	_	\$ 35.3	\$ 35.3	\$ _
Corporate bonds		2.8		0.1		_	2.9	_	2.9
Certificates of deposit		2.2		_		_	2.2	_	2.2
Total short-term investments	\$	40.1	\$	0.3	\$	_	\$ 40.4	\$ 35.3	\$ 5.1
<u>December 31, 2019</u>									
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

⁽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)	2020	1	2019						
Raw materials	\$	30.7	\$	23.3					
Work-in-process		59.6		40.3					
Finished goods		64.0		37.4					
Total inventories	\$	154.3	\$	101.0					

Note 8. Property, Plant and Equipment, Net

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

	As of De	cember 31,
(in millions)	2020	2019
Land	\$ 2.5	\$ 2.5
Building and building improvements	147.3	116.9
Machinery and equipment	318.7	194.8
Furniture and fixtures	14.8	12.7
Leasehold improvements	4.4	1.6
Construction in process	119.6	161.5
Total property, plant and equipment	607.3	490.0
Less: accumulated depreciation	(128.6)	(90.6)
Property, plant and equipment, net	\$ 478.7	\$ 399.4

Depreciation expense related to property and equipment was \$38.0 million, \$25.2 million and \$13.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. Construction in process primarily consists of manufacturing equipment located at the Company's U.S. manufacturing facility in Acton, Massachusetts and new contract manufacturer in China, most of which is expected to be placed into service during 2021.

Note 9. Goodwill and Other Intangible Assets, Net

Goodwill

The changes in the carrying amount of goodwill for 2020 and 2019 were as follows:

		December 31,			
(in millions)		2020		2019	
Beginning balance	\$	39.8	\$	39.6	
Foreign currency adjustment		_		0.2	
Ending balance	\$	39.8	\$	39.8	

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,												
				2020			2019							
(in millions)	Gross Carrying Amount		Accumulated Amortization		Net Book Value		Gross Carrying Amount		Accumulated Amortization		Net B	ook Value		
Customer relationships (1)	\$	43.3	\$	(18.3)	\$	25.0	\$	9.9	\$	(2.8)	\$	7.1		
Internal-use software		11.4		(8.6)		2.8		12.0		(6.8)		5.2		
Intellectual property		1.1		(0.2)		0.9		1.0		(0.1)		0.9		
Total intangible assets	\$	55.8	\$	(27.1)	\$	28.7	\$	22.9	\$	(9.7)	\$	13.2		

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

Intangible asset amortization expense was \$17.4 million, \$2.7 million and \$1.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. Amortization expense associated with the intangible assets included on the Company's consolidated balance sheet as of December 31, 2020 is expected to be as follows:

Years Ending December 31,	(in millions)
2021	\$ 6.5
2022	5.1
2023	3.9
2024	3.0
2025	2.3

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)	2020	2019	
Employee compensation and related costs	\$ 53.1	\$ 45.8	
Professional and consulting services	19.1	19.3	
Accrued rebates	13.1	7.5	
Supplier purchases	7.1	2.4	
Value added taxes payable	5.0	1.8	
Other	40.7	26.4	
Accrued expenses and other current liabilities	\$ 138.1	\$ 103.2	

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

	Years Ended December 31,		
(in millions)	 2020	2019	
Product warranty liability at beginning of year	\$ 8.5	\$	6.4
Warranty expense	10.7		13.4
Warranty claims settled	(12.5)		(11.3)
Product warranty liability at end of year	\$ 6.7	\$	8.5

Note 11. Leases

As of December 31, 2020, 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, and some include options to terminate the leases at certain times within the lease term. As of December 31, 2020, the Company included options to extend certain leases for 5 years in the measurement of the lease liability.

As of December 31, 2020, operating lease assets and operating lease liabilities were included in the following consolidated balance sheet accounts in the amounts shown:

Years Ended December 3		
 2020		2019
_		
\$ 14.9	\$	16.1
\$ 4.9	\$	3.6
12.0		14.4
\$ 16.9	\$	18.0
\$ \$ \$	\$ 14.9 \$ 4.9 12.0	\$ 14.9 \$ \$ 12.0

The Company's total operating lease cost was \$5.4 million and \$4.3 million for the years ended December 31, 2020 and 2019, respectively. Total rental expense was \$3.3 million for the year ended December 31, 2018. Cash paid for amounts included in the measurement of lease liabilities was \$4.6 million and \$3.6 million for the years ended December 31, 2020 and 2019, respectively. Operating lease liabilities arising from obtaining operating lease assets was \$2.5 million and \$9.8 million for the years ended December 31, 2020 and 2019, respectively.

Maturities of lease liabilities as of December 31, 2020 are as follows:

Years Ending December 31,	(in n	nillions)
2021	\$	5.6
2022		5.4
2023		2.9
2024		2.8
2025		1.9
Thereafter		0.1
Total future minimum lease payments		18.7
Less: imputed interest		(1.8)
Present value of future minimum lease payments	\$	16.9

As of December 31, 2020, the weighted average remaining lease term for operating leases was 3.8 years and the weighted-average discount rate used to determine the operating lease liability was 5.6%.

Note 12. Debt

The components of debt consisted of the following:

	As of December 31,		
(in millions)	2020		2019
1.375% Convertible Senior Notes, due November 2024	\$	402.5	\$ 402.5
0.375% Convertible Senior Notes, due September 2026		800.0	800.0
Equipment financing, due May 2024		22.2	_
Equipment financing, due November 2025		36.4	_
5.15% Mortgage, due November 2025		69.7	_
Unamortized debt discount		(252.5)	(294.8)
Debt issuance costs		(19.0)	(19.8)
Total debt		1,059.3	887.9
Less: current portion		15.6	_
Total long term-debt	\$	1,043.7	\$ 887.9

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 to then 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 recorded as a reduction to the value of the conversion feature allocated to equity. The remaining \$7.6 million of debt issuance costs was recorded 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.

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 to then 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 recorded 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 each balance sheet date 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.

1.25% 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.

Equipment Financings

In October 2020, the Company entered into a Master Equipment Lease Agreement for a loan of \$60.0 million secured by two manufacturing lines located at the Company's Acton, Massachusetts manufacturing facility. The loan for the first manufacturing line is payable over 42 months and has an effective interest rate of 5.8%. The loan for the second manufacturing line is payable over 60 months and has an effective interest rate of 4.8%.

5.15% Mortgage

In October 2020, the Company entered into a Mortgage Loan Agreement (the "Mortgage"), which provides for a \$70.0 million loan with an effective interest rate of 5.7%. Proceeds under the Mortgage are secured by the Company's Acton, Massachusetts headquarters. The Mortgage is repayable in monthly installments of \$0.5 million, with the outstanding principal balance of the loan due in November 2025. The Mortgage contains customary covenants, none of which are considered restrictive to the Company's operations.

Maturity of Debt

The maturity of debt as of December 31, 2020 is as follows:

Years Ending December 31,	(in millions)
2021	\$ 15.6
2022	15.9
2023	16.7
2024	415.4
2025	67.2

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, 2020 and 2019 are as follows:

	As of December 31,						
	20)20			20	19	
(in millions)	 Carrying Value		Estimated Fair Value (1)	,	Carrying Value		Estimated Fair Value (1)
1.375% Convertible Senior Notes	\$ 323.9	\$	1,104.2	\$	306.9	\$	512.8
0.375% Convertible Senior Notes	609.2		902.0		581.0		840.0
Total	\$ 933.1	\$	2,006.2	\$	887.9	\$	1,352.8

⁽¹⁾ Fair value was determined using the Company's quoted stock price and contractual conversion rate.

The Mortgage and equipment financings carrying values of \$69.7 million and \$58.6 million, respectively, approximate their fair values.

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 then 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 then current and former 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 into an escrow account for 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, the amount of which 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 then 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.

In June 2020, Roche Diabetes Care, Inc. ("Roche") filed a patent infringement lawsuit against the Company in the United States District Court for the District of Delaware alleging that the Company's manufacture and sale of its Omnipod Insulin Management System, Omnipod Starter Kit and Omnipod 10 Pod Pack in the United States infringed Roche's now-expired U.S. Patent 7,931,613. Roche is seeking monetary damages and attorneys' fees and costs. Since the patent expired in 2019, Roche is not seeking injunctive relief and the lawsuit will have no impact on ongoing sales of the Company's products. The Company believes that it has meritorious defenses to Roche's claims and intends to vigorously defend against them. The court has set a trial date of July 25, 2022. At this time, based on available information regarding this litigation, the Company is unable to reasonably assess the ultimate outcome of this case or determine an estimate, or range of estimates, of potential losses, which could be material.

In July 2020, the Company filed a patent infringement claim against Roche Diabetes Care Limited ("Roche Ltd.") in the United Kingdom alleging that Roche Ltd.'s manufacture and sale of the Accu-Chek® Solo insulin pump and its consumable components infringes European Patent No. 1 335 764 in the United Kingdom. The Company is seeking an injunction to last until expiry of the patent and monetary damages. Roche Ltd. has responded to the complaint and argues that the patent is invalid and not infringed.

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. Other than as described above, 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 was subject to an arbitration proceeding in Switzerland. In December 2020, Insulet entered into a settlement agreement with the former distributor pursuant to which the Company paid the distributor an additional one-time payment of \$36.2 million, for a total fee of \$41.2 million, representing the cost to acquire the customer relationships. This amount was recorded as an intangible asset on the consolidated balance sheet. Since the customer relationships were acquired on July 1, 2018, the Company recorded cumulative amortization in the amount of \$14.6 million during the fourth quarter of 2020, as if the total fee for the intangible

asset had been amortized since the acquisition date.

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, 2020, 3.6 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, 2020, 2019 and 2018 was recorded as follows:

	Year Ended December 31,								
(in millions)	2020			2019 2018					
Cost of revenue	\$	1.2	\$	1.0	\$	0.8			
Research and development		10.9		9.1		8.2			
Selling, general and administrative		23.8		18.6		28.5			
Total	\$	35.9	\$	28.7	\$	37.5			

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, 2019	1,729,512	\$ 45.39		
Granted	68,832	\$ 202.18		
Exercised	(674,542)	\$ 38.39		\$ 115.9
Forfeited and canceled	(45,314)	\$ 89.64		
Outstanding at December 31, 2020	1,078,488	\$ 57.99	5.4	\$ 213.2
Vested, December 31, 2020	868,407	\$ 43.33	4.8	\$ 184.4
Vested or expected to vest, December 31, 2020	1,056,479	\$ 56.36	5.4	\$ 210.5

The aggregate intrinsic value of options exercised for the years ended December 31, 2019 and 2018 was \$119.2 million and \$23.5 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,					
	2020	2020 2019					
Risk-free interest rate	0.3% - 1.4%	1.8% - 2.6%	2.2% - 2.9%				
Expected life of options (in years)	4.5	4.4 - 4.8	4.5 - 5.4				
Dividend yield	<u> </u>	<u> </u>	<u> </u>				
Expected stock price volatility	39.5% - 41.7%	6 40.1% - 40.5%	38.7% - 40.7%				
Fair value per option	\$ 69	.90 \$ 34.98	\$ \$ 30.34				

As of December 31, 2020, there was \$6.7 million of unrecognized compensation cost related to non-vested stock options. This cost is expected to be recognized over a weighted average period of 2.5 years.

Restricted Stock Units

Restricted Stock Units ("RSUs") generally vest in equal annual installments over a three-year period, however during the fourth quarter of 2020, the Company issued a company-wide grant, a significant portion of which immediately vested. 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, 2019	352,287	\$ 83.44
Granted	137,647	211.77
Vested	(206,257)	100.29
Forfeited	(23,990)	120.64
Outstanding at December 31, 2020	259,687	\$ 134.90

The weighted-average grant-date fair value per share of RSUs granted was \$96.62 and \$76.03 for the years ended December 31, 2019 and 2018, respectively. The total fair value of RSUs vested was \$20.7 million, \$11.6 million and \$14.7 million for the years ended December 31, 2020, 2019 and 2018, respectively.

As of December 31, 2020, there was \$22.5 million of unrecognized compensation cost related to time-based RSUs, which is expected to be recognized over a weighted-average period of 1.8 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, 2019	299,156	\$ 73.35
Granted	141,942	202.23
Vested	(187,660)	48.66
Forfeited	(23,349)	105.58
Outstanding at December 31, 2020 (1)	230,089	\$ 110.63

⁽¹⁾ Based on 154% achievement of the performance metrics, approximately 83,000 shares of Insulet were earned for awards that were granted in 2018 for the performance period ended December 31, 2020. These shares vested in February 2021.

The weighted-average grant-date fair value per share of PSUs granted was \$95.91 and \$75.07 for the years ended December 31, 2019 and 2018, respectively. The total fair value of PSUs vested was \$9.1 million, \$3.2 million and \$7.6 million for the years ended December 31, 2020, 2019 and 2018, respectively.

As of December 31, 2020, there was \$12.4 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 participate 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 38,313, 51,502 and 46,343 shares of common stock for the years ended December 31, 2020, 2019 and 2018, respectively, to employees participating in the ESPP. As of December 31, 2020, 508,762 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,					
	2020	2018				
Risk-free interest rate	0.1% - 0.2%	1.6% - 2.3%	2.1% - 2.5%			
Expected term (in years)	0.5	0.5	0.5			
Dividend yield	<u> </u>	<u> </u>	<u> % </u>			
Expected stock price volatility	29.7% - 38.5%	27.5% - 31.4%	23.4% - 27.0%			

The weighted average grant date fair value of the six-month option inherent in the ESPP was \$55.10, \$46.30, and \$26.01, for the years ended December 31, 2020, 2019 and 2018, respectively.

As of December 31, 2020, 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 Income (Loss)

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

(in millions)	Foreign Currency Translation Adjustment	Unrealized (Losses) Gains on Available-for- sale Securities	Accumulated Other Comprehensive Income (Loss)
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)
Other comprehensive income (loss)	6.8	(0.1)	6.7
Balance, December 31, 2020	\$ 5.2	\$ 0.3	\$ 5.5

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 6% 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 \$5.4 million, \$5.3 million and \$3.6 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Note 17. Interest Expense, Net

Interest expense, net of portion capitalized was as follows:

	Years Ended December 31,								
(in millions)		2020		2019		2018			
Contractual interest	\$	9.5	\$	9.5	\$	9.8			
Accretion of debt discount		42.3		32.8		26.7			
Amortization of debt issuance costs		2.9		2.8		2.6			
Capitalized interest		(6.6)		(10.5)		(10.2)			
Interest expense, net of portion capitalized		48.1	,	34.6		28.9			
Interest income		(3.0)		(6.9)		(7.6)			
Interest expense, net	\$	45.1	\$	27.7	\$	21.3			

Note 18. Income Taxes

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

	Years Ended December 31,								
(in millions)		2020	2019			2018			
U.S.	\$	(1.6)	\$	2.5	\$	(3.0)			
Foreign		11.3		12.0		8.2			
Income before income taxes	\$	9.7	\$	14.5	\$	5.2			

Income tax expense consists of the following:

	Years Ended December 31,						
(in millions)	·	2020	2019		2018		
Current:							
U.S. State	\$	0.2	\$ 0.2	\$	0.2		
Foreign		4.0	3.4		2.1		
Total current expense		4.2	3.6		2.3		
Deferred:							
U.S. Federal		_	(0.1)		_		
Foreign		(1.3)	(0.6)		(0.4)		
Total deferred expense		(1.3)	(0.7)		(0.4)		
Income tax expense	\$	2.9	\$ 2.9	\$	1.9		

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

	Years	Years Ended December 31,					
	2020	2019	2018				
U.S. statutory rate	21.0 %	21.0 %	21.0 %				
Foreign rate differential	7.0	4.2	(2.4)				
State taxes, net of federal benefit	1.3	1.3	2.9				
Tax credits	(40.5)	(15.4)	(13.7)				
Stock-based compensation	(311.1)	(158.7)	(159.1)				
Loss on extinguishment of debt	_	14.8	_				
Non-deductible officers' compensation	30.0	1.9	81.3				
Permanent items	2.1	3.0	16.8				
Foreign income taxed in the U.S.	(21.0)	19.0	26.1				
Change in valuation allowance	336.2	130.6	67.0				
Other	4.6	(1.9)	(2.9)				
Effective income tax rate	29.6 %	19.8 %	37.0 %				

As of December 31, 2020, 2019 and 2018 the Company had no uncertain tax positions.

No provision for income taxes has been provided on undistributed earnings of the Company's foreign subsidiaries, except for Canada, because such earnings are indefinitely reinvested in the foreign operations. The Company has recorded a deferred tax liability for withholding tax that could be incurred upon repatriation of earnings from its Canadian subsidiary, the amount of which is not significant. A deferred tax liability related to the repatriation of approximately \$24.3 million indefinitely reinvested earnings would not be material to the Company's consolidated financial statements, primarily due to treaty-based withholding tax rates in the jurisdictions in which the Company operates.

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 U.S. federal and state tax returns are currently open to examination for tax years 2017 through 2019. The Company is currently under exam in Ontario, Canada. There are no uncertain tax positions or adjustments associated with the exam at this time. In addition, the Company's U.S. net operating loss carryforwards from 2001 and forward may be subject to examination if the losses are utilized in future years.

Interest and penalties are classified as a component of income tax expense and were not material for any period presented.

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

	As of December 31,							
(in millions)	 2020	2019						
Deferred tax assets:								
Net operating loss carryforwards	\$ 173.8 \$	144.6						
Tax credits	21.3	15.2						
Capital loss carryforwards	12.2	12.7						
Stock-based compensation	5.8	8.9						
Other	15.4	13.8						
Total deferred tax assets	228.5	195.2						
Deferred tax liabilities:								
Prepaid assets	(3.5)	(2.1)						
Depreciation and amortization	(6.9)	(2.2)						
Amortization of debt discount	(60.6)	(73.4)						
Capitalized contract acquisition costs	(7.5)	(7.1)						
Other	(4.6)	(5.0)						
Total deferred tax liabilities	(83.1)	(89.8)						
Net deferred tax asset before valuation allowance	145.4	105.4						
Valuation allowance	(143.4)	(104.4)						
Net deferred tax asset	\$ 2.0 \$	1.0						

The Company maintained a valuation allowance of \$143.4 million and \$104.4 million at December 31, 2020 and 2019, respectively, against U.S. federal and state deferred tax assets, as management has determined that it is more-likely-than-not that these net deferred tax assets will not be realized. The valuation allowance is based on cumulative tax losses in the U.S. and the uncertainty of generating future taxable income in the U.S. to utilize our loss and credit carryforwards. The \$39.0 million increase in the Company's valuation allowance during the year ended December 31, 2020 was primarily due to current-year net operating losses in the U.S.

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

	Years End	Years Ended December 31,							
(in millions)	2020		2019						
U.S. Federal	\$ 732.4	\$	607.4						
State	\$ 341	\$	298.8						
Foreign	\$ 5.4	\$	_						

For U.S. federal tax purposes, \$192.1 million of the net operating losses have an indefinite carryforward period. The remaining U.S. federal carryforwards, if not utilized, will begin to expire in 2021 and will continue to expire through 2037, and the state net operating loss carryforwards expire through 2040. 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 in the U.S. Research and development and other tax credits were \$22.8 million and \$16.1 million at December 31, 2020 and 2019, respectively. If not utilized, federal research and development credits will begin to expire in 2022. These loss and credit carryforwards, which may be utilized in a future period, may be subject to limitations based on changes in the ownership of the Company ordinary shares.

Note 19. Net Income Per Share

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding for the period. Diluted net income 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 weighted-average number of common shares used in the computation of basic and diluted net income per share were as follow:

	Years Ended December 31,					
(in thousands)	2020	2019	2018			
Weighted average number of common shares outstanding, basic	64,735	60,594	58,860			
Stock options	1,025	1,487	1,678			
Restricted stock units	186	223	470			
Weighted average number of common shares outstanding, diluted	65,946	62,304	61,008			

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

	Years Ended December 31,					
(in thousands)	2020	2019	2018			
1.25% Convertible Senior Notes	_	_	5,911			
1.375% Convertible Senior Notes	4,319	4,319	4,319			
0.375% Convertible Senior Notes	3,528	3,528	_			
Unvested restricted stock units	282	431	290			
Outstanding stock options	58	13	237			
Total	8,187	8,291	10,757			

${\bf SCHEDULE~II-VALUATION~AND~QUALIFYING~ACCOUNTS}$

The following table sets forth activities in the Company's valuation allowance accounts:

Description	Balance at Beginning of Year	Ad	ditions Charged to Costs and Expenses	Other ⁽¹⁾	Deductions	Balance at End of Year
(in millions)						
Year Ended December 31, 2020						
Allowance for credit losses	\$ 3.8	\$	3.3	\$ 1.1	\$ (5.3)	\$ 2.9
Reserve for rebates	\$ 12.1	\$	82.5	\$ _	\$ (77.7)	\$ 16.9
Deferred tax valuation allowance	\$ 104.4	\$	61.7	\$ _	\$ (22.7)	\$ 143.4
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

⁽¹⁾ Increase in allowance for credit losses from the adoption of ASU 2016-13, *Credit Losses (Topic 326)*. Refer to Note 2 to the consolidated financial statements included in Item 8 for additional information.

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, 2020. 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, 2020, 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, 2020 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, 2020. 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, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020 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 2021 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, 2020.

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	966,052	\$ 60.79	3,624,340 (2)
Equity compensation plans not approved by security holders (3)	112,436	\$ 33.90	_
Total	1,078,488	\$ 57.99	3,624,340

⁽¹⁾ Includes our 2017 Plan and our 2007 Plan. Outstanding restricted stock units convert to common stock without the payment of consideration. As of December 31, 2020, 489,776 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 \$60.79. For more information relating to our equity compensation plans, see Note 14 to our consolidated financial statements.

- one inducement grant of 499,468 shares of non-qualified stock option awards made to the Company's former CEO Patrick J. Sullivan in September 2014 (439,468 of which have been exercised as of December 31, 2020); and
- one inducement grant of 79,936 non-qualified stock options made to Shacey Petrovic upon being hired by us in February 2015 (27,500 of which have been exercised as of December 31, 2020)

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.

⁽²⁾ The shares available for future issuance are under our 2017 Plan, which includes shares related to awards outstanding under the 2007 Plan that are terminated by expiration, forfeiture or cancellation.

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

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:

<u>Number</u>	<u>Description</u>
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*	<u>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)</u>
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)

10.27*

August 12, 2015)

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) Form of Executive Officer Cliff Vesting Performance Restricted Stock Unit Agreement under the Insulet Corporation Third Amended 10.13* 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) 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) 10.14* 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) 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 10.16* August 4, 2016) 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 10.17* June 30, 2016, filed August 4, 2016) 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, 10.18* 2016, filed August 4, 2016) Form of Non-Executive Employee Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Third Amended and 10.19* 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) 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 10.20* ended December 31, 2015, filed February 29, 2016) 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 10.21* ended December 31, 2015, filed February 29, 2016) 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 10.22* December 31, 2015, filed February 29, 2016) 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) 10.23* 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) 10.24* 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) 10.25* Form of Canada Time Vesting Restricted Stock Unit Agreement under the Insulet Corporation Second Amended and Restated 2007 10.26* 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)

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 guarter ended June 30, 2015, filed

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*	<u>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)</u>
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, 201 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 Decemb 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 In 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 or Quarterly Report on Form 10-Q filed May 3, 2019).		
10.56*#	Offer Letter between Dan Manea and Insulet Corporation, dated March 19, 2020.		
10.57++#	Second Amendment to Materials Supplier Agreement between Insulet Corporation and Flextronics Medical Sales and Marketing, Ltd, entered into on December 17, 2020 and made effective as of October 1, 2020.		
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, 2020 formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets; (ii) the Consolidated Statements of Income; (the Consolidated Statements of Comprehensive Income; (iv) the Consolidated Statements of Stockholders' Equity; (v) the Consolidated Statements of Cash Flows		
+	Confidential treatment granted as to certain portions of this exhibit.		
++	Certain portions of this exhibit are considered confidential and have been omitted as permitted under SEC rules and regulations.		
*	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 23, 2021 /s/ Shacey Petrovic

Shacey Petrovic Chief Executive Officer (Principal Executive Officer)

February 23, 2021 /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 23, 2021.

<u>Signature</u>	<u>Title</u>
/s/ Shacey Petrovic	Chief Executive Officer
Shacey Petrovic	(Principal Executive Officer)
/s/ Wayde McMillan	Chief Financial Officer
Wayde McMillan	(Principal Financial Officer)
/s/ Lauren Budden	Chief Accounting Officer and Controller
Lauren Budden	(Principal Accounting Officer)
/s/ Sally Crawford	_
Sally Crawford	Director
/s/ John A. Fallon, M.D.	_
John A. Fallon, M.D.	Director
/s/ Wayne A.I. Frederick, M.D.	_
Wayne A.I. Frederick, 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

March 19, 2020

Dan Manea Mendha, NJ

Dear Dan:

Insulet Corporation ("Company") is pleased to offer you the full-time position of Senior Vice President, Chief Human Resources Officer reporting to me. We are excited about the prospect of you joining Insulet and look forward to your meaningful contributions to the Company as we embark on an exciting new chapter in the Company's history. This offer of employment is contingent upon the satisfactory completion of professional references and a background check prior to your start date. We will determine a mutually beneficial start date upon acceptance of this offer.

Your salary will be \$16,346.15 biweekly (equivalent to \$425,000 on an annualized basis), paid in accordance with the Company's normal payroll practices as established or modified from time to time. You will be eligible to participate in our annual bonus program beginning fiscal year 2020 with a target bonus opportunity that is equal to sixty percent (60%) of your annual base salary. Payout typically takes place in the first quarter following the end of the calendar plan year.

The Company is committed to sharing its continued success with its employees through long term incentive opportunities. You will be eligible to participate in the Company's long-term incentive program, which currently provides for annual equity awards. For fiscal 2020, the Company will issue an award to you with a grant date value equal to six hundred thousand dollars (\$600,000) ("FY20 Annual Equity Award"). The Company grants off-cycle equity awards on the first trading day of each month and, therefore, the grant date for your FY20 Annual Equity Award under these circumstances will be the first trading day of the month that immediately follows your employment commencement date. Fifty percent (50%) of the FY20 Annual Equity Award will be delivered to you in the form of performance stock units ("PSUs") and the remaining fifty percent (50%) will be delivered to you in equal portions of restricted stock units ("RSUs") (i.e., 25% of the grant date fair value) and non-qualified stock options (i.e., 25% of the grant date fair value). The actual number of PSUs and RSUs granted to you for the FY20 Annual Equity Award will be calculated by dividing the grant date value of the respective award by the closing price of a share of Company common stock on the grant date. The actual number of stock options granted to you for your FY20 Annual Equity Award will be calculated by dividing the dollar value of the option award by the Black-Scholes option valuation of the closing price of a share of Company common stock on the grant date. These awards will vest on the same terms and conditions as established by the Compensation Committee of the Board of Directors for purposes of the fiscal 2020 annual equity award. The material terms of these equity awards will be contained in a terms and conditions document which will be issued to you at the time of grant. The terms and conditions document under which each award is issued shall govern.

In addition, you will receive a sign-on equity award, with a grant date value equal to three hundred thousand dollars (\$300,000), which will be delivered to you in the form of RSUs. The actual number of RSUs granted to you for your sign-on award will be calculated by dividing the dollar value of the RSU award by the closing price of a share of Company common stock on the grant date. These RSUs will vest in substantially equal installments on the first, second and third anniversary of the grant date. The grant date for your sign-on equity award will be the first trading day of the month that immediately follows your employment commencement date. The material terms of your sign on award will be contained in a terms and conditions document which will be issued to you at the time of grant. The terms and conditions document under which each award is issued shall govern.

The Company will pay to you a one-time cash signing bonus of one hundred fifty thousand dollars (\$150,000) payable within thirty (30) days of your employment commencement date. This is considered taxable income. If you leave the Company voluntarily within two years of your employment commencement date, you will be required to pay back the signing bonus and any relocation benefits paid on your behalf on a pro-rata basis.

You will be eligible for severance and change in control benefits pursuant and subject to the terms of the Insulet Corporation Amended and Restated Executive Severance Plan ("Severance Plan"). You will also be eligible to participate in the Company's employee benefits programs to the same extent as, and subject to the same terms, conditions and limitations applicable to, other similarly situated employees of the Company. For a more detailed understanding of these employee benefits and the applicable eligibility requirements, please consult the summary plan descriptions for the programs.

By signing this offer letter, you confirm that you will not disclose any confidential information from any other employer to Insulet. You will be required to sign the Company's standard Inventions, Non-Disclosure, Non-Solicitation, Non-Servicing and Non-Competition Agreement for Massachusetts Employees as a condition of your employment with the Company.

Also, just as the Company regards the protection of our trade secrets and other confidential information as a matter of great importance, we also respect that you may have obligations to your present or other prior employer (including safeguarding its confidential information), and we expect you to honor them as well. To that end, we expect that you will not take any documents or other confidential information from your employer of any kind, if and when you depart. Further, you should not bring with you to the Company, or use in the performance of your responsibilities for the Company, any confidential or proprietary business information, materials or documents of a former employer.

While we are hopeful and confident that our relationship will be mutually rewarding, satisfactory and sustaining, this letter shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at will, under which both you and the Company remain free to end the employment relationship,

for any reason, at any time, with or without notice. Similarly, nothing in this letter shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as otherwise provided in the Severance Plan. Also, this letter constitutes our entire offer regarding the terms and conditions of your employment by the Company, and it supersedes any prior agreements, or other promises or statements (whether oral or written) regarding the offered terms of employment. Your employment with Insulet shall be governed by and construed under the internal laws of the Commonwealth of Massachusetts, without giving effect to conflict of law principles.

On your first day of work, you should plan to arrive at our Acton offices at 8:45am and check in with the Receptionist upon arrival. For the purpose

of completing the I-9 form, please bring with you sufficient documentation to demonstrate your each As required by federal law, this verification must occur by the third day of your employment.	ligibility to work in the United States of America.
It is with great pleasure that we welcome you to Insulet. We recognize that our success is the dedicated and talented workforce. We look forward to further strengthening the Insulet team with	
Best regards,	
/s/ Shacey Petrovic Shacey Petrovic	
President and Chief Executive Officer	
Acceptance: Your signature below confirms your acceptance of the offer to join Insulet as Senior and also confirms you have reviewed the job description for this position and that you meet the m indicate your anticipated start date below.	
/s/ Dan Manea	Anticipated 5/2/20
Signature	Start Date

CERTAIN INFORMATION HAS BEEN OMITTED FROM THIS DOCUMENT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. OMISSIONS ARE MARKED [*].

SECOND AMENDMENT TO MATERIALS SUPPLIER AGREEMENT

This Second Amendment to the Materials Supplier Agreement (this "**Second Amendment**") is dated as of the 1st day of October 2020 (the "**Second Amendment Effective Date**"), by and between Insulet Corporation ("**Insulet**") and Flextronics Medical Sales and Marketing, Ltd. (the "**Supplier**"). Insulet and Supplier are referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, the Parties entered into that certain Materials Supplier Agreement, dated as of September 1, 2016 (the "Original Agreement");

WHEREAS, the Parties entered into that certain First Amendment to Materials Supplier Agreement, dated as of January 1, 2018 (the "First Amendment", and together with the Original Agreement, the "Agreement"); and

WHEREAS, the Parties desire to further amend the Agreement as described herein.

NOW, THEREFORE, in consideration of these premises, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree that the Agreement shall hereby be amended as follows:

- 1. <u>Definitions</u>. Capitalized terms used herein and not otherwise defined shall have the meaning ascribed to such terms in the Original Agreement.
- 2. Exhibit A. Amended Exhibit A is hereby deleted in its entirety and replaced with Exhibit A-2 which is attached hereto and made a part hereof. Upon the execution hereof, the Parties hereby agree that [*] provisions and [*] obligations set forth in Section [*] of the Amended Exhibit A are satisfied. The Parties further agree that the terms and conditions in Section [*] of the Amended Exhibit A, including without limitation the [*], shall survive including any expiration or termination of the Agreement. Notwithstanding anything herein to the contrary, the pricing set forth in Exhibit A-2 will remain in effect until the Parties enter into the New Pricing Agreement (as defined below).
- 3. As of the Second Amendment Effective Date, Section 4(a) of the Agreement, "General" is hereby amended by adding the following at the end of the first paragraph:

"General". For the period from [*] through [*] ("Second Amendment Term"), pricing is set in accordance with the formulas set forth on Exhibit A-2 (including those for Products added to Exhibit A-2). All prices shall be in U.S. Dollars and subject to the requirements in Exhibit A-2. The purchase price shall include all costs for adequate packaging as suitable for transport by road and/or as further specified under the Specifications listed in Exhibit A-2.

- 1. As of the Second Amendment Effective Date, the following sections are added to the Agreement:
 - a. Tooling and Automation Equipment. As of the Second Amendment Effective Date, the Parties agree that within [*] days, Insulet will [*], and Supplier will fully cooperate and assist with [*].
 - b. [*] Agreement. Upon execution of this Second Amendment, the Parties agree to work together to negotiate and enter into a mutually agreeable [*] agreement. The Parties agree that if they are not able to agree to a [*] agreement by [*], that the Agreement shall terminate as of [*]
 - c. Volume Commitment. During the Second Amendment Term, Insulet agrees to [*] Pods in the aggregate [*].
 - d. <u>Cancellation</u>. Insulet agrees to not exercise its rights under Section 15 of the Agreement related to cancellation for convenience during the Second Amendment Term.
 - e. New Pricing Agreement. Upon the execution of this Second Amendment, the Parties agree to work on new pricing to be effective as of [*] ("New Pricing Agreement"). [*]. The Parties agree that if for whatever reason whatsoever they are not able to agree to a New Pricing Agreement by [*], that the Agreement shall terminate as of [*].
- 2. No Other Amendments. Except as modified herein, all other terms of the Agreement shall remain in full force and effect.

- 3. <u>Conflicts</u>. In the event of a conflict between this Second Amendment, the First Amendment and the Original Agreement, this Second Amendment shall govern.
- 4. <u>Counterparts</u>. This Second Amendment may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

Signature page follows

IN WITNESS WHEREOF, this Second Amendment has been executed by the duly authorized representatives of Insulet and Supplier effective as of the date first set forth above.

Flextronics Medical Sales and Marketing, Ltd.

By:

Name: B. Vijayandran A/L

S. Balasingam Title: Director

Date: December 11, 2020

INSULET CORPORATION

By:

Name: Peter Griffin

Title: VP Global Procurement Date: December 17, 2020

MATERIALS SUPPLIER AGREEMENT

between

INSULET CORPORATION ("Insulet")

and

FLEXTRONICS MEDICAL SALES AND MARKETING, LTD ("Supplier")

Exhibit A-2

PRODUCTS AND PRICES

A. PDMs

2PDMs with 2021 VAM \$ Price Table:

Models	<u>CY2021</u> <u>VAM \$</u>	
[*]	[*]	

- a. The value-added manufacturing pricing ("VAM") is fixed for duration of the Second Amendment Term. Steps to determine the total quarterly price of PDMs are as follows:
 - i. Establish costed bill of materials (the "CBOM") based on changes in part pricing for each PDM bill of materials; and
 - ii. Add CBOM to relevant VAM price from the table above.

The above PDM Pricing Table shall be effective from [*] through the end of the Second Amendment Term and is based upon the following assumptions:

- The PDM Pricing Table assumes the PDM demand forecast of at least [*] units annually. If volume is less than [*] units annually, the Parties agree to negotiate new PDM Pricing.
- The PDM Pricing Table assumes Pod production continues at [*] units or greater in a given year in which PDMs are purchased. If volume is less than [*] Pods annually, the Parties agree to negotiate new PDM pricing.

B. Pods

1. Finished Pod Assemblies listed below:

INSULET PART NUMBER	GENERATION	DESCRIPTION
[*]	[*]	[*]

2. Pricing for all finished Pod Product is as follows:

- a. The value-added manufacturing pricing ("VAM") effective as of [*] is fixed as follows:
 - [*] VAM for all Pod variants will be [*]
 - [*] VAM for all Pod variants will be [*]

[*] exception: Pod pricing above is based on [*] volume less than or equal to [*] of total quarterly Pod volume. If quarterly [*] forecast is greater than [*], [*] VAM will increase [*]/Pod for each [*] increment. Examples: If [*] forecast

is [*] of total quarterly Pod volume, Pod VAM\$ will be [*]. If Horizon forecast is [*] of total quarterly Pod volume, Pod VAM\$ will be [*].

For [*] Pods, Insulet agrees to continue to reconcile quarterly for "below the line" extra labor based on actual # units produced.

This VAM cost will be based upon balanced demand per monthly capacity provided by Supplier with [*], estimated at [*] Pods/day ("Monthly Capacity"), however Insulet will [*].

- b. Steps to determine the total quarterly price of Pods are as follows:
 - i. Establish costed bill of materials (the "CBOM") based on changes in part pricing for each finished Pod bill of materials;
 - ii. Add CBOM to relevant VAM price from step (a) above; and
 - iii. Adjust for changes in currency per Section D.1 below.

C. PDK PRICING

[*]

- **D. PRICING CONSIDERATIONS AND ADJUSTMENTS.** Except as otherwise set forth herein, the prices set forth above are subject to the following conditions ("**Pricing Conditions**"):
- 1. If the exchange rate on the [*] day of a calendar quarter-end month is outside the range of [*] CNY to [*] USD according to the Wall Street Journal (WSJ), pricing for the subsequent quarter shall be as follows: Pod Price + [[*] x [*]]. For purposes of the formula in the preceding sentence, (i) Pod Price shall be taken from B.2 above and (ii) [*] shall be the applicable WSJ exchange rate on [*] day of the quarter-end month.

SUBSIDIARIES OF THE REGISTRANT

Name of Entity State/Country of Organization

Insulet Australia GmbH Insulet Australia Pty Ltd Insulet Canada Corporation

Insulet Consulting (Shenzhen) Co., Ltd.

Insulet France SAS
Insulet Germany GmbH

Insulet International Holdings Ltd.

 $In sulet\ International\ Ltd.$

Insulet MA Securities Corporation Insulet Mexico, S. de R.L. de C.V.

Insulet Netherlands B.V.

Insulet Netherlands Holdings B.V. Insulet Realty Holdings LLC Insulet Singapore Private Limited Insulet Switzerland GmbH Sub-Q Solutions, Inc. Australia Canada China France Germany

United Kingdom
United Kingdom
Massachusetts
Mexico
Netherlands
Netherlands
Delaware
Singapore
Switzerland
Delaware

Consent of Independent Registered Public Accounting Firm

We have issued our report dated February 23, 2021, 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, 2020. We consent to the incorporation by reference of said report in the Registration Statements of Insulet Corporation on Forms S-3 (No. 333-238195, 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 23, 2021

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 23, 2021

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 23, 2021

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, 2020, 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 23, 2021

/s/ Wayde McMillan Wayde McMillan Chief Financial Officer

Date: February 23, 2021